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PRESENTATION



Sur – International Journal on Human Rights is a biannual publication that presents an analytical and balanced standpoint on human rights in Southern Hemisphere countries. With the aim to strengthen the South-South and the South-North dialogue among human rights activists, scholars and UN officials, this journal promotes a critical debate on several issues related to the theme. It breaks away from a pseudo-consensus and opens up spaces to improve the quality of this discussion. It therefore invites dissent, since we believe that a consistent human rights doctrine will only be put into place after a wide-ranging exchange of ideas.

We firmly believe that the information that is being produced must be widely publicized and, for this reason, this journal is issued in three languages (English, Portuguese and Spanish). Approximately 6,000 copies of the first two issues have been distributed free of charge in over 100 countries and, to ensure an extended readership, we have made an unabridged version available at <www.surjournal.org>, in the three languages.

For this edition, papers have been submitted from thirteen countries (Argentina, Brazil, Cameroon, Chile, India, Ireland, Namibia, Nigeria, Switzerland, Tanzania, Uganda, United Kingdom, and United States). After a selection by an International Editorial Board, whose members are human rights scholars, specialists and UN officials, we are publishing eight contributions, one of which reports on a research project. The subject matters dealt with are: security and human rights; trade and human rights; access to justice on domestic and international levels; and land reform.

Two papers contributed by participants of the Knowledge Development Group, organized by **Sur** in April 2005, focus on the subject of **trade and human rights**. Caroline Dommen discusses mechanisms that, by protecting human rights, actually favor the trade practices in which they are inserted. Carlos Correa depicts the progresses made in the

process to lend more flexibility to the TRIPS Agreement for medical drugs, and shows how the Doha Declaration and the 2003 Decision of the TRIPS Board are insufficient to ensure a reduction in prices and the negotiation of voluntary licenses.

Tracing a bridge between **security and human rights**, the article of Bernardo Sorj deals with the concept of human security applied to Latin American problems.

Four articles – contributed by Alberto Bovino, Nlerum S. Okogbule, Maria José Guembe and José Roberto Cunha – discuss different aspects concerning **access to justice**, on domestic and international planes. From an international perspective, Bovino dwells on the peculiarities of evidence evaluation conducted by the Inter-American Court of Human Rights, underlining the flexibility shown by this jurisdictional body in dealing with grievous infringements of rights. Okogbule weighs the specific obstacles hampering access to justice in the Nigerian context. Guembe discusses the decision of the Supreme Court of Argentina, which deemed unconstitutional the amnesty laws that benefited military personnel involved in violations of human rights during the dictatorship. Cunha presents the results of his survey among magistrates in the state of Rio de Janeiro, Brazil, as to the extent of their familiarity with and their actual use of international law in issues involving human rights.

Land reform in Namibia is the theme of the text by Nico Horn, who considers the implications of the colonizing process and custom-law.

Although very varied in their themes and approaches, all these papers share a common point of departure – the contextualization of human rights – attempting to contribute to the reconstruction of these rights, with a view at their implementation, and to ensure a better coverage of local and regional demands.

We are wrapping up this issue with a summary of the plan of action submitted by the High Commissary for Human Rights, Louise Arbour, who proposes mechanisms to increase the effectiveness of human rights protection in the several UN member countries.

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ABSTRACT

The TRIPS Agreement brought about very important changes in international standards relating to intellectual property rights. Because of its far-reaching implications it is one of the most controversial components of the WTO system. On the initiative of developing countries, the concerns raised regarding the implications of the TRIPS Agreement on public health were reflected in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, in 2001. The Declaration was followed by a Council for TRIPS Decision in 2003 on the implementation of its paragraph 6. In this article, the author states that as adopted, the implementation of paragraph 6 is unlikely to put strong pressure on patent owners to lower their prices or negotiate voluntary licenses. The author highlights that controversies are likely to continue, especially as developed countries seek TRIPS-plus protection via interpretation or negotiation of bilateral and regional agreements, and as patents over trivial developments are granted and used to block or delay generic competition. [Original article in English.*]

KEYWORDS

Trade – Intellectual property – WTO – Doha Declaration – Health

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TRIPS AGREEMENT AND ACCESS TO DRUGS IN DEVELOPING COUNTRIES

Carlos M. Correa

The Doha Declaration on TRIPS and public health

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹ brought about very important changes in international standards relating to intellectual property rights. Because of its far-reaching implications, particularly with respect to developing countries, the agreement has been one of the most controversial components of the WTO System. Strong disagreements on the scope and content of the Agreement emerged during the Uruguay Round negotiations, both between developed and developing countries and among developed countries themselves. Implementation of the Agreement and its review under the “built-in agenda” have also been contentious.²

This has notably been the case in relation to pharmaceuticals. By their very essence, patents enable pharmaceutical manufacturers to charge prices above marginal costs, recover research and development expenditures and make a profit. The AIDS crisis in Africa, and growing evidence on the negative implications of patents for access to medicines by the poor, have brought the relationship between TRIPS and health to the forefront. With more than 30 million people

1. The TRIPS Agreement provides for minimum standards for the protection of patents, trademarks, copyrights and other intellectual property rights. See the text of the agreement in <www.wto.org>.

2. See, e.g. various contributions in Brigitte Granville (ed.), *The Economics of Essential Medicines* (London: The Royal Institute of International Affairs, 2002); and Peter Drahos & Ruth Mayne (ed.), *Global Intellectual Property Rights. Knowledge, Access and Development* (New York: Palgrave Macmillan-Oxfam, 2002).

living with HIV, most of them in the poorest regions of the world, the need to address the problem of access to patented medicines has emerged as a global priority. While it is true, as argued by the pharmaceutical industry, that other factors such as infrastructure and professional support play an important role in determining access to drugs,³ it is also true that the prices resulting from the existence of patents ultimately determine how many will die from AIDS and other diseases in the years to come.

The concerns raised about the implications of the TRIPS Agreement on public health were reflected in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health⁴ upon the initiative of developing countries, at the Fourth WTO Ministerial Conference (9-14 November 2001). The Doha Declaration recognizes the “gravity” of the public health problems afflicting many developing and least developed countries, especially – but not limited to – those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. However, the Declaration reflects the concerns of developing and least developed countries regarding the implications of the TRIPS Agreement on public health in general, without limitation to certain diseases.

While acknowledging the role of intellectual property protection “for the development of new medicines”, the Declaration specifically recognizes concerns about resulting effects on prices. The Declaration affirms (paragraph 4) that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and that it should be interpreted accordingly:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The Doha Declaration clarifies members' rights to adopt an international principle of exhaustion of rights (under which parallel imports may be accepted).⁵ It 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” (paragraph 5d). Similarly, the Declaration confirms the

3. International Intellectual Property Institute, “Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa” (Washington DC, 2001), p. 23.

4. WT/MIN(01)/DEC/W/2, 14 November 2001, hereinafter the Doha Declaration.

members' rights to grant compulsory licenses on grounds determined by each member. It also allowed least developed countries to delay the introduction of pharmaceutical patents until 2016. The Declaration also makes clear that "public health crises" can represent "a national emergency or other circumstance of extreme urgency". "Emergency" in this context may be either a short-term problem, or a long-lasting situation.

Confirmation that the TRIPS Agreement leaves room for flexibility at the national level has important political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement. In legal terms, it means that panels and the Appellate Body must interpret the TRIPS Agreement and laws and regulations adopted to implement it in light of the public health needs of the individual members.

In paragraph 6 the Doha Declaration instructed the Council for TRIPS to address this delicate issue: how can members lacking or having insufficient manufacturing capacities make effective use of compulsory licensing.⁶ 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 of 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 development capabilities.

When the TRIPS Agreement becomes fully operative (after 2005), many countries may face difficulties in acquiring medicines at affordable prices. Today, for example, some countries, such as India, do not provide patent protections for pharmaceutical products, and produce generic versions at a fraction of the price of the patented products. A member country where the price of patented products 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 by 2005 at the latest, they will no longer be able to produce and export cheap generic copies of patented medicines. Consequently, the sources of affordable new medicines will dry up and countries without sufficient

5. According to the principle of international exhaustion of rights, a patent holder "exhausts" his rights after the first legitimate sale of patented products in a foreign country. Hence, he cannot prevent the subsequent transborder movement of such products.

6. A "compulsory license" is the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general interest (e.g., absence of working, public health, anticompetitive practices, emergency, national defense).

manufacturing capacity and market demand will not be able to grant a compulsory license either for the local production or for the importation of such medicines: they will become entirely dependent upon expensive patented versions.

The Doha Declaration requested the Council for TRIPS “to find an expeditious solution to this problem and to report to the General Council before the end of 2002” by the end of 2002. An agreement was only reached on August 30, 2003,⁷ after a diplomatic battle, when the United States finally accepted a text covering all diseases, as mandated by the Declaration.⁸ The agreed “solution” is based on a compromise developed by the Chair of the TRIPS Council⁹ and on a “Statement by the Chair” proposed by the US as a condition to accept the deal and satisfy the American pharmaceutical industry.

For the purposes of the Decision, “eligible importing member” means any least developed country member, as well as any other member that has made a notification to the Council for TRIPS of its intention, to use the system as an importer. Some countries have notified the Council that they will only use the system in cases of national emergencies or in other circumstances of extreme urgency or in cases of public non-commercial use, and in others that they will not use the system. The eligible importing country must make a notification to the Council for TRIPS, that:

- specifies the names and expected quantities of the product(s) needed;
- confirms that the eligible importing member in question, other than a least developed country member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and
- confirms that, 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 this Decision.

In addition, the compulsory license issued by the exporting member shall contain the following conditions:

- Only the amount necessary to meet the needs of the eligible importing member(s) may be manufactured under the license and the entirety of this production shall be exported to the member(s) which has notified the Council for TRIPS of its needs.

7. See IP/C/W/405, available at <www.wto.org> (hereinafter “the Decision”).

8. The US initial position aimed at limiting the possible solution to HIV/AIDS, malaria and tuberculosis.

9. See the text of the Chairman of the Council for TRIPS of 16 December 2002 (JOB(02)/217). Available at <www.wto.org>.

- Products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.
- Before shipment begins, the licensee shall post on a website the following: (1) the quantities being supplied to each destination; and (2) the distinguishing features of the product(s).

Further, the exporting member shall notify the Council for TRIPS of the granting of the license, including the conditions attached to it. Where a compulsory license is granted by an exporting member, adequate remuneration pursuant to Article 31.h of the TRIPS Agreement¹⁰ shall be paid to that member taking into account the economic value to the importing member of the use that has been authorized by the exporting member. This means that, although the remuneration would be paid by the exporter, the “economic value” taken into account to determine the amount of remuneration is that of the importing country. Where a compulsory license is granted for the same products to the eligible importing member, the obligation of that member under Article 31.h shall be waived in respect of those products for which remuneration is paid by the exporting member.

One of the main concerns voiced by developed countries during the negotiation of the Decision, was the possible diversion of the exported products to rich countries.¹¹ The Decision establishes that eligible importing members shall take all reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of products that have actually been imported into their territories under the system. In the event that an eligible importing member that is also a developing country member or a least-developed country member experience difficulty in implementing this provision, developed country members shall

10. Article 31.h: “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”.

11. The risk of diversion has probably been overstated. Trade in medicines is subject to stringent national regulations that erect effective barriers to market access. The European Commission has noted that “the industry acknowledges that to date there is no re-importation of medicines from the poorest developing countries into the European Union, i.e. the problem of re-importation is still largely theoretical”, in European Commission (DGTrade, 2002). “Tiered Pricing for Medicines Exported to Developing Countries, Measures to Prevent their Re-Importation into the EC Market and Tariffs in Developing Countries” (Brussels: Working Document, 22 April), p. 10.

provide, on request, and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation. Additionally, members shall ensure the availability of effective legal means to prevent the importation into, and sale of, within their territories, products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that member.

The Chair's Statement added that the special conditions (as set out in paragraph 2b(ii) of the Decision)¹² apply not only to formulated pharmaceuticals but also to active ingredients produced and supplied under the system as well as to finished products that have been produced using such active ingredients. The Statement also adds (though there is no evidence to support this statement), that it "is the understanding of members that in general special packaging and/or special coloring or shaping should not have a significant impact on the price of pharmaceuticals". In addition the Statement introduces a monitoring system, including verification of how the member in question has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector.¹³

The Statement also indicates that members recognize 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". The only reasonable reading of this statement is that the **importing** country should use the system for public health reasons, but it certainly does not exclude the supply of the required medicines which have a profit objective by commercial entities. Without the possibility of making a profit, potential suppliers will lack the incentive to make the investments (including the covering of legal costs) necessary to satisfy the requirements of countries without manufacturing capacity.

12. Article 2(b)(ii): "The products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price".

13. One of the noticeable ambiguities in the Decision is the concept of "manufacturing capacity". It is unclear, in particular, whether such capacity should be determined on technical grounds only, or taken into account the economic feasibility of manufacturing. This latter interpretation seems the most reasonable on efficiency grounds, and given that economic feasibility may be as an important barrier for local manufacturing as the lack of technical capacity.

Changing national laws

The Decision takes the form of an interim waiver, which allows countries producing patented products under compulsory licenses to export the products to eligible importing countries, provided that a compulsory license has also been granted in the importing country and that various other conditions, as discussed above, are met. The waiver would last until the TRIPS Agreement is amended.¹⁴

It is important to note that the system under paragraph 6 of the Doha Declaration will operate in a scenario in which there is only one world supplier of a patented drug and, therefore, there will be no available source of generic products. The use of such a system will be necessary when the patent owner **refuses to supply** a patented drug in a country (with insufficient or no manufacturing capacity in pharmaceuticals) at a price or under other conditions acceptable to the interested country. The basic assumption for the application of the system is, therefore, a situation where (a) a drug is available and **could** be sold to the country in need by the patent owner, and (b) the patent owner refuses to do so.

This means that whatever humanitarian reasons underlie the country's demand for a given drug, nothing in the adopted system will compel the patent owner to supply the needed drugs. He may just passively watch how the country in need strives to fulfill the conditions imposed by the Decision, while people remain without treatment. He may also facilitate the process by conferring a voluntary license to a potential exporter. It may also occur that the patent owner exploits the intricacies and complexities of the system, and exercises his rights under the relevant national laws to block the unauthorized use of his patent. The system under paragraph 6 may, in fact, be applied **in a context of conflict** between the demanding country and the patent owner unwilling to supply.

A WTO waiver means that a member shall not initiate a complaint against another member if the latter acts under the terms of the adopted waiver. But to the extent that the national law is not aligned with the waiver, it will not prevent the patent owner from invoking provisions in the national laws to prevent the acquisition of the patented drug from other sources. Therefore the actual

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

implementation of the Decision will depend on the extent to which national laws allow the waived acts.

Under the adopted system, for instance, is recognized the possibility (fully consistent with the TRIPS Agreement) of granting a compulsory license to **import** a patented drug. The problem, however, is that many developing countries provide for the granting of compulsory licenses for the **manufacture** of patented subject matter, and not for importation. Hence, in order to make operative any solution under paragraph 6, those developing countries would need to amend their national patent laws accordingly. This may be unnecessary if the national laws included provisions for non commercial government use of patented inventions, allowing for either local manufacturing or importation.¹⁵

Similarly, amendments to national laws will be necessary in the potential exporting countries. Compulsory licenses are granted under grounds specified by national laws. The supply of export markets is not an accepted ground in most national laws.¹⁶ Moreover, in implementing Article 31.f of the TRIPS Agreement,¹⁷ WTO members have established compulsory licenses to supply “predominantly” the domestic market. If a company receives a request under paragraph 6 to supply a foreign country, it would not be able to obtain a compulsory license exclusively to export, unless the national law has been amended accordingly. The extent to which governments will be willing to start the complex process of amending the patent law – especially on the basis of an interim waiver – is open to question. Nothing in the Decision precludes developed countries from acting as exporters of generic drugs under the system, but it is uncertain how their governments would react if requested to amend their laws and grant compulsory licenses for supplying under paragraph 6. In

15. It is to be noted that the Decision only refers to “compulsory licenses” and not to government use for non-commercial purposes. However, the waiver is adopted with regard to Article 31, paragraphs (f) and (h) of the TRIPS Agreement, which equally covers both forms of uses without authorization of the patent holder. Any good faith interpretation of the Decision, therefore, should admit such government uses.

16. However, Article 168 of the Australian Patent Act and Article 55(2) of the Patent Act of New Zealand, permits exports under an agreement with a foreign country to supply products required for the defense of that country. Article 48B(d) and (i) of the UK Patent Act provides for a compulsory license in respect of a patent whose proprietor is not a WTO proprietor when the owner’s failure to license the patent on reasonable grounds means that a market for the export a patented product made in the UK is not being supplied. Article 45.g of the Argentine patent law permits the granting of a compulsory license not predominantly for the domestic markets when necessary to remedy anticompetitive practices or in cases of health emergencies or national security.

17. Article 31.f: “any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use”.

fact, most observers expect the large generic producers in the developing world (such as India, China, Brazil, Thailand and South Africa) to undertake this production and export.¹⁸

The effective use of a compulsory license in both the importing and exporting country will also depend on procedures. In some countries (e.g. Argentina) an appeal by the patent owner against the grant of a compulsory license does not suspend its immediate execution (e.g. Article 49, Argentine Patent Law n. 24481, as amended). In other countries, this may not be the case. The patent owner may file an appeal or obtain an injunction and thereby stop exports under a compulsory license until a final administrative or judicial decision is taken, perhaps a few years later. National patent laws, hence, will have to be amended, as necessary, in order to make the use of compulsory licenses for export an effective mechanism to address public health needs.

Conditions for use of the waiver

Numerous conditions are established in the text of the Decision, as interpreted by the Chair's Statement, for allowing exports of patented medicines. In order to get the supply of drugs under this mechanism the following steps must be followed:¹⁹

1. Unless the prior request of a voluntary license does not apply,²⁰ an entity in the importing country must seek a voluntary license from the patent owner.²¹

18. K. Maskus, "TRIPS, Drug Patents and Access to Medicines-Balancing Incentives for R&D with Public Health Concerns", in *Knowledge Economy, Development Gateway* (2003), at <www.developmentgateway.org/download/206719Maskus_on_TRIPS,_Drug_Patents,_Medicines.pdf>. Last access on 12 September 2005.

19. See Brook K. Baker, "Vows of Poverty, Shrunk Markets, Burdensome Manufacturing and other Nonsense at the WTO" (*Health GAP*, 27 August 2003). Available at IP-Health website: <www.healthgap.org/press_releases/03/092703_HGAP_BP_WTO_Cancun.html>. Last access on 7 September 2005.

20. This would generally be the case – depending, however, on national law – when an authorization is given on grounds of extreme urgency, anti-competitive practices or non-commercial public use (Article 31 (f) and (k) of the TRIPS Agreement).

21. In requesting a compulsory license both in the importing and the exporting country, it will be necessary to identify and include all the patents that may affect the supply of a drug, since normally there are patents covering the active ingredient, acceptable formulations, polymorphs, manufacturing processes etc. of the same drug. On patenting practices in pharmaceuticals, see Correa, *Trends in Drug Patenting* (Buenos Aires: Corregidor, 2001).

2. Failing this, an application for a compulsory license must be submitted to the government of the importing country and the license be obtained there (unless there is no applicable patent in that country).
3. The importing country must assess the capacity of its generic industry to produce the required medicine locally.
4. If capacity is insufficient, it must notify the WTO of its decision to use the paragraph 6 system.
5. The interested importing party must identify a potential exporter.
6. That exporter must in turn seek a voluntary license from the patent owner on commercially reasonable terms for a commercially reasonable period of time.
7. If the voluntary license is refused, the potential exporter must seek a compulsory license (to be granted on a single-supply basis) from its own government.
8. The exporter will need to seek product registration and prove bio-equivalence and bioavailability, as required by national law.
9. If exclusive rights (as promoted by the US) are granted²² in the importing country with regard to data submitted for registration of a medicine, the supplier will have to obtain authorization by the possessor of the data to use them, or to develop its own studies about toxicity and efficacy (unless the use of such data is authorized under the compulsory license).
10. Before shipment begins, the licensee shall post on website information about the quantities being supplied and the distinguishing features of the product.
11. The exporting member must notify the Council for TRIPS of the granting of the license, including the conditions attached to it.

This process must be fulfilled over and over, since only the amount necessary to meet the needs of one particular eligible importing member may be manufactured under the license, and the entirety of this production shall be exported to the member that has notified its needs to the Council for TRIPS.

Economic feasibility

As discussed elsewhere,²³ in order to be effective, a solution to the problem described in paragraph 6 should be economically viable, and not only

22. See Correa, "Protection of Data Submitted for the Registration of Pharmaceutical Products. Implementing the Standards of the Trips Agreement" (Geneva: South Centre, 2002).

diplomatically acceptable. Does the Decision provide the incentives to encourage potential suppliers to make the necessary investment and take the associated risks? In addition to complying with the legal procedures involved in the application of a compulsory license and the marketing approval of the product, the potential exporter will have to develop (when produced for the first time) the chemistry and formulate the drug, and then produce the active ingredients and/or formulations with shape, color, label and packaging different from of the patent owner's product, and at a low price affordable to the acquiring party. Pharmaceutical firms are unlikely to make the required investment if there is no reasonable profit expectation.

The Decision recognizes that the viability of the "solution" largely depends on the existence of economies of scale that justify production. According to paragraph 6 of the Decision, however, the realization of economies of such scale is only envisaged in cases where the importing country is a party to a regional trade agreement with at least half of its current membership made up of least developed countries. In this case the obligation of that member under Article 31.f of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. Given the requirement about participation of least developed countries, this exception will only apply to some regional agreements in Africa but not in other regions,²⁴ thereby limiting the effect on economies of scale that could have been obtained.

As noted by Maskus (2003, op. cit.), though overall needs in the poor nations are immense, "even if some poor countries in a trade agreement covered by this exception pooled their demands for a particular medicine, the scale may be still too low to become attractive for potential suppliers ... because the eligible import markets in really small countries will not be large, generic producers may not be interested in producing such small volumes and foregoing chances for economies of scale".

23. See Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (Geneva: World Health Organization, 2002), p. 33. Available at <www.who.int/medicines/library/par/who-edm-par-2002-3/doha-implications.doc>. Last access on 7 September 2005. See also "Integrating Intellectual Property Rights and Development Policy" (London: Commission on Intellectual Property Rights, 2002). Available at <www.iprcommission.org>. Last access on 7 September 2005.

24. For instance, Mercosur and the Andean Community do not qualify under the Decision as a single market for the purposes of the Decision.

Conclusions

The implementation of the Decision on paragraph 6 of the Doha Declaration will require adaptations in national laws and entail, in particular cases, significant transaction costs. As adopted, it is unlikely to put strong pressure on patent owners to lower their prices or to negotiate voluntary licenses, nor is it likely to provide incentives to potential suppliers to make the investments necessary to develop and produce the needed drugs. Subventions from the international organizations and donor governments made be necessary to make this “solution” workable.²⁵

Despite the quite obvious limitations of and many constraints imposed by the examined Decision, countries in need of acquiring patented drugs should test the viability of the system. The Decision should be interpreted, in line with the Doha Declaration on the TRIPS Agreement and Public Health, in a manner that facilitates an increase in the supply of medicines to poor countries. It is also necessary to elaborate a **permanent** solution to the problem affecting countries with limited or without manufacturing capacities in this field, based on an amendment to the TRIPS Agreement. Such an amendment should be based on a simpler and more straightforward approach,²⁶ which provides the economic incentives for the solution to be effective.

It is also important to note that the system under paragraph 6 seems to be built upon the assumption that a patent owner is legitimized to prevent access to products under his control, even in the presence of compelling humanitarian reasons. This is certainly not consistent with the Doha Declaration on the TRIPS Agreement and Public Health (particularly paragraph 4), nor with States’ commitments under the International Covenant on Economic, Social and Cultural Rights, especially its Article 12 (recognizing the human “right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and obliging the taking of steps to fully realize this right, including “those necessary for ... the prevention, treatment and control of epidemic, endemic, ... and other diseases”). The adoption of the Decision, hence, cannot prevent the use of

25. See K. Maskus, 2003, *op. cit.*

26. For instance, on 3 October 2002, the European Parliament adopted Amendment 196 to the European Medicines Directive, which provides that “manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country”.

other means when the owner of the relevant patent or patents refuses to supply a needed drug. Countries should be encouraged to develop disciplines to deal with such refusals in the context of the “essential facilities” doctrine,²⁷ or other concepts under competition and public health law.

Finally, it should be recalled that **paragraph 6 only describes one of the problems** arising in the context of the TRIPS Agreement with regard to public health. The intellectual property protection of pharmaceuticals will continue to pose significant challenges to public health policies in developing countries, even if the agreed “solution” were proven to be viable and effective. The agreement on paragraph 6 does not mean an end to the controversies around intellectual property and public health. They are likely to continue, especially as developed countries seek TRIPS-plus protection via interpretation²⁸ or negotiation of bilateral and regional agreements,²⁹ and as patents on marginal or trivial developments (sometimes called “ever-greening” patents) are granted and used to block or delay generic competition.³⁰

27. See John Taladay & James Carlin Jr., “Compulsory Licensing of Intellectual Property under the Competition Laws of the United States and European Community” (*George Mason Law Review* 10, n. 3, Spring 2002), p. 443.

28. The United States Trade Representative (USTR), for instance, interprets that Article 39.3 of the Agreement requires the granting of an exclusive period of protection for data submitted for the marketing approval of pharmaceuticals and agrochemicals.

29. See, e.g., the recent US–Chile and US–Singapore bilateral agreements.

30. “Ever-greening” refers to the acquisition of patent rights over minor or trivial modifications or formulations of existing drugs, with the aim of delaying the entry of generic competition. See Correa, 2001, *op. cit.*