

TRIPS and public health

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The pharmaceutical industry is unique in that it can make exploitation appear a noble purpose. – Dr Dale Console

My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death – Indira Gandhi

Public health has once again become a vital issue of concern the world over, especially in the wake of major epidemics like HIV/AIDS, malaria, tuberculosis, and a host of other diseases affecting the human populace. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) attempts the arduous task of balancing private and public interests. On the one hand, it protects the interests of the pharmaceutical companies that invest heavily in research and development of drugs and, on the other, it allows nations that belong to the World Trade Organisation (WTO) to promote public health in their respective countries. However, patents on pharmaceutical products have adversely affected industrially developing and least developed countries, hampering their ability to formulate appropriate public health policies that would enable their ailing citizens to access medicines. For instance, pharmaceutical patents have raised the cost of life-saving drugs, effectively putting them out of the reach of the majority of the world's population.

Developing and least developed countries are supposed to have the benefit of a moratorium^[1] on implementing pharmaceutical patents until the years 2005 and 2016 respectively. However, this is of little consolation^[2] since the concession has been effectively neutralised by industrially developed nations. On the one hand, they have narrowly interpreted the flexibility provided within the agreement to promote public health so as to enable their multinational drug companies to maximise profits.^[3] On the other, they have managed to get large nations like Brazil and India to amend their patent laws and bring them in line with the TRIPS agreement. Thus the advantages of the moratorium have been more or less nullified well ahead of the deadlines. The efforts of developing countries to use the mechanisms provided under TRIPS to promote public health

have come under pressure from industrialised countries and multinational pharmaceutical companies[4] in a variety of ways.

For example, a number of pharmaceutical companies challenged the South African legislation empowering the minister of health to issue compulsory license (granting permission to a third party to manufacture a patented drug) under certain circumstances. The law was based on the premise that expensive drugs, such as the anti retro viral (ARV) drugs used in the treatment of HIV/AIDS, were unaffordable to large sections of society and that the consequent lack of access to drugs was leading to a serious health crisis within the country. The action of the pharmaceutical industry against the South African initiative led to widespread criticism of the TRIPS agreement by the developing world, NGOs and human rights activists. The controversy led to the Doha Declaration on Public Health of November 2001. This paper outlines the events leading up to the Doha Declaration and examines whether or not the declaration provides for sufficient flexibility to fulfil the public health needs of all WTO member countries. The furore over access to drugs Once TRIPS was adopted in 1994, developing and least developed countries were obliged to effect changes in their patent laws in accordance with the agreement. They were given time until 2000 and 2006 respectively to make the necessary changes. But, in the meantime, they were to provide Exclusive Marketing Rights (EMR) to those who had obtained patents in other member countries on or after the date of the entry into force of the TRIPS agreement. They were also required to create a mechanism to enable the filing of patent applications pending the expiry of the moratorium on the implementation of pharmaceutical patents. EMR is virtually a patent, enabling manufacturers to have the exclusive right to market their products in a country even though the product has not been examined for novelty or non-obviousness in the country concerned.

In addition, some member countries were compelled by developed countries like the United States of America to bring their patent laws in line with TRIPS even before the moratorium was to expire. For example, Thailand was forced to introduce legislation on product patents long before they were legally bound to do so under the TRIPS agreement, thereby foregoing any advantage that would have enabled them to deal with the public health crisis. The AIDS epidemic worsened the public health situation across the world as millions of HIV-infected people in developing countries could not

access the drugs they needed because of the high cost. In theory, developing and least developed countries in Africa with large numbers of HIV+ people could have used the TRIPS provisions recognising their right to promote public health in order to import cheaper generic medicines from countries like India.

However, they were prevented from doing so by developed countries which held that such measures would be in contravention of the agreement. For example, the South African decision to legitimise through compulsory licenses (ie, non-voluntary licenses granted by the government to third parties to make the patented product) the production of generic versions of ARV as a means of addressing the problem of access was challenged by multinational pharmaceutical companies in the country's courts. This action drew widespread criticism from both NGOs and governments of developing countries, who alleged that TRIPS was being used by the pharmaceutical industry to enhance profits at the cost of human lives.

The controversy ultimately led to the withdrawal of the case and catalysed a much-needed discussion on public health and intellectual property rights at the WTO's Doha round of discussions in 2001, which culminated in a landmark declaration on public health known as the Doha Declaration on Public Health. Reinterpreting the objectives The objective of the Doha Declaration on the TRIPS Agreement and Public Health was to clarify the official stand on certain provisions of TRIPS relating to public health. It recognises the concerns of developing countries and LDCs on the issue. The Declaration clarifies that 'public health crises' can represent 'a national emergency or other circumstances of extreme urgency', and that an 'emergency' may be either a short-term problem, or a long-lasting situation. [5] It recognises the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[6] It accepts as legitimate concerns regarding the pricing of drugs, its effect on access to drugs and the impact of lack of access on public health.[7]

At the same time, it acknowledges that intellectual property protection is important for the development of new medicines. The Declaration also reiterates that the agreement should be interpreted

and implemented in the light of members' right to protect public health and promote access to medicines for all.[8] Paragraph 5(a) reiterates that each provision of the agreement shall be interpreted in the light of its objectives and principles.

According to the document, each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, based on the understanding that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.[9] However, significantly, the Doha Declaration does not define the term 'public health'. A narrow interpretation of the term would clearly render many public health initiatives futile. While member countries are theoretically empowered by the document to decide what constitutes a national emergency or other circumstances of extreme urgency, the possibility of a narrow interpretation by the panel remains, leaving them at the mercy of the whims and fancies of the WTO Dispute Settlement Body.

The Doha Declaration does recognise the obvious problems faced by developing countries in promoting public health, especially in the wake of epidemics like AIDS, malaria, tuberculosis, etc. But the very fact that the document restricts itself to certain specific epidemics creates a problem as the flexibility may be allowed only in the case of these particular diseases, if at all. The pharmaceutical industry would certainly like to interpret this provision restrictively, leaving out certain diseases prevalent in member countries which may not be internationally recognised as epidemics. For example, diabetes, cancer and certain tropical diseases that are endemic in the developing world may not be given the same importance even though they represent serious public health concerns in many countries.[10]

Another inherent defect is built into the system through the stipulation that member countries can make use of options such as the compulsory license mechanism to promote public health only when a health crisis has arisen, especially in the form of an epidemic affecting the populace at large. This limitation clearly weakens their right to utilise the apparent flexibility to take preventive and precautionary action before a disease becomes a full-blown crisis. The Declaration does recognise the problems

posed by the pricing of drugs and the impact of this on access. At the same time, it accepts the importance of intellectual property rights for the development of new medicines. Through this apparent even-handedness it does little to reassure member countries that they can undertake action to ensure wider access to medicines without the threat of legal disputes. Further, the Declaration states that the agreement has to be interpreted in the light of its objectives and principles, which means it has to be read with Articles 7 and 8 of TRIPS.

Those provisions are liable to be interpreted by developed countries to justify increased patent protection so that pharmaceutical companies can carry out research and development. R&D costs are invariably cited as the inevitable reason for the high price of drugs, which naturally put them out of the reach of most people in developing countries,[11] leading to the situation prior to the Doha Declaration. At the same time, pharmaceutical companies rarely undertake research and development relating to the various diseases affecting large numbers of people in developing countries since the products would not be profitable. In the final analysis, by failing to clarify key terms – including ‘public health’ – the Doha Declaration on Public Health leaves the field open for their interpretation in accordance with the interests of the pharmaceutical industry and developed countries.

As a result it effectively fails to address a number of important issues and falls short of taking a clear stand on public health. Clarification on parallel import Parallel imports occur when a product sold by a patent holder in one country is exported by a buyer to another country where the price for the same patented drug is higher. This effectively reduces the profits of the patent holder as the phenomenon of parallel import usually reduces the price of the product in the country to which it is exported. For instance, if patent holder A sells a product for \$5 in country M and at \$10 in country N, this is usually held to be a practice of price discrimination. If buyer B, who acquires the product in country M exports the same product to country N and sells it there at \$7, then A would be faced with a situation where his/her own product sold in country M reduces his/her profits in country N. Article 28 of TRIPS provides exclusive rights to the patent holder to prevent third parties from making, using, offering for sale or importing the

patented product to member countries where a patent holder has obtained patents for the same.

But the footnote to the Article subjects it to the provision in Article 6 of the TRIPS agreement, which is as follows: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." The exhaustion of IPR rights refers to a situation wherein a patent holder is unable to use his/her exclusive rights to sell or dispose of the patented good once the patented product has been placed in the market for sale. As a result, he/she is not in a position to prevent any act of importation by third parties.

This provision stipulates that member countries can import pharmaceutical products from other countries only if the exclusive right is exhausted. It apparently allows developing and least developed countries with no manufacturing capacity of their own to import drugs from countries manufacturing generic medicines. But the problem arises with the interpretation of the doctrine of exhaustion and the question of whether domestic or international principles of exhaustion are to be followed. Developed countries perceive this provision as a major threat, fearing that cheaper drugs could flood their markets and undercut their profits. Thanks to their vehement opposition, the hope of interpreting the provision in the light of the imperative of promoting public health has faded.[12] This issue was discussed in 2001 at the Doha convention which resulted in the review of Article 28 of the TRIPS Agreement. Paragraph 5(d) of the Doha Declaration on Public Health deals with parallel importation as follows: "Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include: d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4." This provision leaves it to member countries to determine the exhaustion of intellectual property rights without discriminating between local and foreign patent holders. A member country is, therefore, supposed to apply a single system of exhaustion of patent rights. For instance, if a member country opts for a local interpretation of exhaustion of rights, then the same

interpretation should apply to both foreign and domestic patent holders. Compulsory licensing Article 31 of TRIPS enables member countries to grant the production and sale of a patent by a third party without the authorisation of the patent holder, but limits such use predominantly for the domestic market of the member state authorising such use.

The Article reads as follows: “Where the law of a Member allows for other use^[13] of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:... (f)any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use.” Although the provision allows member countries to promote public health by issuing a compulsory license to a third party, it limits the use predominantly for supply to the domestic market. As a result, member countries without local manufacturing capacities will not be able to make use of this provision as they cannot issue licenses to manufacturers based in another member state; nor can they import from other member states.

This limitation would frustrate attempts by such countries to promote public health by providing citizens with access to cheap medicines. Developed country members are not in favour of compulsory licenses because they fear that generic drugs manufactured through the use of such licenses may flow back to the patent holder’s country and/or to territories where the patent is protected. They have been very hostile towards any member country issuing compulsory license, assuming that such a step would encourage other member countries to follow suit. The US has used the threat of sanctions as well as the dispute settlement mechanism to prevent Brazil from amending its patent laws to allow compulsory licensing on the basis of lack of local working of the patents.

Further, member countries are authorised such use only on certain reasonable commercial terms and conditions, in case of a national emergency or other circumstances of extreme urgency, or in case of non-commercial use. And, in any case, the scope and duration of such use is limited according to the purpose for which it was authorised. The agreement also envisages that the patent holder be

paid adequate remuneration, taking into account the economic value of the authorisation.[14]

The threat of being challenged and having to bear the burden of proving that a situation of national emergency or extreme urgency existed for the grant of compulsory license has led to a situation where this provision is hardly used by developing countries. Apart from that, since member countries can only use compulsory licensing if they face a problem of substantial proportion -- i.e., amounting to a national emergency or a situation of extreme urgency -- the provision is of no use for preventive measures that could help avoid such public health catastrophes.

The grant of compulsory license also involves paying suitable compensation to the patent holder. It is necessary for the member country concerned to notify the patent holder about the grant of the compulsory license; only in situations of extreme urgency can they issue compulsory license without notifying the patent holder. It also limits the duration of the license as it ceases once the purpose for which it was issued, like an emergency situation or an epidemic, ceases to exist. Consequently, the option cannot be exercised on a long-term basis to promote public health. The Doha Declaration attempts to redress the above problems. Paragraph 4 of the Declaration says that the agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicine for all. According to Paragraph 5 (a), a member country has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses can be granted. It also allows members to determine what constitutes 'national emergency' and 'circumstance of extreme urgency'.

But they have to wait until the disease reaches a scale or proportion that justifies that kind of cataclysmic description. Even then their declaration of a national emergency invariably invites opposition from pharmaceutical companies and developed countries which tend to question the enormity and/or seriousness of the situation. Can a disease causing just a few deaths constitute a national emergency? Can member states use compulsory license as an instrument of preventive action to nip a disease in the bud before it assumes epidemic proportions? These questions remain unanswered even in the Declaration. In addition, the Doha

Declaration fails to address the fact that some countries do not have the requisite technology and/or manufacturing capacity to take full advantage of the compulsory license provision. It has left unresolved the question of whether compulsory licenses could be issued for importing medicines from other member countries if the concerned nation does not have the capacity to manufacture the required drug locally.

Paragraph 6 of the Doha Declaration reads as follows: “We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002. ” The option of issuing compulsory license to import generic medicines from other member countries was not adopted because the pharmaceutical industry raised objections, fearing a reduction in their profits if every country without sufficient manufacturing capacity issued compulsory licenses to import medicines from other countries, and apprehending the possibility of price undercuts.

This issue was supposed to be resolved by the TRIPS Council by the end of 2002, but it has not yet come up with any viable solution to the problem. The text proposed by Mexican Ambassador Eduardo Pérez Motta , chairperson of the TRIPS Council, in December 2002 did not get the approval of developing countries as it proposed the grant of permission to countries to export medicines to LDCs and to a very small number of developing countries that meet the test of insufficient manufacturing capacity. The proposal suggests that there should either be no manufacturing capacity or insufficient manufacturing capacity within the country to meet its own needs. Since this, in effect, meant that any member with some capacity to manufacture would be ineligible to import, developing countries rejected the Motta text. In August 2003, WTO member countries agreed that compulsory license can be issued to import generic medicines from other countries subject to certain conditions. All the LDCs are considered to have insufficient manufacturing capacity, thus allowing them to import medicines without notifying the TRIPS Council.

However, developing countries intending to import medicines using compulsory license have to notify the Council and prove that they have no/insufficient manufacturing capacity. The exporting countries will have to disclose the quantity of drugs exported and distinguish them by adopting a different method of packaging. It is important to recognise that these restricted provisions cannot be used to promote public health on a long-term basis.

An amendment to the TRIPS agreement including these provisions would be a more substantial and sustainable development in favour of the promotion of public health. Conclusion The TRIPS agreement apparently provides for flexibility to member countries to implement policies and programmes to promote public health. However, the contradictions in the agreement make it difficult for developing countries and LDCs to use it to promote any long-term public health policy. The provisions are either too ambiguous or too vulnerable to restrictive interpretations that serve the interests of developed countries and the pharmaceutical industry. Although some of the recent changes in the provisions – such as those outlined in the Doha Declaration – have the potential to provide increased access to medicines under certain, specified circumstances, TRIPS in its present form cannot, in the longer run, be used to promote public health.

Endnotes: [1] paragraph 7 of the Doha Declaration on Public Health [2] (US-India mailbox case) referred in: Frederick.M.Abbott, (2002) "The TRIPs Agreement, Access to Medicines, and the WTO Doha Ministerial Conference," Journal of World [3] OXFAM Report [4] Ellen 't Hoen, :TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha [5] Carlos Correa, Implications of Doha Declaration on the TRIPS Agreement and Public Health [6] paragraph 1 of the Doha Declaration on TRIPS Agreement and Public Health [7] paragraph 3 of the Doha Declaration on TRIPS Agreement and Public Health [8] paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health [9] paragraph 5 (c) of the Doha Declaration on TRIPS Agreement and Public Health [10] Oxfam Report [11] Ellen 't Hoen, (2002), TRIPS, Pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha, Chicago Journal of International Law [12] South African Aids Case: 39 pharmaceutical companies challenged the Article 15c of the South African Medicines and Medical Devices Regulatory Authority Act ("Medicines Act"). This article also

permitted parallel import. [13] "Other use" refers to use other than that allowed under Article 30. [14] Article 3