CHAPTER VII

DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH
CHAPTER VII
DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), as the most controversial component of the WTO’s “package deal” struck in 1994, has received many different commentaries, either praise or blame. 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.1 According to a paper published by the World Health Organisation (WHO), the standards stipulated in TRIPs Agreement are not necessarily appropriate for all countries’ level of development. The important feature of the various new IPR regimes is for strengthening the rights of the owners of IPRs whereas their obligations have been significantly diluted.2 Anguish and plight of HIV/AIDS crisis the Africans are suffering, the loud protests rising high in to 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 clear.

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 regime regarding public health. Clarifying the flexibilities in the TRIPS agreement, the declaration entitles developing country members’ autonomy to make and implement domestic public health policies 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. 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.³

Declaration on TRIPs agreement and public health recognizes the gravity of public health problems afflicting the poor countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. For core areas of concern the declaration provides that each country has the right to grant compulsory licenses and have also freedom to determine the grounds upon which such licenses are to be granted. Further it is also stated in the declaration that in

³ Supra note 1.
applying the customary rules of interpretation of public international laws, each provision of the TRIPS agreement should be read in the light of its objectives and principles.

7.1 Background to the Doha Declaration or Pre-Doha Deliberations

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 HIV/AIDS-50 percent more than the World Health Organisation (WHO) had estimated ten years earlier. Of the total 16.4 million are women and 1.5 million are children. More than 25 million Africans are living with HIV/AIDS, accounting for nearly 70 percent of infected adults and children worldwide. On the contrary, high price of certain drugs limit access to the effective treatments of HIV/AIDS, in particular for 90 percent of sufferers who are in developing countries. A new analysis of access to treatment shows that the 6 million people in the developing world are in need of antiretroviral drug therapy, just 2,30,000 i.e. less than 4 percent, were receiving antiretroviral drugs at the end of 2001. According to Joint United Nations Programme on HIV/AIDS (UNAIDAS), the high prices of HIV/AIDS treatment are in part due to patent protection, which allows control over their manufacture and sale. Subject to serious HIV/AIDS epidemic, in November 1997, the South African Government

---

5 Ibid.
amended the Medicine and Related Substances Control Act in order to promote the availability of more affordable HIV/AIDS related drugs by way of parallel imports and compulsory licence. Surprisingly, 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 with drew their complaint in April 2001. Generally 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. 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, were required to provide patent protection of pharmaceutical products form 1 January 2005 according to the TRIPs agreement.

Meanwhile, certain international organizations have made every endeavour to search feasible schemes, which will enable many developing countries to effectively combat the HIV/AIDS epidemic. In April 2001 the WHO and the WTO jointly held the workshop on differential pricing and Financing of Essential Drugs in Norway. In the same month, the 57th session of the United Nations

---


7 Details of this workshop are available at http://www.WTO.org/english/tratop-e/trips-e/hosbijor/presentations-e/hosbijor-presenttions-e.htm.
Commission on Human Rights adopted Resolution 2001/33 on “Access to Medication in the context of pandemics 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 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”8 and “WHO medicines strategy”.9 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, 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 importation, to increase access to health care and stated that 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.

---

8 WHA 54 10.
9 WHA 54.11.
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 traditionally manufactured goods and for their agricultural products in exchange for codified obligations to respect intellectual property rights in the non-traditional products and processes that are the stock in trade of the technology exporting countries.\(^\text{10}\) The TRIPs agreement requires all WTO members to adopt 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 the conclusion of the agreement. Against this ground, it is not surprising that WTO developing (including least-developed) members face difficulties in implementing the agreement.\(^\text{11}\) The agreement provides most of the developing country members with 10 years delayed application of patent protection for pharmaceuticals products. However, the agreement places restrictions on this transitional


arrangements with so called “mailbox rule” requiring developing country members to establish mechanisms for receiving and preserving priority in respect of pharmaceutical products patent application and granting exclusive marketing rights to the applicants.\textsuperscript{12} It was argued that mailbox and exclusive marketing rights requirements are 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.\textsuperscript{13} 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 Right 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 individuality 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 right to self

\textsuperscript{12} Article 70.8 and 70.9 TRIPs agreement.

\textsuperscript{13} Article 31(f) TRIPs agreement.
Accordingly, appeals for mainstreaming human rights into the TRIPs agreement are becoming stronger.

In September 2001 the TRIPs council met and discussed the access issue. The African group presented draft text for a ministerial declaration on TRIPs and public health emphasizing that "nothing in the TRIPs agreement shall prevent members from taking measures to protect public health". As a consequence of these pre Doha deliberations, Mike Moore, WTO Director General, announced at the outset of the Doha Meeting in November 2001 that "the TRIPs and Health issue could be a deal breaker for a new trade round".

Recognizing the gravity of the public health problems afflicting many developing country members, at the Doha Ministerial Conference WTO members 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 and it is a significant milestone.15

The Director-General of the World Health Organisation commented as follows:

---


Indeed this is the first time in the 50 years history of the multilateral trading system that a separate ministerial declaration is being considered on intellectual property and public health issues. The Doha Ministerial Conference is providing a historic opportunity for WTO members to ensure that the TRIPs agreement does not stand in the way of access to life saving medicines, especially in the poorest countries.\textsuperscript{16}

According to the Doha Declaration, TRIPs 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.\textsuperscript{17} 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.\textsuperscript{18} The Declaration clearly outlines all the key flexibilities available in TRIPs including:

(i) The right of members to use compulsory licensing and to determine the ground upon which such licences are granted;\textsuperscript{19}

(ii) The right of members to determine what constitutes a national emergency or other circumstances of extreme urgency, which can ease the granting of compulsory licences.\textsuperscript{20}

\footnotesize
\textsuperscript{16} Statement WHO/17,9 November 2001. (by Dr.Harlem Brundtland)
\textsuperscript{17} Declaration on the TRIPs Agreement and Public Health, WTO Ministerial Conference, Fourth Session Doha (20 November 2001), WT/MIN(01)/DFC/ 2, para 4.
\textsuperscript{18} Ibid., para 5 (a).
\textsuperscript{19} Ibid., para 5(b).
(iii) The right of members to determine their own parallel import regimes, subject to the MFN and national treatment provisions of Article 3 and 4,\textsuperscript{21} and
(iv) The right of least developed country members to postpone providing of pharmaceutical patents until at least 2016, and possibly longer.\textsuperscript{22}

\textbf{7.2 Important provisions of Doha Declaration}

The Doha Declaration includes preambular as provisions,\textsuperscript{23} a provision aimed at confirming the interpretation of certain rules of the TRIPs agreement\textsuperscript{24} and two operative provisions requiring action by the council of TRIPs in relation to countries with no or insufficient manufacturing capacity in pharmaceuticals\textsuperscript{25} and for the extension of transitional period of LDCS in relation to the protection pharmaceutical products.\textsuperscript{26}

The problems addressed by the Doha Declaration are defined in paragraph 1 in broad terms. Members recognize the gravity of the public health problems afflicting many developing and least developed countries (LDCs), especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

While some developed countries attempted to limit the scope of the Declaration to the HIV/AIDS crisis, the adopted text reflects the concerns of

\textsuperscript{20}Ibid., para 5(c).
\textsuperscript{21}Ibid., para 5(d).
\textsuperscript{22}Ibid., para 7.
\textsuperscript{23}Paragraph 1 to 4 of Doha Declaration.
\textsuperscript{24}Paragraph 5 of Doha Declaration.
\textsuperscript{25}Paragraph 6 of Doha Declaration.
\textsuperscript{26}Paragraph 7 of Doha Declaration.
developing countries and LDCS about the implications of TRIPs agreement with regard to public health in general, without limitations to certain diseases. The reference to some specific “epidemics” 27 does not imply that the Declaration is limited to them. It covers any “public health problem”, including those that may be derived from diseases that affected the population in developing as well as developed countries, such as asthma or cancer.

Further, though access to medicines was the main preoccupation that led to the Doha Declaration, the Declaration covers not only medicines, but any products method or technology for health care. Thus, the Declaration applies to pharmaceutical products process and uses, surgical therapeutic and diagnostic methods, 28 diagnostic kits as well as medical equipments. Finally while patents have been the focus of the debate on this issue, the Declaration applies to all areas of intellectual property covered by the TRIPs agreement, including protection of test data submitted for the marketing approval of pharmaceuticals. 29

Para 2 and 3 of the Doha Declaration expresses the members’ view with regard to the role of TRIPs and IPRs in the context of public health. The consensus achieved on patent protections impact on drug prices may be considered one of the major political achievements of the developing countries in the Doha Ministerial Declaration.

27 “Epidemics” is a disease prevalent among community at a special time; one of the draft texts of the Doha Declaration alluded instead to “Pandemics” i.e. a disease prevalent over the whole of the country or over the whole world.
28 It should be noted that WTO members can exclude these methods from patentability, Article 27.3(a) of the TRIPs agreement.
29 Para 7 of the Doha Declaration.
7.2.1 Public health measures

Paragraph 4 of the Doha Declaration was one of the most controversial provisions of the document and the subject of intense negotiations during the preparations for and at the Ministerial Conferences in Doha. Developing Countries’ negotiating target was to obtain recognition that nothing in the TRIPs agreement shall be interpreted as preventing members from adopting measures necessary to protect public health.30

Developing countries were essentially seeking a declaration recognizing their right to implement certain pro-competitive measures, notably compulsory licenses and parallel imports as needed to enhance access to health care. They were frustrated by the opposition and pressure exerted on some countries by the pharmaceutical industry and the governments. Moreover, some felt that the final proviso in Article 8.1 establishing that any measures adopted *inter alia*, to protect public health should be consistent with the provisions of the TRIPs agreement,31 provided less protection for public health than under the corresponding exceptions of Article XX (b) of GATT and the Sanitary and Phytosanitary Measures and Technical Barriers to trade agreements.

30 Paragraph 4 provides that: "we agree that the TRIPs agreement does not and should not prevent members from taking measures to protect public health. Accordingly while reiterating our commitments to the TRIPs agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and in particular, to promote access to medicines for all. In this context we affirm the right of WTO members to use, to the full, the provisions in the TRIPs agreement, which provide flexibility for this purpose".

31 TRIPs Article 8.1; “members may in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement".
Developed countries did not view the TRIPs agreement as representing a barrier to the achievement of public health objectives and they were not prepared to undermine any of the obligations under the agreement. According to European Union, “The TRIPs cannot be held responsible for the health crisis in developing countries, while it must not stand in the way for action to combat the crisis”. The EU was consequently “ready to contribute constructively to any debate concerning the interpretation of its provisions”.32

The text drafted by the chair of the WTO general council, which provided the basis for the negotiations in Doha, offered two options for paragraph 4. The wordings of the first part of the paragraph 4, reflects the delicate compromise reached in Doha. It reaffirms members’ rights to take measures “to protect public health” in much less elaborated way than Article XX (b) of GATT. The second part of paragraph 4 of the Doha Declaration reflects one of the main concerns of developing countries in the process leading to the Doha ministerial.33

7.7. 2 Interpretation of TRIPs provisions

The objective of developing countries in proposing sub-paragraph 5(a) of Doha Declaration34 was to stress the importance of Article 7 and 8 of the TRIPs in

33 Ibid.
34 Sub-paragraph 5(a): accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs agreement, we recognize that these flexibilities includes: (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles.
the interpretation of the agreement, particularly in the light of Article 31 of the Vienna Convention. They attained their objective without ignoring, other provisions of the agreement, which contribute to the determination of its object and purpose. The purposes of TRIPs are elaborated in its Article 7 and 8. In Canada patent protection of pharmaceutical products case, the WTO dispute settlement panel argued, in connection with Article 30 of the TRIPs agreement, that, "the goals and the limitations stated in Articles 7 and 8 as well as those of other provisions of the TRIPs agreement which indicated its object and purpose… must obviously be borne in mind" when examining the conditions set forth by said Article. The panel thus determined that Articles 7 and 8 express the "object and purpose" of the TRIPs agreement, but these are not the only provisions establishing the agreement's objectives. It is also relevant to note that the European Community and their member states emphasized the key role of Articles 7 and 8 in the interpretation of the TRIPs agreement, in its submission to the council for TRIPs of 12 June 2001. It stated that:

"Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the agreement, other provisions of the agreement, including where measures are taken by members to meet health objective".

In fact Doha Declaration goes beyond merely confirming the relevance of Article 7 and 8 for the interpretation of the TRIPs agreement. It provides an understanding about the purpose of the TRIPs agreement in relation to public

7.2.3 Compulsory licences

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 strikes a balance between the titleholder's interests and those of the public in the diffusion of knowledge and access to and affordability of the outcomes of innovation and creativity. Moreover, granting compulsory licences for specific classes of technologies (e.g. pharmaceuticals) is an important tool to promote competition and to low prices. Therefore, compulsory licensing functions as a significant instrument to protect public interest 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 Articles 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.

36 Carlos M. Correa, supra note 32.
Developing countries have identified compulsory licensing as one of the key instruments that may limit the exclusive rights of the patent owners when needed to fulfill certain objectives of public policy, particularly in order to ensure the availability of alternative sources for the supply of medicines at lower prices.

Sub paragraph 5(b) of the Doha Declaration deals with an issue central to the interests of developing countries. It simply states what is apparent: Article 31 set forth number of conditions for the granting of compulsory licences, but it does not limit the grounds on which such licences can be granted. Though Article 31 refers to some of the possible grounds such as emergency and anticompetitive practices for issuing compulsory licenses, it leaves member full freedom to stipulate other grounds such as non-working, public health or public interest. Though sub paragraph 5(b) does not add anything substantively to the understanding of TRIPs, the Doha Declaration specifically employs the expression “compulsory licence”, which is not found in the TRIPs agreement. The use of this terminology may help to create awareness, particularly among health ministers in developing countries and least developed countries about the possible utilization of compulsory licences to meet public health and other objectives.

37 Sub paragraph 5(b): Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include... Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

38 Case by case, determination, prior negotiation in certain cases with the patent owner, remuneration etc.
Paragraph 5(c) of the Doha Declaration speaks about what is an unquestionable right of member states, the right to determine “what constitutes a national emergency or other circumstances of extreme urgency”. Such determination may be relevant for the granting of compulsory licences, the establishment of exceptions under Article 30 or the adoption of other measures permitted under Article 8.1 of the agreement.

Paragraph 5(c) also includes a presumption that public health crisis, including those relating to HIV/AIDS tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency. This provision is important for three reasons. Firstly, it clarifies that “public health crisis” can represent “national emergency or other circumstances of extreme urgency”, thereby allowing for the granting of compulsory licences when provided for under national law and pursuant to TRIPs Article 31(b), without the obligation or prior negotiation with the patent owner. Secondly, the reference to “HIV/AIDS tuberculosis, malaria and other epidemics” indicates that an emergency may be not only a short-term problem, but a long lasting situation as is the case with the epidemics specially mentioned for illustrative purposes. This recognition may be deemed as an important achievement for developing countries in Doha Ministerial Conference, since it implies that specific measures to deal

---

39 Paragraph 5(c): Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs agreement, we recognize that these flexibilities include... Each member has the right to determine what constitutes national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
with an emergency may be adopted and maintained as long as the underlying situation persists, without temporal constraints. Thirdly, if a member complains about the qualification of a specific situation by another member as a “national emergency or other circumstances of extreme urgency”, the language of paragraph 5(c) places the burden on the complaining member to prove that such emergency or urgency does not exist. This presents an important difference with respect to earlier GATT/WTO jurisprudence outside of the TRIPs context that under the “necessity test” put the burden of proof on the member making an exception to its obligation.40

7.2.4 Parallel imports

Need for parallel import arises when availability of patented product is not sufficient to meet the demand. This type of contingency can arise similar to the situation as it arose in U.S.A. about the availability of “Anthrax”, availability of HIV/AIDS drugs in African countries, and the most recent phenomena of SARS in China, Hong Kong and certain other countries. There are no effective drugs for SARS so there was no drug to “parallel import”; however if there was a drug then there would have been the need. Therefore the question arose as to should this be rephrased or too complicated and simply omitted. To meet such a kind of contingency it is important that the national legislation must provide for clear-cut provision so that no constraint is raised when parallel imports are authorized. Similarly it should also be possible to import patented products if they are

40 Carlos M. Correa, supra note 32.
available in foreign markets at prices lower than the prices at which the same are being marketed by the patent holder in the country. According to Doha Declaration member countries are free to establish their own regime for such exhaustion of right without challenge. Subject to national treatment and most favoured nation treatment under provisions of Articles 3 and 4 of the TRIPs agreement.41

The authorization of parallel imports under an international principle of exhaustion has also been regarded by the developing countries, as a key component of a patent system sensitive to public health needs. This was one of the key issues raised by pharmaceutical companies against South Africa in the already mentioned case. Developing countries were keen to clarify in the Doha, Declaring the members’ right to adopt an international principle of exhaustion of rights,42 in accordance with Article 6 of the TRIPs agreement. Paragraph 5(d) provides the sought after clarification. It specifically states that, “the effect of the provisions in the TRIPs agreement… is to leave each member free to establish its own regime for such exhaustion without challenge.

Though this paragraph does not add substantively to the TRIPs agreement it certainly resources members wishing to apply an international exhaustion

---

41 TRIPs Agreement and Impact on Health, Report on a National Workshop Yangon, Myanmar, 13-15 October 2003, WHO project; MMREDMOO1

42 This principle permits the import of the patented product in to a country without the authorization of the titleholder or his licensees, to the extent that the product has been put on the market elsewhere in the legitimate manner.
principle that it would be legitimate and fully consistent with the TRIPs agreement to do so.

It is necessary to stress that in order to take advantage of this and other flexibilities allowed by the TRIPs agreement and confirmed by the Doha Declaration, national laws must incorporate appropriate rules in the form of compulsory licences, exceptions and other relevant provisions. Such flexibilities do not protect government from legal actions based on national laws and regulations that fail to make use of the TRIPs agreement’s flexibilities. For example specific legal provisions allowing for parallel imports would be normally necessary in order to benefit from the principle of international exhaustion right.43

A survey of patent laws in developing countries shows that many of such countries have not or only partially used the flexibilities allowed by the TRIPs agreement. The effective implementation of the Doha Declaration in those countries, therefore, would call for an amendment to national laws so as to incorporate the exceptions and safeguards necessary to protect public health.44

Parallel imports are of particular importance as they can prevent market segmentation and price discrimination by patent holders on a regional or international scale. Parallel importation of a patented medicine from a country where it is sold at a lower price will enable more patients to gain cheaper access to

43 Supra note 32.
44 Paragraph 5: we recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs agreement. We instruct the Council of TRIPs to find an expeditious solution to this problem and report to the General Council before the end of 2002.
essential medicines. In this regard, parallel imports must be considered to be a legitimate measure under TRIPs. Developed countries and Pharma giants have been working to discourage parallel imports by propagating that large scale use of parallel importation will force companies to use single price worldwide. They claim this will then affect the prices in developing countries. However several studies have shown that prices of many essential medicines in developing countries are in fact much higher than in developed countries. This can only be looked upon as another bullying method to stifle yet another tool that, developing countries could use to make cheaper medicines available to their citizens.\textsuperscript{45}

The United States in particular questions the policy behind parallel imports on two grounds. First that it may interfere with proposals for tiered pricing by limiting the willingness of drug producers to sell to developing countries. Second, it suggests that parallel imports create risk to public health because of quality of cheap imports and these may further create monitoring problems. Both these however can be refuted. Allowing parallel imports is by no means legally inconsistent. Parallel imports can play extremely important role in ensuring price competition ensuring that WTO members will obtain the lowest world market price. The argument that there is no correlation between patents and monitoring imports is unrelated to intellectual property issues.\textsuperscript{46}

\textsuperscript{46} Ibid.
7.2.5 Members with insufficient or no manufacturing capacities

Paragraph 5 of the Doha Declaration\textsuperscript{47} instructs the council for TRIPs to address a delicate issue how can members lacking or with insufficient manufacturing capacities make effective use of compulsory licensing. The Doha Declaration requests the council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002. Further, it states that in order to be effective such a solution should be not only legally acceptable but also economically viable. A major limitation in compulsory licensing rules under Article 31 (f) of the TRIPs agreement was the requirement that a product made under a compulsory licence be supplied predominantly to the licensee's domestic market, unless the licence were issued to remedy anticompetitive practices.\textsuperscript{48} This means in practical terms, that members with large markets, like India, the UK or the USA, typically could easily grant compulsory licenses for the supply of patented medicines to meet public health needs. However, for member countries with small markets, like the African countries where the AIDS crisis is most severe, it might be extremely difficult to establish economically viable production if the manufactured product has to be "predominantly" sold in the local market.

\textsuperscript{47} Paragraph 6: “we recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs agreement. We instruct the council for TRIPs to find and expeditious solution to this problem and report to the General Council before the end of 2003”.  
\textsuperscript{48} Article 31 (k) of the TRIPs agreement.
The basic problem underlying paragraph 6 is that many developing countries lack or have an insufficient capacity to manufacture medicines on their own. Manufacturing capacities in pharmaceuticals are distributed very unevenly in the world. Not many countries have the capacity to produce both active ingredients and formulations and very few countries maintain significant research and developing capabilities. Given that only a few developing countries have substantial manufacturing capacity in pharmaceuticals, once the TRIPs agreement becomes fully operative, many countries may face difficulties in acquiring medicines at an affordable prices. Today for example, some countries such as India produce generic versions at a fraction of the price of the patented product. A member country where the price of patented product is high has the option of issuing a compulsory license to permit import from such countries. The problem is that, as countries fully comply with the TRIPs agreement, they will no longer be able to produce and export cheap generic copies of patented medicines. Consequently, the source of affordable new medicines will dry up and countries without sufficient manufacturing capacity and market demand will not be able to grant a compulsory licence either for the local production or for the importation of such medicines; they will become entirely dependent on the expensive patented versions.49 This problem had been raised by developing countries during the special session on TRIPs and health at the council for TRIPs and by the EC and their member states in its submission of 12 June 2000. Developing countries

49 E.g. Oxfam, 2002.
argued that, “nothing in the TRIPs agreement prevents members from granting compulsory licences for foreign suppliers to provide medicines in the domestic market... In this respect, the reading of Article 31(f) should confirm that nothing in the TRIPs agreement will prevent members from granting compulsory licences to supply foreign markets”. The EC and their member states noted the problems posed by the limitation imposed by Article 31(f). A member is free to grant a compulsory licence for the importation of goods, which are under patent in its own territory as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired. However, when a patent exits in the potential supplier country, the patent owner may block exports to the country in need of the medicines. Moreover since Article 31(f) requests that a compulsory licensee must predominantly supply the domestic market, that provision would prevent the granting of compulsory licences exclusively or mainly to export to a country in need of certain medicines.

7.2.6 Transfer of technology and extension of transitional period for LDCs

Paragraph 7 of the Doha Declaration reaffirmed “the commitment of developed country members to provide incentives to their enterprises and

50 See IP/C/w/296.
51 Of TRIPs agreement.
52 Paragraph 7: "we reaffirm the commitment of developed countries members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2, we also agree that the least developed country members will not be obliged, with respect to pharmaceutical products to implement or apply sections 5 and 7 of part II of the TRIPs Agreement or to enforce rights provided for under these sections until 1 January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the Trips agreement. We instruct the council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1 of the Trips agreement".
institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2.

Least developed countries have repeatedly raised concerns at the council for TRIPs about the lack of effective action by developed countries to comply with Article 66.2 of the TRIPs agreement. Though some developed countries provide different forms of technical assistance on IPR related issues, LDCs have repeatedly noted that no or little action has been taken by developed countries to specifically implement their obligations under Article 66.2. Though the wording in paragraph 7 is broad, its inclusion in the Doha Declaration indicates that effective incentives should be granted in developed countries in order to specifically foster the transfer to LDCs of health related technologies, including pharmaceutical technologies.

Further the Doha Declaration permits LDCs to opt for an extension of the transitional period provided for under Article 66.1 of the TRIPs agreement. Paragraph 7 establishes the grounds for an extension of the transitional period for LDCs in relation to pharmaceutical patents only. It contains a “duly motivated requests” in terms of Article 66.1 of the TRIPs agreement, on the basis of which the council for TRIPs must give effect to the extension. LDCs do not need to individually follow the procedure provided for under Article 66.1 to enjoy this period. The Declaration however explicitly preserves the right of LDCs to request extension for other matters in accordance with Article 66.1’s procedure without diminishing their right to request further extensions for pharmaceutical patents.
after 2016. The extension applies to “pharmaceutical products”. However, the protection conferred to a patented process encompasses, according to Article 28.1(b) of the TRIPs agreement the protection of the products directly obtained with such process. Hence, the extension of the transition period should also be deemed to apply to process patents. Likewise, extension would apply to cases involving a second indication of a pharmaceutical product, since claims are generally drafted in these cases as product claims on the basis of “Swiss-claims” formulation.53

LDCs that already grant pharmaceutical patents could amend their legislation and not grant product patents until 2016, since they are not contained by the “freezing clause” of the Article 65.5 of the TRIPs agreement.

Another crucial point is whether LDCs will be obliged to grant exclusive marketing rights (EMRs) under Article 70.9 of the TRIPs agreement during the extended transitional period. Paragraph 7 does not explicitly exclude the application of that provision. If LDCs were bound to grant EMRs the value of the concession made by the Doha Declaration to LDCs would be very limited, since access to medicines and other products could be effectively blocked for at least five years.

An alternative interpretation for paragraph 7 is possible. Since EMRs do not constitute a category of intellectual property rights (as amended in Article 1.2 of the TRIPs agreement), the granting of such rights only provides one way of

53 Supra note 32.
enforcing foreign patent rights. As mentioned, paragraph 7 exempts LDCs from the enforcement of rights provided for in accordance with the patents section of the TRIPs agreement. Under this interpretation LDCs would be exempted from compliance with Article 70.9.

In addition in relation to those LDCs that did grant patent protection for pharmaceutical products as of the entry into force of the WTO agreement, Article 70.8 of the TRIPs agreement makes it clear that “mailbox obligation applies to member that did not make available as of the date of entry into force of the WTO agreement, patent protection for pharmaceutical and agricultural chemical products”. Article 70.8 literally interpreted means that LDCs who granted such a protection would not be subject to the obligation to grant exclusive marketing rights.  

7.3 Limitations of Doha Declaration

Doha Declaration has had mixed reviews. Some argue that it did nothing but to restate what was already in TRIPs. Others see it as an important, albeit incomplete, victory for the access campaign and public health advocates. Gillespie-white asserted that the activist's claims of victory were “native and short sighted” and summed up industry’s position as follows: wherever property rights are challenged, in a place where market exists for the sale of particular commodity... and the country which has taken steps to abrogate those rights is perceived to have used its discretion unwisely the property right holder will

54 Ibid.
challenge the decision made. This will happen with or without the Doha Declaration... too much is at stake for the situation to be otherwise.

The Doha Declaration does not cover all the areas where flexibility of the TRIPs agreement exists, such as the exceptions to patent rights and the protection of Data submitted for registration of pharmaceutical products. Nor does it refer to the room left to members to determine the patentability standards in ways that prevent patenting strategies aiming at expanding or temporally extending the protection conferred in the pharmaceutical field.  

The Doha Declaration left a technical legal problem unresolved. This problem, known as the 31(f) problem after the relevant provisions of TRIPs, involves the manufacture of drugs under compulsory license for countries that lack the capability to manufacture the drugs themselves.

7.4 Subsequent developments after Doha Declaration

After the adoption of Doha Declaration in 2001, the TRIPs council held several meetings in the year 2002 to discuss how to find an expeditious solution to the current issue set forth by paragraph 6 of the Doha Declaration. Since there was no compromise reached in the above meetings, members' opinions diverged on how to find on this expeditious solution. Given the significance of the solution and the deadline was approaching, the mini-ministerial meeting of WTO Trade Ministers was held in Sydney on 14-15 November 2002 to discuss this problem. Unfortunately, members failed to reach consensus on the final solution to this

55 Ibid.
problem on the discussion at the TRIPs council in late 2002. Generally, four possible legal mechanisms have been identified for the purpose of implementing paragraph 6 of the Doha Declaration:

(i) In order to overcome the restriction to the possibility to export products manufactured and or sold under a compulsory license, Article 31(f) of the TRIPs agreement could be deleted or amended.

(ii) A waiver with regard to Article 31(f).

(iii) A dispute settlement moratorium with regard to the non respect of the restriction under Article 31(f).

(iv) An authoritative interpretation based on Article 30, enabling the WTO member to use “limited exceptions” to export products manufactured and or sold under this article.  

7.4.1 The WTO decision on implementation of Paragraph 6 of Doha Declaration (August 30 Decision)

Nearly two years later, on August 30, 2003, The TRIPs general council adopted the decision on implementation of paragraph 6 of the Doha Declaration on the TRIPs agreement and public health. The leadership of the WTO hailed the decision as evidence that the organisation could deal effectively with important issues of social concern. However, the reaction among a broad cross-section of stakeholders was more tempered. Non-Governmental Organisations (NGOs) concerned about access to medicines were disappointed by the complexity of the

---

arrangements, arguing that it would be unworkable in practice. Similar misgivings were expressed by developing country producers of generic pharmaceuticals. Spoke persons for the groups of pharmaceutical companies that engage in substantial research and development (commonly known as pharma) said they welcomed the decisions as finally resolving an open issue, but these companies later lobbied actively in Canada to restrict the implementation of legislation. The developing countries that had led the negotiations expressed satisfaction with the result, but the others harbored doubts. United States accepted the decision as a problematic compromise but has since sought to limit its scope of application.57

The basic statement, which was finally cleared on August 30, had actually been formulated in 2001, but was held up by the US Government on behalf of its big pharma lobby. The modified version, which is cleared on August 30 2003, has put in many more restrictions, which drastically limit the ability of importing countries to access cheaper generic substances, and therefore constrain the ability of such generic manufacturers to benefit from economies of scale and emerge as real competitors of the large drug companies. All that the new statement does is waive the obligations of the exporting country under Article 31(f) of the TRIPs agreement with respect to the grant by it of a compulsory licence to a company, which was supposed to be for the domestic market only.

The Decision actually contains three waivers:

(i) Exporting countries' obligations under Article 31(f) are waived, any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries.

(ii) Importing countries obligation on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.

(iii) Exporting constraints are waived for developing and least developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least developed countries at the time of the decision. That way country can make use of economies of scales.

Export can be permitted to importing countries that fulfill the following conditions:

First the eligible importing member can only be a least developed country or a developing country that does not have adequate facilities to produce the drug in question. The importing country has to notify to the TRIPs council the following details:

(a) the names and expected quantities of the products needed;

(b) that the eligible importing member in question has established that it has sufficient or no manufacturing capacities in the pharmaceutical sector for the products in question in one of various ways which are specified; and
(c) Where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPs agreement and the provisions of the decision. 58

Importing countries also have to ensure legal administrative means of preventing re-exportation of any such drugs. Similarly the compulsory licence issued by the exporting member has to contain the following conditions:

(a) only the amount necessary to meet the needs of the eligible importing members may be manufactured under the license and the entirety of this production shall be exported to the member(s) which has notified its needs to the council for TRIPs;

(b) products produced under the license shall be clearly identified as being produced under the system set out in this decision, distinguish such products through special packaging and for special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price;

(c) before shipment begins, the licensee shall post on a website information relating to the quantities being supplied to each destination and the distinguishing features of the products; and

(d) the exporting member has to notify the TRIPs council of the grant of the license, including the conditions attached to it. The information provided

has to include the name and address of the licensee, the products are to be supplied and the duration of the license, and the address of the relevant website.\textsuperscript{59}

The waiver provided by the decision is interim the ultimate goal was to amend the TRIPs agreement itself within the first half of the 2004, i.e. the August 30, 2003 WTO decision will be in effect until there is a formal amendment to TRIPs incorporating its substance. Amendment negotiations first began in November 2003 and were, scheduled to be completed by June 2004. However the disagreement amongst developed members on the nature and scope of such an amendment led to the negotiations continued until just prior to the December 2005 Hong Kong Ministerial.

\textit{Criticism of August 30 Decision}

The decision adopted by the WTO on August 30, 2003 has been criticized by Frederic M. Abbott saying that it is not a solution to the HIV/AIDS pandemic or myriad other public health problems confronting developing (and developed) countries. The Global response to HIV/AIDS remains a continuing catastrophe and more generally, billions continue to live with inadequate health care.\textsuperscript{60}

The decision waves the obligation of importing countries to provide remuneration to the patent holder when it is paid in the exporting member. In the

\textsuperscript{59} Ibid.
\textsuperscript{60} Supra note 57.
exporting member, the level of remuneration should take into account the situation of the importing member.

The chairperson's statement provides that "the system... should be used in good faith to protect public health and without prejudice to paragraph 6 of the decision, not be an instrument to pursue industrial or commercial policy objectives". Because the system is essentially "demand driven" in the sense that exporting countries will act on the basis of requests from importing countries to meet public health needs, the principle of good faith use does not appear to constitute an impediment to the effective implementation of the decision. Also, "industrial or commercial policy objectives" do not refer to whether an export is undertaken by a private or public enterprise, or whether for profit or non-profit. Most medicines production and export under the decision is expected to be pursued for profit by commercial enterprises. The pursuit of "industrial or commercial policy objectives" refers to steps taken by governments with the predominant aim of promoting national industrial development, in contrast with helping to address legitimate public health needs.

The decision appears to offer a "transaction-by-transaction" solution to the problem of low cost supplies of generic medicines. Understood in this way, the system may prove difficult to use in practice since a pharmaceutical producer might have difficulty in justifying the time and expenses needed to develop and
produce a generic version of a patented medicine when there is only one customer, even if that customer might be fairly substantial. 61

James Love of the consumer project on Technology has written that, “the persons who have negotiated this agreement have given the world a new model for explicitly endorsing protectionism”. Oxfam and Medicine Sans Frontiers, two groups who have closely followed the negotiations, have called the solution “unworkable” saying the “deal was designed to offer comfort to the US and the western pharmaceutical industry” and that “global patent rules will continue to drive up the price of medicines”. 62

C.P.Chandrasekhar and Jayathi Ghosh in their article have opined that “the decision does not provide much relief either to poor countries that may need to import drugs or to generic manufacturers of drugs in developing countries”. They further stated that “this agreement, which had been held up for so long by the developed countries and the multinational drug lobby, has now been hammered down the throats of the unfortunate developing country negotiators, simply in order to show some results before the Cancun meeting”. 63

7.4.2 Amendment of TRIPs agreement to make flexibility permanent

WTO members on December 2005 approved changes to the intellectual property agreement making permanent a decision on patents and public health

61 Ibid.
62 Supra note 58.
originally adopted in 2003. This General Council decision means that for the first time a core WTO agreement will be amended.

The decision directly transforms the 30 August 2003 “waiver” into a permanent amendment of the WTO agreement on Trade related Aspects of Intellectual Property Rights (TRIPs). That waiver made it easier for poorer countries to obtain cheaper generic version of patented medicines by setting aside a provision of the TRIPs agreement that could hinder export of pharmaceuticals manufactured under compulsory licences to countries that are unable to produce them.\(^\text{64}\) This will now be formally built in to the TRIPs agreement when two thirds of the WTO members have ratified the change. They have set themselves until 1 December 2007 to do this. The waiver remains in force until then.

The latest decision comes a week after WTO members agreed to extend the transition period for least developed countries, allowing them until 1 July 2013 to provide protection for trademarks, copyrights, patents, and other intellectual property under the WTO agreement, least developed countries had already been given until 2016 to protect pharmaceutical patents.

“The agreement to amend the TRIPs provisions confirms once again that members are determined to ensure that WTO trading system contributes to humanitarian and development goals as they prepare for Hong Kong ministerial Conference” Director-General Pascal Lamy said:

The amendment is designed to match the 2003 waiver as closely as possible. Other procedures used in 2003 are also matched, including a statement read out by the General Council chair. In order to achieve this, delegations have been involved in intricate legal discussions aimed at ensuring that the legal meaning and weight, and the hierarchy of provisions, are preserved as exactly as possible.

The amendment completes a process that began with the declaration on TRIPs and health that ministers made at the Doha Ministerial Conference in November 2001. The deadline for least developed countries to protect pharmaceutical patents revised in June 2002. This was followed by the waiver in August 2003, which itself called for the eventual amendment. 65

The Decision

Article 31(f) of the TRIPs agreement says that production under compulsory licensing must be predominantly of the domestic market. The concern was that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are not patented.

As with the 2003 waiver, the permanent amendment will allow any member country to export pharmaceutical products made under compulsory license for this purpose. They may need to change their own laws in order to do so.

65 Ibid.
A group of developed countries are listed as announcing the system to import. A number of other countries announced separately that if they use the system as importers it would only be for emergencies or extremely urgent situations.\textsuperscript{66}

\textit{The amendment}

The amendment itself is in three parts. Five paragraphs come under Article 31 \textquote{bis} (i.e. an additional article after Article 31). The first allows pharmaceutical products made under compulsory licenses to be exported to countries lacking production capacity. Other paragraphs deal with avoiding double remuneration to the patent owner, regional trade agreements involving least developed countries, non-violation and retaining all existing flexibilities under the TRIPs agreement.

A further seven paragraphs are in a new annex to the TRIPs agreement. These set out terms for using the system, and cover such issues as definitions, notification, avoiding the pharmaceuticals being diverted to the wrong markets, developing regional systems to allow economies of scale and annual reviews in the TRIPs council. An \textquote{appendix} to the annex deals with assessing lack of manufacturing capability in the importing country. This was originally an annex to the 2003 decision.

The new Article 31\textquote{bis} and annex of the TRIPs agreement are attached to a protocol of amendment. This in turn is attached to a General Council decision,\textsuperscript{66} \textit{Ibid.}
which adopts the protocol and opens it for members to accept it by 1 December 2007. 67

7.5 Conclusion

As it is acknowledged that the TRIPs agreement is not, in its current format, clear enough on its support for public health, the Doha Declaration is an important interpretive tool. Doha Declaration affirmed the sovereign right of governments to take necessary measures to protect public health. This is an important achievement because it gives clear primacy to public health over private intellectual property and clarifies member’s right to use the TRIPs safeguards. Contrary to proposals of certain developed country members, the Declaration clearly speaks about public health and does not limit the use of safeguards to crisis situations such as HIV/AIDS and pandemics.

The Declaration aimed to clarify ambiguities in WTO intellectual property rules about countries’ ability to produce and import affordable drugs. It reaffirmed members’ rights to determine what constitutes a national emergency or other circumstances of extreme urgency, and to determine the grounds for granting compulsory licenses authorizing the production of patented medicine without the consent of the patent holder.

However the wording of the Doha Declaration has not been followed and the dead line for an answer on how to address the inefficient compulsory licensing scheme has not been met. The Decision on the implementation of paragraph 6 of  

67 Id.
the Doha Declaration was not only delayed eight months, but also insufficient. Both the Doha Declaration and the new decision are steps towards helping the people suffering in poor countries, but they do not address the issue fully. The international legal framework for exports and imports of pharmaceutical products produced under compulsory licensing is in places but it is not clear enough to be used, as the issue tends to fall flat as a victim of negotiations with unequal parties, the US and its pharmaceutical industry being able to dictate the technical terms and conditions under which to promote global public health. The pharmaceutical industry is too powerful a lobby group but cannot be blamed for this as it is up to governments to act and react to help people in need. So far not a single country has used the waiver. Nevertheless, in December 2005, WTO members agreed to make the 30 August 2003 decision a permanent amendment to the TRIPs agreement. The amendment will enter into force when two thirds of the WTO's 150 members ratify it. To date, three countries have ratified the amendment, the US, EU and Salvador. In the mean time waiver decision remains in effect. At a 14 November meeting in Geneva to commemorate the fifth anniversary of the declaration Ellen't Hoen of the Campaign for Access to Essential Medicines suggested that since some major generic producers such as India are now providing patent protection for newer medicines, their prices are being driven up. "it should alarm us", she said "we are getting back to where we were five years ago".
It has been alleged that the key provisions of Doha Declaration have not been taken seriously by the net exporters of IPRs and that this lack of political courage is, although legal, still immoral and is causing unnecessary harm not only to international relations but also to millions of people suffering from lack of medical care and pharmaceutical products.