Abstract

This article discusses two critical issues concerning the TRIPS Agreement and public health. One is how to assist the developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing under the TRIPS Agreement. And it makes a detailed analysis of the emerging problem under the Article 31(f) of the TRIPS Agreement and brings forth its Article 30-based solution under this Agreement. The other one is about the potential application of non-violation complaints to the TRIPS-related disputes. The latter issue is largely neglected in the discussion of the TRIPS Agreement and public health. This article renders valid reasons for not implanting non-violation complaints into the settlement of the TRIPS-related disputes and provides a new insight into this issue from a primary perspective of public health.

Reshaping the TRIPS Agreement concerning Public Health
---- Two Critical Issues

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I. INTRODUCTION

Trade liberalization can affect public health in multiple ways. Sometimes the impact is direct and the effect is obvious, as when a disease crosses a border together with a traded good. Other times the effects of trade liberalization are more indirect [1] and even subtle. For example, changing international rules concerning patent protection may affect the prices of medicines and vaccines.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as the most controversial component of the WTO's "package deal" struck in 1994,[2] has received many different commentaries, either praise or blame.[3] In effect, the TRIPS Agreement has exerted negative influence on implementing domestic public health policies in many developing country Members by adversely affecting their access to medicines. Conforming with the Agreement by providing or strengthening the protection of pharmaceutical products with intellectual property rights has posed a special challenge for many developing country Members, worsening the opportunities for access to medicines, particularly for the poor.

Anguish and plight of HIV/AIDS crisis the Africans are suffering, the loud protests rising high into the sky above Seattle squares and the heated debates among the attendants at many international conferences, these are all the heavy pressures that the TRIPS Agreement has felt from all sides, and appeals to the Agreement to undertake reform on the public health issues have never been louder and clearer.

The Declaration on The TRIPS Agreement and Public Health made at the Doha Ministerial Conference (the Doha Declaration), enables the people on the globe to see the aurora of reform in the intellectual property regimes regarding public health. Clarifying the flexibility in the TRIPS Agreement, the Declaration entitles developing country Members autonomy to make and implement domestic public health policies

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[1] See *WTO Agreements and Public Health*, a joint study by the WHO and the WTO Secretariat, 2002, p. 23; Carlos M. Correa, *Implementing National Public Health Policies in the Framework of WTO Agreements*, 34 The Journal of World Trade, 2000, p. 89. Normally, "public health" refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life of the population as a whole.

[2] J.H. Reichman, *Taking the Medicine, with Angst: An Economist's View of the TRIPS Agreement*, 4 Journal of International Economic Law , 2001, p. 795.

[3] Some relevant international organizations and experts have been engaged in the research about the impact of implementing the TRIPS Agreement on the developing countries. See UNCTAD•*The TRIPS and Developing Countries*, New York and Geneva, 1996; UNCTAD, *Training Tools on the TRIPS Agreement: The Developing Countries ' Perspective*, January 2002, Geneva; Keith E. Maskus, *Intellectual Property Rights in the Global Economy*, Institute for International Economics,2000•Carlos M. Correa, *Intellectual Property Rights•The WTO and Developing Countries: The TRIPs Agreement and Policy Options*, Zed Books Ltd., 2000; Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries,* Oxford University Press, 2001; W. Lesser, *The Effects of TRIPS-Mandated Intellectual Property Rights on Economic Activities in Developing Countries*, WIPO Research Paper, 2001.

with respect to intellectual property protection. Nevertheless, this Declaration does not fully dismantle obstacles created by the TRIPS Agreement, which significantly constrain the autonomy of national legislatures to shape intellectual property laws in the public health perspective. Ambassador B.G. Chidyausiku observes:

"The question is now, how do we make it effective? How do we make it deliver the medicines to the people? How do we avoid this declaration ending up as a dead letter?"[4]

If a WTO Member has insufficient or no manufacturing capacities in the pharmaceutical sector, it would face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. And how to solve this problem is of great significance to actually make the Declaration effective.

Moreover, the non-violation complaint which is currently inapplicable to the TRIPS-related disputes, will potentially function as a tool to circumscribe the developing country Member from effectively using flexibility concerning public health in the TRIPS Agreement. This issue is largely neglected in the discussion of the TRIPS Agreement and public health.

This article seeks to shed some light on these two issues which are vitally important to the discussion on the TRIPS Agreement and public health. Its first section is dedicated to a general introduction to the context of the discussion on the TRIPS Agreement and public health, and the result of the Doha Declaration and its subsequent development. Section II makes a detailed analysis of the emerging problem under the Article 31(f) of the TRIPS Agreement and brings forth its Article 30-based solution under this Agreement. Section III renders valid reasons for not implanting non-violation complaints into the settlement of the TRIPS-related disputes primarily from a public health perspective.

II. A PRELIMINARY EXCURSION INTO THE TRIPS AGREEMENT AND PUBLIC HEALTH

A. Context of the Discussion on the TRIPS Agreement and Public Health

Currently, many developing countries are enveloped by quick and terrifying spread of HIV/AIDS and this epidemic poses an enormous threat to development in those countries. At the end of 2000, there were more than 36 million people in the world living with of HIV/AIDS –50 percent more than the World Health Organization (WHO) had estimated ten years earlier. Of the total, 16.4 million are women and 1.5 million are children. More than 90 percent of all cases occurs in developing countries. Only in Africa, more than 25 million Africans are living with HIV/AIDS, accounting for nearly 70 percent of infected adults and children worldwide.[5] On the contrary, high price of certain drugs limit access to the effective treatments of HIV/AIDS, in particular for 90 percent of suffers who are in developing countries. A new analysis of access to treatment shows that of the 6 million people in the developing world in need of antiretroviral drug therapy, just 230,000, less than 4%, were receiving antiretroviral

[4] Ambassador B.G. Chidyausiku, Zimbabwe, on the Doha Declaration. Quoted from *Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance- How to Get It Right*, Conference report, 28th March 2002, International Conference Centre of Geneva (CICG).

[5] See Tshimanga Kongolo, *Public Interest versus Pharmaceutical Industry's Monopoly in South Africa* , 4 The Journal of World Intellectual Property , 2001, pp. 626-627. See *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, WIPO Research Paper, 2000, pp.4-6. See also, See UNAIDS, *Report on Global HIV/AIDS Epidemic 2002*, p. 8.

drugs at the end of 2001.[6] According to Joint United Nations Programme on HIV/AIDS (UNAIDS), the high prices of HIV/AIDS treatments are due, in part, to patent protection which allows control over their manufacture and sale.[7] Subject to serious HIV/AIDS epidemic, in November 1997, the South African government amended the Medicine and Related Substances Control Act in order to promote the availability of more affordable HIV/AIDS-related drugs via parallel imports and compulsory license. Surprisingly, a number of pharmaceutical companies lodged protests against this amendment act. In February 1998, these pharmaceutical companies submitted a formal complaint to the Pretoria High Court in South Africa, challenging the lawfulness of the above act. Due to strong pressure from domestic and international public opinion, those companies withdrew their complaint in April 2001.[8]Generally speaking, the settlement of the lawsuit is considered as the triumph or victory of public interest against the egoistic interests and monopoly rights of pharmaceutical companies. [9] Nevertheless, many developing countries express concerns about diminishing access to the low-price HIV/AIDS-related drugs since the major generic drug-producing countries such as Argentina, Brazil, and India, are required to provide patent protection for pharmaceutical products from 1 January 2005 according to the TRIPS Agreement.

Meanwhile, certain international organizations have made every endeavor to search feasible schemes which will enable many developing countries to effectively combat the HIV/AIDS epidemic. In April 2001, WHO and WTO jointly held the workshop on Differential Pricing and Financing of Essential Drugs in Norway. [10]In the same month, the 57th Session of the United Nations Commission on Human Rights adopted Resolution 2001/33, on "Access to Medication in the Context of Pandemics such as HIV/AIDS", calling upon States at the national level, on a non-discriminatory basis for all to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them. Further, in May 2001, the 54th World Health Assembly also approved two Resolutions: "Scaling Up the Response to HIV/AIDS" [11]and " WHO Medicines Strategy "[12]. In the former resolution, the World Health Assembly recalls efforts to make drugs available at lower prices for those in need. And in the latter one, it notes that the impact of international trade agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated. Later on, in June 2001, the General Assembly of the United Nations held a Special Session on HIV/AIDS. Secretary General to this meeting attached great importance on the need to find ways of more effectively using trade policy provisions, such as compulsory licensing or parallel

[6] *Ibid*., UNAIDS Report, Annex 1.
[7] See *Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference*, Seattle, 30 November-3 December 1999. High prices are not the only reason behind the limited access to HIV treatments. Other reasons include limitations in infrastructure for diagnosis and treatment, lack of epidemiological data on the patterns of opportunistic diseases, gaps in the supply system and poor financing. See UNICEF/UNAIDS/WHO/EDM/MSF project*, Selected drugs used in the care of people living with HIV: sources and prices*, October 2000, p. 1.
[8] Pharmaceutical Company Lawsuit against the Government of South Africa, Case No. 4183/98 of 18 February 1998, available at: http://www.cptech.org/ip/health/sa/pharmasuit.html.
[9] Kongolo ,supra footnote 5, p.620.
[10] Details of this workshop are available at
[11] WHA54.10.
[12] WHA54.11.

importation, to increase access to care. And the availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with guarantees of their quality.

Accompanied with the worldwide campaign against HIV/AIDS epidemic, the TRIPS Agreement suffered adverse criticisms regarding public health issues. It is generally acknowledged that the success of the Uruguay Round of multilateral trade negotiations largely depended on the fact that the developing countries were offered greater access to market for traditional manufactured goods and for their agricultural products in exchange for codified obligations to respect intellectual property rights in the nontraditional products and processes that are the stock in trade of the technology-exporting countries.[13] The TRIPS Agreement requires all WTO Members to adapt their laws to the minimum standards set out in the Agreement within the established transitional periods. Although the obligations established by the TRIPS Agreement were likely to have substantial impact on prices of, and access to, medicine, there was very limited participation by public health experts and officials in the negotiating process, although pharmaceutical industry representatives played a major role in pressing for conclusion of the Agreement. Against this ground, it is not surprising that WTO developing (including least-developed) Members face difficulties in implementing the Agreement.[14] It can be given several concrete examples. The Agreement provides most of the developing country Members with 10-year (1 January 1995 - 1 January 2005) delayed application of patent protection for pharmaceutical products.[15] However, the Agreement places restrictions on this transitional arrangements with so-called "mailbox rule " requiring developing country Members should establish mechanisms for receiving and preserving priority in respect of pharmaceutical product patent application and should granting exclusive marketing rights to the applicants.[16]If mailbox and exclusive marketing rights requirements must be implemented, this will materially reduce the time during which generic products of low price may be available. Moreover, with regards to granting compulsory licenses, the Agreement provides many complicated restrictive provisions, one of which especially requires compulsory licenses shall be authorized predominantly for the supply of the domestic market of the Member.[17] Obviously, this paragraph operates as a significant restriction on the capacity of developing Members to make and acquire medicines and other public health-related products. Consequently, United Nations Commission on Human Rights pointed out in its Report (2000) on "Intellectual Property Rights and Human Rights" that there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other, since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the

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[13] J. H. Reichman & David Lange, *Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 Duke Journal of Comparative International Law, 1998, p.18. For detailed negotiating history of the TRIPS Agreement, see Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, 1998; John Croome, *Reshaping the World Trading System: A History of Uruguay Round*, Kluwer Law International, 1999.

[14] See Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 The Journal of World Intellectual Property 1, 2002, p.15.

[15] Article 65.4 of the TRIPS Agreement.

[16] Article 70.8 and 70.9 of the TRIPS Agreement.

[17] Article 31(f) of the TRIPS Agreement.

right to self-determination.[18] Accordingly, appeals for mainstreaming human rights into the TRIPS Agreement are becoming stronger.[19]

B. Results of the Doha Declaration and the Subsequent Developments

Recognizing the gravity of the public health problems afflicting many developing country Members, WTO members on Doha Ministerial Conference made attempts to integrate the TRIPS Agreement into part of the international action to address the public health problems. Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPS Agreement could be used, the Doha Declaration helps to prevent situations where developing country Members could not avail themselves fully of the flexibility provided in the TRIPS Agreement because of the pressure from interested groups. The Doha Declaration marked a turning point a political and legal relations at the WTO. It is a significant milestone.[20]

As the Doha Declaration states, intellectual property protection is important for the development of new medicines, [21]however, the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, 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. [22] 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. [23]The Declaration clearly outlines all the key flexibilities available in TRIPS, including:

- The right of Members to use compulsory licensing and to determine the grounds upon which such licenses are granted;[24]
- The right of Members to determine what constitutes a national emergency or other circumstances of extreme urgency, which can ease the granting of compulsory licenses;[25]

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[18] UN Commission in Human Rights: *Intellectual Property and Human Rights*, 2000, E/CN/.4/Sub.2/ 2000/7, para.2.

[19] See Ernst-Ulrish Petersmann, *The WTO Constitution and Human Rights*, 3 Journal of International Economic Law , 2000, 19-25; Ernst-Ulrish Petersmann, *From "Negative" To "Positive" Integation In The WTO: Time For 'Mainstreaming Human Rights' Into WTO Law?*, 37 Common Market Law Review, 2000, 1370-1377; Ernst-Ulrish Petersmann, *Human Rights* and International Economic Law in the 21st Century: The Need to Clarify their Interrelationships, 4 Journal of International Economic 1 Law , 2001, 3-39; Hoe Lim, *Trade and Human Rights: What's at Issue?*, 35 Journal of World Trade, 2001,275-300; UN Commission in Human Rights**,** *Th Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights***,** Report of the High Commissioner, 27 June 2001, E/CN.4/Sub.2/2001/13; UN Commission in Human Rights, *Globalization and its impact on the full enjoyment of human rights*, Progress report submitted by J. Oloka-Onyango and Deepika Udagama, in accordance with Sub-Commission resolution 1999/8 and Commission on Human Rights decision 2000/102, 2 August 2001, E/CN.4/Sub.2/2001/10.

[20] The negotiating history of the Doha Declaration, see Frederick M. Abbott, *The Doha Declaration on The TRIPS Agreement and Public Health: Lightening a Dark Corner in WTO*, 5 Journal International Economic Law, 2002, pp. 480-489.

[21] Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Forth Session Doha, 20 November 2001, WT/MIN(01)/DEC/2, para.3.

[22] *Ibid*., para. 4.

[23] *Ibid*., para. 5 (a).

[24] *Ibid*., para. 5 (b).

[25] *Ibid*., para. 5 (c).

- The right of Members to determine their own parallel import regimes, subject to the MFN and national treatment provisions of Articles 3 and 4; [26]and
- The right of least developed country Members to postpone providing pharmaceutical patents until *at least* 2016, and possibly longer.[27]

In addition, the Declaration 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. [28]Particularly, considering the fact that many developing 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, Ministers to the Conference directed the TRIPS Council to find an expeditious way to facilitate effective use of compulsory licensing to address public health needs and to report to the General Council before the end of 2002.[29]

According to Decision on Implementation-Related Issues and Concerns, The TRIPS Council should continue its examination of the scope and modalities for non-violation complaints which are closely related to the issues discussed in the Doha Declaration. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement.[30]

Furthermore, subject to exception pursuant to paragraph 7 of the Declaration, it is imperative to resolve the issue whether exclusive marketing rights requirements contained in paragraph 9 of Article 70 of the TRIPS Agreement. Considering that obligations of granting exclusive marketing rights, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration, the General Council adopted a waiver decision in July 2002. Pursuant to this decision, the obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016. The decision is part of WTO members' ongoing efforts to ensure that intellectual property protection supports and does not obstruct poorer countries' need to tackle serious public health problems. Therefore, the former WTO Director-General Mike Moore comments as follows:

I am pleased that WTO members have acted promptly to implement this important part of the Doha Declaration on TRIPS and public health, and have seen fit to go beyond the strict reading of that declaration by also approving a draft waiver on exclusive marketing rights.[31]

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[26] *Ibid*., para. 5 (d).

[27] *Ibid*., para. 7. The TRIPS Council has made the decision that 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. See *Extension of the Transition Period under Article 66..1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with respect to Pharmaceutical Products*, Decision of the TRIPS Council of 27 June 2002, IP/C/25, para. 1.

[28] *Ibid*., para. 7. Pursuant to Decision on Implementation-Related Issues and Concerns, the provisions of Article 66.2 of the TRIPS Agreement are mandatory. The TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed-country Members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and information shall be updated by Members annually. See Implementation-Related Issues and Concerns, Decision of 14 November 2001, WT/MIN(01)/17, para, 11.2.

[29] *Ibid*. para. 5(e).

[30] *Implementation-Related Issues and Concerns*, Decision of 14 November 2001, WT/MIN(01)/17, para, 11.1.

[31] See *Council approves LDC decision with additional waiver*, WTO Press Release.

This waiver indicates that the reform in the TRIPS Agreement concerning public health will take the developing country Members' essential needs into account. And the issues unsolved in the TRIPS Agreement concerning public health will have more optimistic prospect.

III. COMPUSORY LICENSING AND PUBLIC HEALTH: THE EMERGING PROBLEM UNDER THE TRIPS AGREEMENT AND ITS RESOLUTION

A. Compulsory Licensing and Public Health

Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder, reducing the adverse effects of patents on price and availability. It mitigates the restrictive effect of exclusive rights and strike a balance between the title-holders' interests and those the public in the diffusion of knowledge and access to, and affordability of the outcomes of innovation and creativity. Moreover, granting compulsory licenses for specific classes of technologies (e.g. pharmaceuticals) is an important tool to promote competition and to low prices.[32] Therefore, compulsory licensing functions as a significant instrument to protect public interests and promote innovation, dissemination of newly-developed technologies, and reduce the adverse effects of patents on price and availability. And it well reflects the objectives and principles contained in Article 7 and 8 in the TRIPS Agreement, namely the balance of rights and obligations, the promotion of technological innovation and transfer and dissemination of technology, the mutual advantage of producers and users of technological knowledge, social and economic welfare, and the protection of public health and nutrition.

Compulsory licensing is essential to many developing country Members that sources of generic or low-cost drugs be made available. [33] However, developing country 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. This predicament confronts many developing country Members simply because those Members don't have fundamental manufacturing capacities to effectively use the granted compulsory license. Accordingly, some commentators pointed out that the only way to dismantle the barrier is through importation of low-price drugs under compulsory licenses. [34]

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[32] Carlos M. Correa, *Intellectual Property Rights and the use of Compulsory Licenses: Options for Developing Countries,* South Centre, Trade-Related Agenda, Development and Equity Working Paper 5, p. 24. Professor Correa also empathizes that countries should examine the potential negative impact of compulsory licensing, as with other measures limiting patentees' rights. The consequences include the possibility of discouraging foreign investment, transfer of technology, and research, including research into local diseases. See Carlos M. Correa, *Integrating Public Health concerns into Patent Legislation*, South Centre, Books, 2000, pp. 91-100.

[33] Frederick M. Abbott , *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Quaker United Nations Office – Geneva, Occasional Paper 9, p. 17.

[34] Carlos M. Correa, *Intellectual Property Rights• The WTO and Developing Countries: The TRIPs Agreement and Policy Options*, Zed Books Ltd., 2000, 93; Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement—Two Proposals*, 4 The Journal of World Intellectual Property , 2001, 323-336; Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 The Journal of World Intellectual Property, 2002, 23-29.

Nevertheless, Article 31(f) of the TRIPS Agreement stipulates that compulsory licenses shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use, making it impossible for WTO Members to grant a compulsory license to its manufacturer to produce the drugs solely for exporting to the Members experiencing grave public health problems yet without adequate manufacturing capacities in the pharmaceutical sector. Pursuant to paragraph 6 of Doha Declaration, the TRIPS Council should find an expeditious solution to this problem and to report to the General Council before the end of 2002. So the nature of this problem that needs to be addressed in the discussion of the TRIPS Council is to dismantle the hindrance created by the restrictions contained in Article 31(f) when WTO Members are making attempts to fight against public health crises.

Discussions on the fundamental problems concerning " TRIPS Agreement and Public Health " commenced at the TRIPS Council in June 2001.Based on the Doha Declaration, the TRIPS Council hold two meetings in March and June 2002 respectively, discussing how to find an expeditious solution to the above problem pursuant to paragraph 6 of the Declaration on " TRIPS Agreement and Public Health ". As to the "expeditious solution" , certain WTO Members participating in the discussion put forward several suggestions as follows:

- delete Article 31(f);[35] or

- an amendment to Article 31 in order to overcome the restriction, under Article 31(f), to the possibility to export products manufactured and/or sold under a compulsory license;[36] or

- a waiver with regard to Article 31(f);[37]or

- an authoritative interpretation based on Article 30, enabling the WTO Member to use "limited exceptions" export products manufactured and/or sold under this article.[38]

According to Marrakesh Agreement on Establishing The World Trade Organization (WTO Agreement) and the TRIPS Agreement, there are four ways to the amend the TRIPS Agreement:

- amendments to Article 4 of the Agreement shall take effect only upon acceptance by all Members; [39]and

- amendments to provisions of the Agreement, of a nature that would alter the rights and obligations of the Members, shall 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; [40]and

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[35] Joint Communication from the African Group in the WTO, *Proposals on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 24 June 2002, IP/C/W/351.

[36] Joint Communication from the African Group in the WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 24 June 2002, IP/C/W/351; Communication from the European Communities and their member States, *Concept Paper Relating to Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, 4 March 2002 , IP/C/W/339; Communication from the European Communities and their member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, 20 June 2002,IP/C/W/352.

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

[38] Communication from the United Arab Emirates, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, 24 June 2002, IP/C/W/354; Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, 24 June 2002, IP/C/W/355.

[39] Article X:2 of Agreement Establishing The World Trade Organization (hereinafter WTO Agreement).

[40] *Ibid*. at Article X: 3.

- amendments to provisions of the Agreement, of a nature that would not alter the rights and obligations of the Members, shall take effect for all Members upon acceptance by two thirds of the Members; [41]and

- amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the TRIPS Council.[42]

As to the waiver procedure, the WTO Agreement stipulates that a request for a waiver concerning the TRIPS Agreement, shall be submitted initially to the TRIPS Council, and the Council shall submit a report to the Ministerial Conference within the consideration time-period of 90 days. Then, the request for a waiver shall take effect for related Members normally according to the practice of decision-making by consensus .[43]

The first or second resolution recommending to make a amendment associated with Article 31(f), is of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members in the Fifth Ministerial Conference according to the preceding analysis of the amendment of the TRIPS Agreement. Similarly, the third resolution will come into effect on the next Ministerial Conference. Paragraph 6 of the Doha Declaration WTO directed the TRIPS Council to find an *expeditious* solution to the problem. Nonetheless, it is not until the next Ministerial Conference will the first and second solution be adopted. Consequently, these suggested resolutions may take long to effect for lack of the characteristics of *expeditiousness*.

Furthermore, Article 31(f)-based solution would require amendments in the national legislation of the exporting country Member. It would also require the granting of compulsory licenses in both the exporting and importing countries, and possibly entail double remuneration to the patent right holders. The first resolution, suggesting to delete Article 31(f), will break through the restriction of territory in compulsory licensing. And further, it will damage the negotiated delicate balance of the patent protection, resulting in protest from most of the developing country Members.

Apart from the time-consuming decision process, one drawback of the waiver mechanism other than is that it is temporary, although there is no definitive outer limit to duration established by the WTO Agreement. The consequence of potential limitation of the duration of a waiver is that WTO Members (and enterprises within them) may have difficulty engaging in long term planning regarding the supply of medicines.[44]

Under the WTO Agreement, the Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of the Multilateral Trade Agreements, including the TRIPS Agreement. In the case of an interpretation of the TRIPS Agreement, they shall exercise their authority on the basis of a recommendation by the TRIPS Council overseeing the functioning of the Agreement.

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[41] *Ibid*. at Article X: 4.
[42] Article 71.2 of the TRIPS Agreement.
[43] Article IX of the WTO Agreement.
[44] Frederick M. Abbott , *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Quaker United Nations Office – Geneva, Occasional Paper 9, pp. 20-21.

The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members. Therefore, an interpretation of the TRIPS Agreement requires that the TRIPS Council make a related recommendation first, and then take effect upon the a three-fourths majority of the Members at the General Council. In comparison with the time-consuming amendment or waiver procedure, the interpretation procedure has the feature of *expeditiousness*, meeting the requirement set in the paragraph 6 of the Doha Declaration. From this point of view, the fourth resolution, which suggests make an authoritative interpretation based on Article 30 to address the problem, is more appealing.[45]

It is more important that, under Article 30-based solution, prospective exporting Members are entitled to use "limited exceptions" provided in Article 30 of the TRIPS Agreement to import health-related drugs. Therefore, with the interpretation of Article 30 of the TRIPS Agreement, prospective exporting Members could avoid cumbersome procedures of granting compulsory license and would accelerate the pace of addressing public health problems. Conspicuously, Article 30-based solution, not only enable prospective exporting Members to detour the barriers created by Article 31(f), but also keep the delicate balance of rights and obligations in patent protection due to the limits set out in Article 30.

B. The Interpretation of Article 30 of the TRIPS Agreement

Among the WTO Agreements, the TRIPS Agreement is probably the most difficult to interpret. [46] Underlying the superficial certainty of the TRIPS Agreement substantive prescriptions are existing gulfs of interpretative difference regarding the meaning of many of its rules.[47] The wording of TRIPS Article 30 is particularly ambiguous and this provision has no direct counterpart in the Paris Convention or the common-law of WTO Members pre-dating the Uruguay Round negotiations, there is no substantial uncertainty regarding how its criteria should be applied. [48] Although the Panel in the *Canada-Generics* case has made some analyses of Article 30, its interpretation is not definitive. Nor does it provide guidance on the legitimacy of all types of regulatory review exceptions or other relevant aspects of national patent regimes.[49] Moreover, that case was dealing with a context substantially different than that suggested here, and it is difficult to predict how the precedent of that case would be applied in terms of the TRIPS Agreement and public health.

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[45] Article 30 of the TRIPS Agreement provides, "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

[46] Oliver Cattneo, *The Interpretation of the TRIPS Agreement –Considerations for the WTO Panels and Appellate Body*, 3 The Journal of World Intellectual Property, 2000, p. 679.

[47] Frederick M. Abbott, *WTO Dispute Settlement and Agreement on Trade-Related Aspects of Intellectual Property Rights*, in E.-U. Petersmann(ed.), *International Trade Law and the GATT/WTO Dispute Settlement Systems*, Kluwer Law International, 1997, p. 415.

[48] Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 The Journal of World Intellectual Property 1, 2002, pp. 27-28.

[49] Dara Williams, *Developing TRIPS Jurisprudence—The First Six Years and Beyond* ", 4 The Journal of World Intellectual Property, 2001, p. 191.

1. Basic Principles of the Interpretation

(a) Principle of Protecting Public Health

The TRIPS Agreement is intended to achieve a balance between the protection of intellectual property rights and other social and economic policies and it is important that Members have the necessary flexibility to adjust intellectual property laws to maintain the desired balance. The Agreement does not and should not prevent Members from taking measures to protect public health.[50] Accordingly, the TRIPS Council should reaffirm 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.

(b) Principle of Good-Faith Interpretation

The Doha Declaration requires that 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.[51] The fundamental rule of treaty interpretation as set out in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (the "Vienna Convention")[52] had attained the status of a rule of customary or general international law.[53]

In the framework of the TRIPS Agreement, which incorporates certain provisions of the major pre-existing international instruments on intellectual property, the context to which the TRIPS Council may have recourse for purposes of interpretation of specific TRIPS provisions, in this case Article 30, is not restricted to the text and Preamble of the TRIPS Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement, as well as any agreement between the parties relating to these agreements within the meaning of Article 31(2) of the Vienna Convention on the Law of Treaties. Thus, as the Council will have occasion to elaborate further below, Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (1971) (the Berne Convention)[54] is an important contextual element for the interpretation of Article 30 of the TRIPS Agreement. As a consequence of the extended context that has to be taken into account when interpreting provisions of the TRIPS Agreement, the TRIPS Council, in considering the negotiating history of the TRIPS Agreement, should adopt that interpretation may go beyond the negotiating history of the TRIPS Agreement

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[50] Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Forth Session Doha, 20 November 2001, WT/MIN(01)/DEC/2, para. 4.

[51] *Ibid*., para. 5(a).

[52] Vienna Convention on the Law of Treaties, done at Vienna, 23 May 1969, entered into force on 27 January 1980.

[53] See *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, p. 17. *See* also Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, p. 11; Appellate Body Reports, *India—Patents*, para. 46; *European Communities—Customs Classification of Certain Computer Equipment*, WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68AB/R, adopted 22 June 1998, para. 84; *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, para. 114; and James Cameron and Kevin R. Gray, *Principles of International Law in the WTO Dispute Settlement Body* , 50 International and Comparative Law Quarterly, 2001, pp. 254-256.

[54]

proper and also inquire into that of the incorporated international instruments on intellectual property.[55]

2. Basic Ingredients of the Interpretation

Discretion whether to use the exceptions under Article 30 is in the hands of the Member that would grant the authorization. However, the following content of the interpretation would help prevent Members from not fully carry out the obligations pertaining to the protection of intellectual property rights under the TRIPS Agreement.

(a) Pharmaceutical Product Coverage

Article 30 authorizes "limited exceptions", meaning that Member may deviate from general rules of the patent protection under the TRIPS Agreement within the established boundaries. When a WTO Member uses "limited exceptions" under Articles 30 of the TRIPS Agreement, it is of great significance to determine the coverage of the exporting pharmaceutical products, in order to guarantee that this action does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner.

African group advocates that the coverage should include medicines, related technical processes, and related technical equipment, whereas some WTO Members, for example Japan, maintains that the scope of the products should be limited to the treatments of diseases listed in the Declaration, namely HIV/AIDS, malaria and tuberculosis. [56]On one hand, a broad-based scope of product may probably prejudice the legitimate interests of the pharmaceutical product patent owner and weaken new R&D in new drugs. On the other hand, a narrow-based scope of product merely covering the treatments of HIV/AIDS, malaria and tuberculosis, may probably creates impediments to address the public health crises resulting not only from diseases other than the three foresaid ones but also from other potential diseases. The Doha Declaration does not refer just to situations that relate to serious public health problems like HIV/AIDS, malaria and tuberculosis, but it relates also to all other public health policy problems. Paragraphs 4 and 5 recognize the need for flexibility for this purpose, including the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Therefore, the best coverage should be refined to the on-patent pharmaceutical products conducive to addressing public health problem. In addition, the on-patent pharmaceutical products associated with the treatments of HIV/AIDS, malaria and tuberculosis diseases should be particularly laid much importance on. While the TRIPS Council determines the scope of the products, it could make reference to the Essential Drugs List issued by WHO.

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[55] See *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R, adopted on 5 February 1997, paras.1.4 –1.6; *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted on 17 March 2000, paras.7.1-7.3; *United States—Section 110(5) of the U.S. Copyright Act*, adopted on 4 February 1999, WT/DS160/R, paras. 1.26-1.27; *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, adopted 6 August 2001, paras. 1.1-1.3.

[56] *Proposals on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation* , Note by the Secretariat ,1 July 2002, IP/C/W/363, p. 4.

(b) Eligible Beneficiary Importing Members

a. Scope

Due to insufficient GNP, limited government financial capacity, and lacking well-established pharmaceutical industries and sophisticated pharmaceutical technologies, many developing country Members, especially least-developed country Members which are vulnerable to grave public health crises yet with insufficient or no manufacturing capacities in the pharmaceutical sector, should constitute the beneficiary importing Members. Since none of the developed country Members face the above mentioned difficulties, developed country Members should not be included in this scope.

b. Assessment of Insufficient Manufacturing Capacity

Firstly, least-developed country Members listed in the report annually issued by ECOSOC or World Bank, should be deduced automatically to have insufficient or no manufacturing capacities in the pharmaceutical sector. Secondly, as to developing country Members, it is appropriate to entitle these Members to determine in prior whether they have with insufficient or no manufacturing capacities in the pharmaceutical sector. Then these Members should promptly submit reports on the assessment on their manufacturing capacities of certain pharmaceuticals pertaining to the addressing of domestic public health problems.

(c) Eligible Exporting Members

a. Scope

Owing to the fact that the vast majority of low-price generic drugs are produced in some developing country Members, the eligible exporting Members should consist of the developing country Members with sufficient manufacturing capacities in the pharmaceutical sector and requested by the eligible exporting Members which is afflicted with grave public health problems. If the supply of certain pharmaceuticals is beyond the manufacturing capacities in developing country Members, a requesting country would have to have its medicines supplied by a developed country Member.

b. Remuneration to patent right holders

Article 31(h) of the TRIPS Agreement ambiguously provides that in light of compulsory license, the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. In light of the using " limited exceptions" under article 30 analogous with granting compulsory licence, the right holder should be appropriately compensated. Although there is an inherent contradiction between compulsory licensing, which aims to increase competition, and a profit-based standard for compensation that would preserve the monopoly right of the patent, [57]the patent right holder should be willing to accept the remuneration lower than the normal in the case of WTO Member's using " limited exceptions " analogous with granting compulsory licence to address public health problems.

Article 30 is silent on the issue of remuneration and it neither compels nor prohibits Members from establishing the form of compensatory adjustment when using the exception rules contained in their domestic patent laws. In order to obviate the problem of double remuneration, the burden should fall on the exporting Members which make effective use of " limited exceptions ". The TRIPS Council should establish guidelines for calculating remuneration. And simultaneously, it is also

[57] Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement—Two Proposals*, 4 The Journal of World Intellectual Property , 2001, p. 331.

important to establish an international fund to financially assist the exporting Members which assume the remuneration burden.

(d) Reasonable Safeguards Against Trade Diversion

Reasonable safeguards against trade diversion aim to prevent Members' abuse of rights undermining the legitimate interests of related right holders. The exporting Members shall ensure that the entirety of the requested production is directly exported to the eligible importing Members and prevent diversion of the relevant pharmaceuticals into their domestic markets. Besides, these Members shall make a binding confirmation with regards to the quality and delivery condition of the relevant pharmaceuticals. As regards importing Members, they shall take necessary measures to ensure that pharmaceutical products are only sold or distributed domestically and not re-exported to other Members.

(e) Establishment of Transparent Procedure

Considerable importance should be attached to establish a set of fully transparent procedures for the sake of keeping balance of rights and obligations in the intellectual property protection system and accelerating the pace of addressing public health problems. Both importing and exporting Members shall carry out the obligations of publishing and notifying relevant information, and providing consulting service under article 63 of the TRIPS Agreement. The procedures involve that importing Members shall notify the information pertaining to the granting compulsory on the basis of public health needs and to having insufficient or no manufacturing capacities in the pharmaceutical sector, to the TRIPS Council in the shortest time possible. Equally, the exporting Members shall notify the information pertaining to the request of the importing Members and the process of manufacturing and delivering pharmaceuticals to the TRIPS Council without any delay. In this way, with the foregoing publicly available information, both the TRIPS Council and the interested Members will be constantly kept well-informed and monitor the on-going actions.

IV. NON-VIOLATION COMPAINTS:TIME TO ANSWER THE QUESTION WHETHER THIS TYPE OF CLAIM SHOULD BE APPLICABLE TO THE TRIPS-RELATED DISPUTES

A. Why Non-violation Complaints Are in Close Correlation to Public Health under the TRIPS Agreement

1. The Concept of Non-violation in the GATT/WTO Legal System

Naturally, non-violation complaints originated from U.S. bilateral trade agreements between 1920s and 1940s proceeding World War II. [58] Then, it was introduced into GATT multilateral trading systems by the trade diplomats as GATT

[58] Thomas Cottier and Krista Nadakavukaren Schefer, *Non-Violation Complaints in WTO/GATT Dispute Settlement: Past, Present and Future*, in Ernst-Ulrish Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, 1997, pp.149-151; Ernst-Ulrish Petersmann, *The GATT/WTO Dispute Settlement System: International law, International organizations, and Dispute settlement,* Kluwer Law International, 1997,pp. 142-143.

framers. [59] In international law, the rule still is that one state is liable for the consequences of breaches of contract or acts which constitute a tort. The concept of non-violation complaints goes further than this. It seeks to render a Member liable for situations in which it has not violated any agreement. Under the GATT/WTO multilateral trading system, [60] the non-violation procedure seeks to render the international liability for injurious consequences of lawful acts. Meanwhile, it is important as it allows, to a certain extent, "the closing-up of a loophole in substantive law, offering the possibility of maintaining the balance of interests even in cases where the substantive law dose not cover the issues at hand". [61] In contrast with violation, non-violation is featured the following four characteristics:

- Objective. Under Article XXIII: 1(b) of the GATT 1994, a Member can bring a "non-violation" complaint when the negotiated balance of concessions between Members is upset by the application of a measure, whether or not this measure is inconsistent with the provisions of the covered agreement. The ultimate goal is not the withdrawal of the measure concerned, but rather achieving a mutually satisfactory adjustment, usually by means of compensation.[62] Compensation, which provides the complaining party with a trade advantage offsetting the loss from the offending measure, eliminates the consequence rather than the measure itself.
- Essential requirements. A review of the experience with nullification or impairment non-violation cases under Article XXIII:1(b) of GATT 1947 and GATT 1994 indicates that the following are the essential requirements that have had to be met by a complaining party in order to mount a successful case: that a measure attributable to the respondent party government exists; that the measure could not reasonably have been expected by the complaining party at the time that it negotiated a commitment with the respondent party; and that the measure adversely upsets the competitive relationship between products established by the commitment in question.[63]
- Burden of proof. The complaining party shall present a detailed justification in support of any complaint relating to a measure which does not conflict with the relevant covered agreement;[64]

- The arbitration procedure. The arbitration provided for in Article 21.3 of DSU, upon request of either party, may include a determination of the level of benefits which have been nullified or impaired, and may also suggest ways and means of reaching a mutually satisfactory adjustment; such suggestions shall not be binding upon the parties to the dispute.[65]

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[59] See Robert E. Hudec, *Enforcing International Trade Law: The Evolution of the Modern GATT Legal System*, 1993, p. 7.

[60] Non-violation complaints are used to settle the disputes(including the ones on intellectual property matters) in some regional organizations, like the North American Free Trade Agreement (NAFTA).

[61] Armin Bogdandy, *The Non-violation Procedure of Article XXIII: 2 of GATT: Its Operational Rational*, 26 The Journal of World Trade, 1992, p. 110.

[62] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, adopted on 19 December 1997, WT/DS50/AB/R, para.41.

[63] TRIPS Council, *Non-Violation Complaints and The TRIPS Agreement*, Note by the Secretariat, 28 January 1999, IP/C/W/124, para. 32.

[64] Article 26.1(a) of DSU. The failure to meet the burden of demonstrating actual nullification and impairment was decisive in a number of cases including non-violation claims, including *Japan – Semi-conductors*, *United States – 1955 Waiver, Japan – Film* and *Korea –Government procurement.*

[65] Article 26.1(c) of DSU.

Although the non-violation remedy is an important and accepted tool of GATT/WTO dispute settlement and has been "on the books" for almost 50 years, we note that there have been only eight cases in which panels or working parties have substantially considered Article XXIII:1(b) claims. [66]In three cases, the non-violation complaint was successful and the Working Party or Panel Reports were adopted. [67] Two were cases where the Panels found the non-violation complaints justified but the Panel Reports were not adopted.[68] In addition, there were three cases in which the non-violation claims failed for lack of a detailed justification. [69] Since the establishment of the WTO, there has been only two Panel reports which substantively considered non-violation claims.[70]

2. The Relationship Between Non-violation Complaints and Public Health----A Negotiating History Perspective

After the Uruguay negotiations, non-violation complaints were extended to apply to the GATS-related disputes. [71]On the contrary, delegations could not reach comprise whether the non-violation complaints should be extended to apply to the TRIPS-related disputes.

Negotiations about the TRIPS-related disputes appeared hard in the Uruguay Round. It was not until December of 1991 did the discussions took place focusing essentially on the compromise proposal and, in particular, on the extent to which it would be necessary to retain the various special provisions relating to TRIPS disputes given the general provisions of the Dispute Settlement Understanding(DSU) that were emerging. On the basis of this discussion, provisions pertaining to the settlement of TRIPS-related disputes in the Draft Final Act, tabled on 20 December 1991, was in substance the same as that presently found in paragraph 1 of Article 64 of the TRIPS Agreement. No other paragraphs were included in the provision on dispute settlement in the draft TRIPS text of 20 December 1991. [72]However, given that the work on the development of an integrated dispute settlement understanding was still incomplete, a footnote was included stating that: "This provision may need to be revised in the light

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[66] *Japan – Measures Affecting Consumer Photographic Film and Paper,* adopted on 22 April 1998, WT/DS44/R, para. 10.36.

[67] Working Party Report, *The Australian Subsidy on Ammonium Sulphate,* adopted on 3 April 1950, BISD II/188; Panel Report, *Treatment of Germany of Imports of Sardines*, adopted on 31 October 1952, BISD 1S/53; and Panel Report, *European Communities – Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins*, adopted 25 January 1990, BISD 37S/86 and Report of the Members of the Original Oilseeds Panel, *Follow-up on the Panel Report 'EEC – Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal Feed Proteins'*, DS28/R, dated 31 March 1992, BISD 39S/91.

[68] 1985 Panel Report, *European Community – Tariff Treatment on Imports of Citrus Products from Certain Countries in the Mediterranean Region,* L/5776, not adopted and 1985 Panel Report, *European Economic Community – Production Aids Granted on Canned Peaches, Canned Pears, Canned Fruit Cocktail and Dried Grapes*, L/5778, not adopted.

[69] Panel Report, *Uruguayan Recourse to Article XXIII*, adopted on 16 November 1962, BISD 11S/95; Panel Report, *Japan – Trade in Semi-conductors*, adopted on 24 May 1960, BISD 35S/116; and Panel Report, *United States – Restrictions on the Importation of Sugar and Sugar-containing Products Applied under the 1955 Waiver and under the headnote to the Schedule of Tariff Concessions*, adopted on 7 November 1990, BISD 37S/228.

[70] *Japan – Measures Affecting Consumer Photographic Film and Paper,* adopted on 22 April 1998, WT/DS44/R.And *Korea- Measures Affecting Government Procurement*, adopted on 1 May 2000 , WT/DS163/R.

[71] See Article XXIII of General Agreement on Service(hereinafter GATS)

[72] MTN.TNC/W/FA.

of the outcome of work on the establishment of an Integrated Dispute Settlement Understanding under the Agreement Establishing the Multilateral Trade Organization".

While the issue of non-violation had not figured in the negotiations that led to this text, the issue had arisen significantly in the negotiations in autumn 1991 of the text of Article 8 of the TRIPS Agreement. The December 1990 Brussels text of Article 8 was, in substance, the same as that presently contained in Article 8 with the exception that, in paragraph 1, the qualifying phrase "provided that such measures are consistent with the provisions of this Agreement" read "provided that PARTIES do not derogate from the obligations arising under this Agreement" and that a similar difference was also contained in the draft of paragraph 2. The issue that arose and which led to quite lengthy negotiations was that some delegations expressed concern about the possible use of the provisions of Article 8 to justify measures which, while not inconsistent with obligations under the Agreement, might have the effect of impairing benefits that other Members could legitimately expect under the Agreement; in other words, that the provision about *protecting national public health* could be used as a defense in a non-violation case on the grounds that the taking of the measures envisaged by Article 8 could only have been reasonably expected at the time that the TRIPS negotiations were concluded. To forestall this effect, the suggestion was made that the phrase "or impair the benefits" might be inserted after the word 'obligations". Subsequently, the negotiations focused on the possible inclusion of the phrase "or otherwise undermine" before the words "the obligations". These modifications were opposed and, in the end, the text that was forwarded by the Chair for inclusion in the Draft Final Act was that presently found in Article 8, which requires that the measures in question conform with the "provisions" of the Agreement rather than forbidding them from derogating from "obligations" under the Agreement. [73]The relationship of negotiations on Article 8 of the TRIPS Agreement with the issue of non-violation complaints indicates that this type of dispute is a potential tool to successfully challenge the legitimacy of developing Members' using Article 8 to protect national public health.

Little progress on matters of substance was made in the Uruguay Round negotiations until the end of 1993. However, in the intervening period, useful work of a legal drafting nature took place. In this context, the issue of non-violation complaints arose in regard to the question of whether the footnote to Article 64 of the Draft Final Act text should be dropped or retained. Some delegations were opposed to its deletion because they wished for an opportunity to revert to the issue of non-violation in the TRIPS context depending on how the ongoing work on the conclusion of the provisions of the Dispute Settlement Understanding, including those relating to non-violation, evolved.[74]

The final substantive phase of the Uruguay Round negotiations took place in autumn 1993. During the TRIPS negotiations in particular, there was significant disagreement regarding the inclusion of a provision on non-violation in the context of intellectual property disputes. Unable to agree on the scope and modalities of non-violation claims in respect of TRIPS-related disputes, negotiators were, in the end, overtaken by time. Press to conclude the Round, they simply placed a moratorium on such claims in order to allow further investigation. In the result, the following two paragraphs limits the availability of non-violation complaints:

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[73] TRIPS Council, *Non-Violation Complaints and The TRIPS Agreement*, Note by the Secretariat, 28 January 1999, IP/C/W/124, paras. 13-14.
[74] *Ibid*., para. 15.

- subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement;[75]

- during the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.[76]

B. Reasons Why Non-violation Complaints Should Not Be Implanted into The Settlement of TRIPS-related Disputes

The potential application of the non-violation remedy to the TRIPS Agreement remains controversial within many WTO Members, legal scholars and commentators. Many of them are concerned that the extension of the non-violation remedy will further imbalance the implementation of the TRIPS Agreement, and have negative implications for the world sustainable economic development.

Virtually all the experts hold the opinions that non-violation claims should not be applicable to the TRIPS-related disputes. After tracing all the related publications, we can find there are three typical opinions. The first argument, and maybe the most convincing one, is based on the substantial difference between the TRIPS Agreement and, the GATT or the GATS. Unlike the GATT and the GATS, the TRIPS Agreement is not intended to leave WTO members with policy autonomy in the field of intellectual property protection that has to be compensated with redress under Article XXIII:1(b) of GATT. And there are no comparable balance of rights and obligations similar with the ones resulting from the exchange of scheduled tariff concessions and commitments on trade in service under the TRIPS Agreement. Besides, a finding of nullification or impairment under the TRIPS Agreement would have legal consequences substantially different from those of such a finding under the GATT and the GATS. [77]The second argument, maybe the most radical one•contends that, from a procedural point of view, the non-violation claims are a relic of the past, part of the old GATT diplomatic mode of dispute settlement now superseded by new legalistic, rule-based system. Given the inherent ambiguity of the non-violation provisions and the concomitant risk that they might be misused, they present several disadvantages, both to panels attempting to resolve disputes under these provisions and to the WTO system as a whole.[78] The third argument finds an alternative reasoning to the discussed issue. It argues that while there is no jurisprudential obstacle to non-violation complaints under the TRIPS Agreement, such claims would effectively give powerful proprietary interests a generalized instrument of trade policy

[75] Article 64.2 of the TRIPS Agreement.
[76] Article 64.3 of the TRIPS Agreement.
[77] See F. Roessler, *The Concept of Nullification and Impairment in the Legal System of the World Trade Organization*, in E.-U. Petersmann(ed.), *International Trade Law and the GATT/WTO Dispute Settlement Systems*, Kluwer Law International, 1997, pp.135-138.
[78] See Sung-joon Cho, *GATT Non-Violation Issues in the WTO Framework: Are they the Achilles' Heel of the Dispute Settlement Process?*, 39 Harvard International Law Journal 2, 1998, pp. 311-355.

which will, even in the absence of an infringement, operate as a serious restraints on the ability of governments to address problems of social and economic dislocation.[79]

Pursuant to Article 64.3 of the TRIPS Agreement, the TRIPS Council started to examine the scope and modalities for non-violation complaints from early 1999. . However, with the failure of the TRIPS Council to make recommendations before 1 January 2000, combined with the failure of the Seattle Ministerial Conference, once raises questions about the status of the moratorium. A number of views about the status of the moratorium have been expressed in the TRIPS Council before and after the Seattle Ministerial Conference. On the basis of papers submitted to and discussions in the TRIPS Council, it seems that only one Member, the United States, supports unqualified application of the non-violation remedy to the TRIPS-related disputes. [80]Other Members, like EU and Canada, oppose the instant application of the non-violation remedy to the TRIPS-related disputes without careful deliberations on its potential impacts on the world-wide protection of intellectual property rights.[81]

This problem has been partly resolved during the Doha Ministerial Conference. The TRIPS Council is directed to continue its examination of the scope and modalities for non-violation complaints and make recommendations to the Fifth Session of the Ministerial Conference. Members agreed that, in the meantime, they will not initiate such complaints under the TRIPS Agreement.[82]

1. Defects Hidden in The Non-violation Provisions

As discussed earlier, non-violation complaints were introduced into the GATT legal systems with the trade diplomats' endless efforts. They were there to correct imbalances that might arise in the benefits governments were actually receiving from the agreement. Therefore, it is a diplomat's concept of legal order.[83] Nonetheless, since non-violation provision was inserted into the multilateral trading systems by the GATT architects. The inherent ambiguity have persistently surrounded this type of claim and the veil on it has never been pierced by the GATT/WTO legal practices.

Firstly, in many non-violation cases, there has been no prominent distinction between violation and non-violation complaints. Moreover, at the initial complaint-filing stage, the non-violation does not provide an independent and definite cause of action. It has played only an auxiliary role as a preceded by the phrase "even if no

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[79] See Gail E. Evans, *A Preliminary Excursion into TRIPS and Non-Violation Complaints*, 3 The Journal of World Intellectual Property, 2000, pp. 867-888.

[80] Communication from the United States of America, *Scope and Modalities of under the TRIPS Agreement*, 17 July 2000,IP/C/W/194.

[81] Communication from Canada, *Non-violation Nullification or Impairment under the Agreement on Trade -Related Aspects of Intellectual Property Rights(TRIPS*), 10 February 1999, IP/C/W/127; Proposal from Cuba, the Dominican Republic, Egypt, Indonesia, Malaysia and Pakistan, *Non-violation Nullification or Impairment under the Agreement on Trade Related Aspects of Intellectual Property Rights(TRIPS*), 29 April 1999, IP/C/W/141; Communication from Canada, the Czech Republic, the European Communities and their member States, Hungary and Turkey, *Non-violation Complaints under the TRIPS Agreement -Suggested Issues for Examination of Scope and Modalities under Article 64.3 of the TRIPS Agreement*, 22 June 2000, IP/C/W/191; Communication from Australia, *Non-violation Complaints under the Agreement on Trade- Related Aspects of Intellectual Property Rights(TRIPS*), 27 September 2000, IP/C/W/212. Communication from Canada, Further consideration of *Non-violation Nullification or Impairment under the Agreement on Trade -Related Aspects of Intellectual Property Rights*, 29 March 2001, IP/C/W/249.

[82] *Implementation-related Issues and Concerns*, Decision of 14 November 2001, WT/MIN(01)/17, para.11.1.

[83] See Robert E. Hudec, *Enforcing International Trade Law: The Evolution of the Modern GATT Legal System*, 1993, p. 7.

violation exists". Moreover, the complaining party often makes little effort to distinguish between a violation claim and a non-violation claim. [84]For instance, in *EEC-Citrus* the United States claimed that the EC's preferential tariffs on citrus imports from certain Mediterranean countries generally caused nullification or impairment with no distinction between violation and non-violation. [85] Since the establishment of the WTO, non-violation claims have also been raised, together with violation claims, in various other requests for consultations or the establishment of a panel. [86] In *Korea –Government procurement* the United States both brought the violation complaints and non-violation complaints. [87]In addition, in some other cases claims of nullification or impairment of benefits have been made without specifying whether this is on a violation or non-violation basis. Therefore, the uncertainty may lead a future complaining party to misuse or rely too heavily on the non-violation claims, thus leading the settlement of disputes into an over-burdensome situation.

Secondly, some key concepts of the non-violation provision has not yet been clarified. Such terms, like "benefit", "measure", "causality" and so on, appearing to be open-end and all-inclusive, has not been given clear-cut definitions. Panels have rarely been explicit in stating the elements of an Article XXIII:1(b) complaint.[88] For example, Article XXIII:1(b) of GATT merely sets the grounds on which WTO Members can have resource to the dispute settlement systems via non-violation complaints, without providing for any *a priori* exclusion as to what a "measure" might be. This term has not yet been explicitly defined by GATT/WTO non-violation cases. The *Japan-Film* Panel believed that it "should be open to a broad definition of the term measure for the purposes of Article XXIII:1(b) which considers whether or not a non-government binding action has an effect similar to a binding one".[89] And the Panel further admitted that "it is difficult to establish bright-line rules in this regard and it will need to be examined on a case-by-case basis". [90] In the TRIPS context, it will become much more difficult to define some key concepts: "benefit

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[84] See Sung-joon Cho, *GATT Non-Violation Issues in the WTO Framework: Are they the Achilles' Heel of the Dispute Settlement Process?*, 39 Harvard International Law Journal 2, 1998, pp. 322-323.

[85] *EEC-Tariff Treatment of Citrus Products from Certain Mediterranean Countries*, adopted on 7 February 1985, L/5776,C/M/186.

[86] These include: *Japan - Measures Affecting Distribution Services,* request for consultations by the United States, WT/DS45/1; *Brazil - Certain Automotive Investment Measures*, requests for consultations by Japan and the United States, WT/DS51/1 and WT/DS52/1; *United States – The Cuban Liberty and Democratic Solidarity* Act, request for establishment of a Panel by the European Communities, WT/DS38/2; *United States - Import Prohibition of Certain Shrimp and Shrimp Products,* request for consultations by the Philippines, WT/DS61/1; *European Communities – Measures Affecting Butter Products*, request for consultations and establishment of a panel by New Zealand, WT/DS72/1-2; *Brazil – Certain Measures Affecting Trade and Investment in the Automotive Sector*, requests for consultations by the United States and the European Communities, WT/DS65/1 and WT/DS81/1; *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, request for consultations by New Zealand, WT/DS93/1; *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, request for establishment of a panel by Canada, WT/DS135/3; *European Communities – Anti-dumping Investigations regarding Unbleached Cotton Fabrics from India*, request for consultations by India, WT/DS140/1; and *United States – Certain Measures Affecting the Import of Cattle, Swine and Grain from Canada*, request for consultations by Canada, WT/DS144/1.

[87] *Korea- Measures Affecting Government Procurement*, adopted on 1 May 2000 , WT/DS163/R.

[88] Adrian T.L. Chua, *Reasonable Expectations and Non-violation Complaints in GATT/WTO Jurisprudence*, 32 The Journal of World Trade, 1998, p. 39.

[89] *Japan - Film,* WT/DS44/R, para. 10.49.

[90] I*bid.,* para. 10.56 The panel of *Japan – Film,*referred to the Panel Report, *Japan – Semi-conductors*, BISD 35S/116, and a 1989 Panel Report, *EEC – Restrictions on Imports of Dessert Apples (Complaint by Chile)*, BISD 36S/93.

accruing directly or indirectly under the TRIPS Agreement", "nullification or impairment of such a benefit" and "impediment to the attainment of any objective of the Agreement".

Thirdly, up till now, the ruling of the non-violation cases lacks sufficient consistency. During the half-century history of the GATT, the dispute settlement procedure has tensely oscillated between two positions of tendencies—one that encourages minimal use of non-violation cases ("restraintism") and another that advocates more extensive use of non-violation cases ("activism"). The former attitude was labeled "supplementary-mode", which seems to fill the "legal gap" with a view towards re-balancing the original value of the tariff concession. And the latter attitude was labeled "independent-mode" that does not call for the existence of specific tariff concession or its connection with a reasonable expectation as the basis for invoking a complaint.[91] With this phenomena, it is hard to establish a fixed mode to successfully deal with non-violation complaints.

Fourthly, in a far more complicated legal background compared with the old GATT, the operation of non-violation claims in WTO dispute settlement system will become more changeable and unpredictable. Generally speaking, the more complicated legal environment evolved in the WTO, the harder to find sufficient guidance to govern the settlement of non-violation claims. The ruling on *Korea – Government procurement*, reveals that non-violation complaints may extend beyond the traditional approach represented by *pacta sunt servanda* [92]in the context of Article XXIII:1(b) of the GATT 1994 and Article 26 of the DSU, and which it suggested reflected general GATT/WTO jurisprudence.[93] This brand-new approach enhances the complexity of the settlement of non-violation claims.

Based on the above analysis, we can safely draw the conclusion that uncertainties surrounding the non-violation provisions still remain unresolved. Consequently, it is not surprising to find that one expert has raised incisive criticisms about the non-violation provisions, which considers such complaints "a legal fantasy", "a useless and dangerous construction" that should never have been included in the DSU.[94] Uncertainties will make it harder for Members to rely on the text of the TRIPS Agreement to define their rights and obligations in the face of non-violation complaints, particularly for least-developed country Members. Given the fact that the inherent ambiguity still persists in the non- violation provisions, it is inappropriate to introduce the non-violation complaints into the settlement of TRIPS-related disputes which are totally different from its counterparts under the GATT and the GATS, without beforehand clarifications in relation to the TRIPS Agreement.

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[91] See Sung-joon Cho, *GATT Non-Violation Issues in the WTO Framework: Are they the Achilles' Heel of the Dispute Settlement Process?*, 39 Harvard International Law Journal 2, 1998, pp. 316-320.

[92] The principle of *pacta sunt servanda* is expressed in Article 26 of the *Vienna Convention* in the following manner: "Every treaty in force is binding upon the parties to it and must be performed by them in good faith."

[93] See *Korea- Measures Affecting Government Procurement*, adopted on 1 May 2000 , WT/DS163/R, paras. 1.4 -1.46. The traditional claim of non-violation does not fit well with the situation existing in this dispute. Non-violation claims, as the doctrine has developed over the course of GATT and WTO disputes, have been based on nullification or impairment of benefits reasonably expected to flow from negotiated concessions. In this case, it was the negotiations which allegedly gave rise to the reasonable expectations rather than any concessions. Alternatively, the question the panel dealt with is whether or not there was a reasonable expectation of an entitlement to a benefit that had accrued pursuant to the *negotiation* rather than pursuant to a *concession*.

[94] See Pierre Pescatore, *The GATT Dispute Settlement Mechanism: Its Present Situation and its Prospect*, 27 Journal of World Trade 1, 1993, p. 5.

2. Distinctive Characteristics of the TRIPS Agreement

In the GATT/WTO legal framework, the establishment of the non-violation procedure aims primarily to prevent the tariff concessions or specific commitments on trade in services from being adversely distorted by the additional trade measures taken by the Members. Its history and application have been in the areas of market access, dating back to the early days of international trade agreements when governments could circumvent the relatively few undertakings by erecting new, non-tariff barriers to undermine the promises contained in the agreements. Its objective is to ensure that these domestic trade measures will not negate the negotiated marker access concessions. Politically, the concept of non-violation complaints in the WTO Agreement is "mainly supported by exporting countries seeking to assure market access and to avoid circumventions of the treaties by actions that not specifically regulated".[95] When it comes to the GATT and the GATS as market access agreements, non-violation complaints is an additional tool with which to balance the rights and obligations concerning market access in the GATT and GATS respectively.

Fundamentally differing from the GATT and the GATS, the TRIPS Agreement is not a market access agreement. It is not "about reciprocal market access rights of governments". [96] Obviously, there is no such counterpart in the TRIPS Agreement to schedules of commitments in the GATT and the GATS respectively. [97] In sharp contrast with the GATT and the GATS, the core content in the TRIPS Agreement is the WTO Members' mutual commitments on the minimum standards in relation to intellectual property protection. These minimum standards are based on the four intellectual property multilateral treaties administered by the WIPO. The intellectual property protection includes matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement, covering copyright and related Rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed information.

This Agreement emphasizes that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. [98] Guided by these principles, the TRIPS Agreement provides minimum standards with regard to the acquisition or exploitation of intellectual property rights and on their scope, as well as

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[95] Thomas Cottier and Krista Nadakavukaren Schefer, *Non-Violation Complaints in WTO/GATT Dispute Settlement: Past, Present and Future*, in Ernst-Ulrish Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, 1997, 148.

[96] Ernst-Ulrish Petersmann, *The GATT/WTO Dispute Settlement System: International law, International organizations, and Dispute settlement,* Kluwer Law International, 1997, p. 149.

[97] These schedules contain the commitments made by individual WTO members allowing specific foreign products or service-providers access to their markets. The schedules are integral parts of the agreements. In the print version these schedules comprise about 30,000 pages for all WTO Members. For goods in general: binding commitments on tariffs. For agriculture: tariffs, combinations of tariffs and quotas, export subsidies and some types of domestic support. As to service in trade, binding commitments on how much access foreign service providers are allowed for specific sectors, including lists types of services where individual countries say they are not applying the "most-favored-nation" principle of non-discrimination.

[98] Article 7 of the TRIPS Agreement.

procedures and measures to enforce those rights, notably by enabling effective action against unauthorized use of those rights by third parties.

While intellectual property rights might facilitate trade and investment, the obligations under the TRIPS Agreement cannot be characterized as market access concessions in the same way as obligations can be characterized under the GATT and GATS. It is difficult to see the analogy between scheduled tariff concessions or specific commitments on trade in service, and the multilateral recognition of the minimum rights of nationals to be provided for by a WTO Member on the basis of the TRIPS Agreement. On this ground, there is no need to extend the application of non-violation complaints to the TRIPS-related disputes.

Compared with the notoriously weak treaties administered by the WIPO, apart from compulsory minimum standards in the TRIPS Agreement, the Agreement simultaneously provides the following three measures to reinforce the effectiveness of those minimum standards:

- enforcements of intellectual property rights Part III of the TRIPS Agreement requires that Members shall ensure that fair and equitable enforcement procedures are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including civil, administrative and criminal procedures.

- dispute settlement. Disputes under the TRIPS Agreement shall be settled by the Dispute Settlement Body(DSB) using the rules of DSU. [99] Moreover, the TRIPS Agreement provided transparent procedures to prevent the potential disputes. Accordingly, Members shall carry out the obligations concerning the publishing or notifying related information, and supplying requested consultations. [100]

- reviews of the TRIPS Council The TRIPS Council shall review the implementation of this Agreement at regular intervals. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement. [101]

In addition, WTO Trade Policy Review Mechanism (TPRM) functions as a tool to promote WTO Members' positive implementation of the provided minimum

[99] Article 64.1 of the TRIPS Agreement.

[100] See Article 63 of the TRIPS Agreement. The TRIPS Agreement obliges the WTO Members to make certain notifications to the Council for TRIPS. These notifications facilitate the Council's work of monitoring the operation of the Agreement and promote the transparency of Members' policies on intellectual property protection. In addition, Members wishing to avail themselves of certain possibilities provided in the Agreement that relate to the substantive obligations have to notify the Council. In order to implement these notification obligations, the Council has adopted procedures and guidelines relating to them. In addition, the Members have agreed to make certain notifications which are not regulated in the Agreement.

[101] See Article 71.1 of the TRIPS Agreement. Article 63.2 of the TRIPS Agreement requires Members to notify the laws and regulations made effective by that Member pertaining to the subject-matter of the Agreement to the Council for TRIPS in order to assist the Council in its review of the operation of the Agreement. These notifications are the basis for reviews of implementing legislation carried out by the Council. Initially, the review exercise focused on those WTO Members who no longer benefit from a transition period, i.e. the developed country Members. The Council started reviews in July 1996 with an examination of the legislation of developed country Members in the area of copyright and related rights. It continued in November 1996 with the legislation in the areas of trademarks, geographical indications and industrial designs, and in May 1997 with the legislation in the areas of patents, layout-designs of integrated circuits, undisclosed information and the control of anti-competitive practices in contractual licences. Legislation in the area of enforcement is scheduled for review in the third week of November 1997. In 2000 reviews began for countries that had delayed notifying their laws until 2000.

standards in the TRIPS Agreement. [102]With these measures, the Agreement leaves WTO Members with no policy autonomy in the field of intellectual property protection of the TRIPS Agreement that has to be compensated with a redress under Article XXIII: 1(b).[103] Therefore, the above-mentioned measures provided in the TRIPS Agreement is strong to enough to enforce WTO Members carry out the obligations under the Agreement. From this point of view, there is definitely no need to extend the application of non-violation complaints to disputes under the TRIPS Agreement. As some trade experts has pointed out, expanded use of the non-violation remedy is difficult to justify within the rules-based WTO system. With the development of substantive rules to address non-tariff barriers, it has become progressively less necessary as a tool to protect market access commitments, and, by introducing legal uncertainty, it may operate in tension with the predictability and security that the system seeks to guarantee. [104]

3. Non-violation Complaints and Public Health

The negotiating history of the paragraphs 2 and 3 of the Article 64, indicates that, there is a close correlation between non-violation complaints and public health problems. Some delegations strongly advocated that non-violation should apply to the settlement of the TRIPS-related disputes, with the aim to prevent other Members from using Article 8.1 of the TRIPS Agreement to address domestic public health problems ,while this kind of action is to what extent in conflict with the interests of certain groups.

As mentioned in Part II, subject to serious HIV/AIDS epidemic, in November 1997, the South African government amended the Medicine and Related Substances Control Act in order to increase the availability of more affordable HIV/AIDS-related drugs via parallel imports and compulsory license. Except for the complaints submitted by the pharmaceutical company group, the United States governments express its views subsequently. The United States claims that, according to the of the TRIPS Agreement, the amendment made by the South African government violates the Article 27.1 which prohibits discrimination with respect to patentable subject-matter, and Article 28 which conferred the exclusive rights on the patent owner. In alternative, the United States claims, in accordance with Article XXIII: 1(b) of GATT1994, that the South African amendment, while not inconsistent with Members' obligations under the TRIPS Agreement, has the effect of impairing the benefits that it could legitimately expect under the Agreement. In response, the South African government argues that the qualification in Article 8.1 indicates that Member should not be subject to claim for non-violation nullification and impairment when taking measures consistent with the TRIPS Agreement in pursuit of societal interest, even where these measures could nullify and impair TRIPS's rights in some way. As no mutually satisfactory solution is reached during consultations, the United States has requested the Dispute Settlement Body (DSB) to establish a panel to examine the matter. In the interim, Member States, representing both developed and emerging

[102] See Bernard M. Hoekman and Petros C. Mavroidis, *WTO Dispute Settlement, Transparency and Surveillance*, 23 The World Economy, 2000, p. 527.
[103] F. Roessler, *The Concept of Nullification and Impairment in the Legal System of the World Trade Organization*, in E.-U. Petersmann(ed.), *International Trade Law and the GATT/WTO Dispute Settlement Systems*,Kluwer Law International, 1997, p. 136.
[104] Mattew Stilwell & Elizabeth Tuerk, *Non-Violation Complaints and The TRIPS Agreement: Some Considerations for WTO Members*, South Centre, Occasional Papers No.1, 2000 • para. 21.

economies, have made submissions to the TRIPS Council against the use of non-violation complaints in respect of disputes involving intellectual property.[105]

The other case was a WTO dispute brought by the United States questioning the compatibility with the TRIPS Agreement of Article 68 of Brazil's Industrial Property Law. The United States argued that this provision for the grant of compulsory licenses in the event that a patented invention was not used in domestic production ("local working" requirement) was a protective industrial policy measure and inconsistent with the provisions of the TRIPS Agreement. The Brazilians took the view that this measure was a necessary part of their programme to combat HIV/AIDS epidemic and was entirely consistent with the TRIPS Agreement. Following bilateral consultations, in July 2001, rather than pursuing the dispute any further in DSU procedures, Brazil and the United States announced that they had reached a mutually agreed solution. However, if this case were in the non-violation context, the result would have been totally different. It is very likely that Brazil will be the loser in the dispute. Because its measure did adversely impair the United States' benefit accruing directly or indirectly under the TRIPS Agreement.[106]

Based on the above two cases, it is easy to find that non-violation complaints are susceptible to be used to pressure developing country Members not to fully explore their rights to take measures, such as compulsory licensing or parallel import, which are consistent with the TRIPS Agreement, to ensure access to essential medicines with the aim to implement the human right to health. Non-violation complaints operate to strengthen the protection of intellectual property rights by means of generalized trade instrument, and further limit the autonomy of developing country Members to circumscribe law and policy in the national interests.

Besides, non-violation complaints may encourage unilateral pressure and speculative claims to force Members to raise protection beyond minimum requirements, or to refrain from using TRIPS-consistent measures such as compulsory licensing. Unilateral pressure based on non-violation complaints may also be applied to constrain the adoption of national measures adopted under Article 8 to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. [107]For example, in the above-mentioned dispute, with a view to protecting its national interest in maintaining the price of pharmaceuticals, the United States initiates unilateral action under Section 301 of the U.S. Trade Law, placing South Africa on the "Watch List" of countries lacking adequate intellectual property protection and threatening trade sanction of the situation was not suitably resolved.[108]

The Panel in *Japan - Film* noted that the non-violation remedy should be approached with caution and should remain an exceptional remedy.[109] Under the GATT/WTO jurisprudence, the non-violation remedy remains an exceptional character. Up till now, there is no consensus on the scope of non-violation complaints made

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[105] See Gail E. Evans, *A Preliminary Excursion into TRIPS and Non-Violation Complaints*, 3 The Journal of World Intellectual Property, 2000, pp. 872-873.

[106] See *Brazil - Measures Affecting Patent Protection - Request for Consultations by the United States*, WT/DS199/1, *Brazil - Measures Affecting Patent Protection - Request for the Establishment of a Panel by the United States*, WT/DS199/3, and *Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution*, WT/DS199/4.

[107] Mattew Stilwell & Elizabeth Tuerk, *Non-Violation Complaints and The TRIPS Agreement: Some Considerations for WTO Members*, South Centre, Occasional Papers 1, 2000•para. 29.

[108] See Gail E. Evans, *A Preliminary Excursion into TRIPS and Non-Violation Complaints*, The Journal of World Intellectual Property, Vol. 3, 2000, p. 871.

[109] Panel Report on *Japan - Film*, WT/DS44/R, para. 10.37.

pursuant to the TRIPS Agreement. Transplanting this remedy of exceptional character into the TRIPS environment is not suitable in the context of intellectual property, and will introduce into the Agreement a deleterious measure of uncertainty nature. By so doing, it risks constraining Members' abilities to introduce new and perhaps vital social, economic development, health, environmental and cultural measures that might be construed as denying ill-defined benefits under the TRIPS Agreement.[110] It seems inconceivable that a non-violation complaint could be applied to measures to protect public health, in particular measures for providing access to essential medicines. [111]

A transparent, predictable and equitable mechanism for settling trade-related disputes regarding intellectual property issues is one of the key systemic benefits of the TRIPS Agreement. If the non-violation complaint is introduced into the settlement of the TRIPS-related disputes, developing country Members might be confronted with difficulties in implementing their domestic public health policies. Therefore, the legitimacy of the TRIPS Agreement and the WTO dispute settlement system might be threatened by the doubts raised by the developing country Members.

CONCLUSION

"Health may not, in the absolute, be the ultimate personal good, but it tends to become it as soon as one loses it. "[112]A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, is an ideal pursued by our forefathers for thousands of years. And good health for all populations is an widely accepted international goal for sustainable economic development. In only 20 years, the HIV/AIDS pandemic has caused untold suffering and death worldwide, destroying entire communities, undoing development gains, and posing a serious threat to whole continents, as is currently the case for Africa. But there is hope. With sufficient will and resources, communities and countries can turn this epidemic around. However, the situation is urgent. It is a "global crisis" requiring "global action". A new UNAIDS report underscores that, in the absence of drastically expanded prevention and treatment efforts, 68 million people will die because of AIDS in the 45 most affected countries between 2000 and 2020, more than five times the 13 million deaths of the previous two decades of the epidemic in those countries. In a number of southern African countries, where prevalence rates are highest, up to one-half of new mothers could die of AIDS. In South Africa alone, it is estimated that at the epidemic's peak there will be 17 times as many deaths among people aged 15-34 than there would have been without AIDS.[113] The unprecedented destruction brought by the HIV/AIDS epidemic over the past 20 years will multiply several times in the decades to come, unless the fight against this disease is dramatically expanded.

Intellectual property protection under the TRIPS Agreement, whose very function is to promote the innovation and marketing of new drugs by providing

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[110] Communication from Canada, *Non-violation Nullification or Impairment under the Agreement on Trade -Related Aspects of Intellectual Property Rights(TRIPS*), 10 February 1999, IP/C/W/127.

[111] Submission by the Brazil African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, *TRIPS and Public Health,* 29 June 2001, IP/C/W/296, para. 46.

[112] Olivier Guillod, *Market Integration in a Small Federal State(Switzerland): The Role of Public Health*, in Thomas Cottier and Petros C. Mavroidis (eds.), *Regulatory Barriers and the Principle of Non-Discrimination*, University of Michigan Press, 2000, p. 225.

[113] See UNAIDS, *Report on Global HIV/AIDS Epidemic 2002*, pp. 9-21.

incentives for research and development, is legitimate when it fully takes the developing country Members' essential interests into account and improve the their access to essential drugs. Intellectual property protection should keep a balance between the need to provide incentives to reward and spur innovation and the need to ensure that society benefits from having maximum access to new creations. Just as too little protection of intellectual property rights can impede innovation and trade, so can too much protection undermine the fundamental human rights.

As a matter of fact, many developing country Members with insufficient or no manufacturing capacities in the pharmaceutical sector, would face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. In light of this fact, the solution to this issue should ensure that those Members will have access to the essential drugs, on one hand, and should keep incentive to R&D in new drugs, on the other hand. Given the merits of Article 30-based solution as discussed in the proceeding analysis, the TRIPS Council should adopt this solution and make relevant interpretation pertaining to the exceptions contained in this article.

As to potential application of non-violation complaints to the TRIPS-related disputes, valid reasons for not implanting this type of claim into the TRIPS regimes have been identified in the proceeding analysis. The TRIPS Council should advance substantive discussion on this issue pursuant to the decision made on the Doha Conference, with the view of protecting public health emphasized by the Doha Declaration.

The reform in the TRIPS Agreement concerning public health, is the one with emphasis on dialogue and communication. It aims to seek mutual understandings of the flexibility contained in the TRIPS Agreement, and to ensure that all WTO Members have the necessary sense of security and legal certainty that enable them to effectively use these provisions.

This reform entails lots of endeavors made by various sides of the world, However, people walking out of the shadow of the fatal disease into the sunshine, singing merrily with smiles, on the green meadows, in the refreshing woods, or on the breezy beach -- this is a scene we may foresee optimistically.