

Appendix C: Views on Intellectual Property Rights in Drugs

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The following resources provide excellent background information on the range of views regarding intellectual property rights and drugs.

1. United Nations Committee on Economic, Social and Cultural Rights. Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights. Statement on Human Rights and Intellectual Property. November 2001. Circulated as UN Document E/C.12/2001/15 dated 14 December 2001. [Summary of committee members' views.]
2. United Nations Committee on Economic, Social and Cultural Rights. General Comment No. 17. The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant). November 2005. Circulated as UN Document E/C.12/GC/17 dated 12 January 2006. [Committee interpretation of Article 15, paragraph 1(c) of the International Covenant on Economic, Social and Political Rights providing guidance to the governments of states that are parties to the Covenant and to other interested persons, groups, and organizations.]
3. World Trade Organization. Fact Sheet: TRIPS and Pharmaceutical Patents. May 2006. From www.wto.org/tripsfactsheet_pharma_2006_e.pdf
4. UNITAID. Statement on Patent Pool Initiative, May 2009. From its website at www.unitaid.eu [As of Nov. 1, 2010, the Medicine Patent Pool has its own website at www.medicinespatentpool.org/]
5. World Trade Organization Director-General Pascal Lamy. Address to the WIPO Conference on Intellectual Property and Public Policy Issues, 14 July 2009. From WTO Website www.wto.org
6. Merck statement on compulsory licensing, July 2008. From company website, www.merck.com

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COMMITTEE ON ECONOMIC, SOCIAL
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Agenda item 3

**SUBSTANTIVE ISSUES ARISING IN THE IMPLEMENTATION
OF THE INTERNATIONAL COVENANT ON ECONOMIC,
SOCIAL AND CULTURAL RIGHTS**

**Follow-up to the day of general discussion on article 15.1 (c),
Monday, 26 November 2001**

Human rights and intellectual property

Statement by the Committee on Economic Social and Cultural Rights

Introduction

1. The Committee on Economic, Social and Cultural Rights recognizes the broad significance of the creation, ownership and control of intellectual property in a knowledge-based economy and the means that it can afford for promoting or inhibiting the enjoyment of human rights, in particular the rights under the International Covenant on Economic, Social and Cultural Rights. The allocation of rights over intellectual property has significant economic, social and cultural consequences that can affect the enjoyment of human rights. The contemporary importance of intellectual property for human rights reflects two developments. The first is the expansion of the areas covered by intellectual property regimes to include, for example, patenting of biological entities, copyright print protections in the digital domain, and private intellectual property claims with respect to cultural heritage and traditional knowledge. The second is the emergence of universal rules on intellectual property protection in the global trading system.

2. The Committee has resolved to prepare and adopt, as soon as possible, a general comment on intellectual property and human rights. The Committee, however, has decided to adopt this statement as its preliminary contribution to the rapidly evolving debate on intellectual property, which remains high on the international agenda. The statement aims only to identify some of the key human rights principles deriving from the Covenant that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes. These basic principles will be further refined, elaborated and applied in the Committee's forthcoming general comment on intellectual property and human rights.¹

3. The principles set out in the present statement apply equally to national legislation and international rules and policies concerning intellectual property protection. In particular, the Committee draws attention to the various intellectual property treaties administered by the World Intellectual Property Organization (WIPO), as well as the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) of the World Trade Organization (WTO), which set out minimum standards for the protection and enforcement of intellectual property rights. Reference could also be made to relevant articles of other treaties, such as the 1992 Convention on Biological Diversity. In this regard, the Committee recalls previous statements it has made in which it emphasized that the realms of trade, finance and investment are in no way exempt from human rights principles and that "international organizations with specific responsibilities in those areas should play a positive and constructive role in relation to human rights."²

4. Article 15.1 (c) of the Covenant, together with article 27 of the Universal Declaration on Human Rights, requires the protection of the moral and material interests of authors in their works. The Committee considers that these intellectual property rights must be balanced with the right to take part in cultural life³ and to enjoy the benefits of scientific progress and its applications.⁴ Moreover, article 15.2 of the Covenant requires that States parties undertake steps necessary for the conservation, development and diffusion of science and culture. To be consistent with a human rights-based approach, intellectual property regimes should be conducive to realizing these goals. The Committee therefore encourages the development of intellectual property systems and the use of intellectual property rights in a balanced manner that meets the objective of providing protection for the moral and material interests of authors, and at

the same time promotes the enjoyment of these and other human rights. Ultimately, intellectual property is a social product and has a social function. The end which intellectual property protection should serve is the objective of human well-being, to which international human rights instruments give legal expression.

Universality, indivisibility and interdependence of human rights

5. Human rights derive from the inherent dignity and worth of all persons, with the human person as the central subject and primary beneficiary of human rights.⁵ The moral and legal guarantees of fundamental freedoms, protections and entitlements both derive from and support people's self-respect and dignity. Consequently, the entire range of civil, cultural, economic, political and social rights, as well as the right to development, are relevant to intellectual property systems. To be consistent with obligations to respect international human rights, intellectual property regimes must promote and protect all human rights, including the full range of rights guaranteed in the Covenant.

6. The fact that the human person is the central subject and primary beneficiary of human rights distinguishes human rights, including the right of authors to the moral and material interests in their works, from legal rights recognized in intellectual property systems. Human rights are fundamental, inalienable and universal entitlements belonging to individuals, and in some situations groups of individuals and communities. Human rights are fundamental as they derive from the human person as such, whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits. In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else.⁶ While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for under article 15 of the Covenant does not necessarily coincide with what is termed intellectual property rights under national legislation or international agreements.

Equality and non-discrimination

7. Human rights are based on the equality of all persons and their equal standing before the law. For that reason, human rights instruments place great emphasis on protection against discrimination. Articles 2.2 and 3 of the Covenant stipulate that States parties undertake to guarantee that the rights enunciated in the Covenant must be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status, and to ensure the equal rights of men and women to the enjoyment of all the rights set forth in the Covenant.

8. A human rights-based approach focuses particularly on the needs of the most disadvantaged and marginalized individuals and communities. Because a human right is a universal entitlement, its implementation is evaluated particularly by the degree to which it benefits those who hitherto have been the most disadvantaged and marginalized and brings them up to the mainstream level of protection. Thus, in adopting intellectual property regimes, States and other actors must give particular attention at the national and international levels to the adequate protection of the human rights of disadvantaged and marginalized individuals and groups, such as indigenous peoples.⁷

Participation

9. International human rights law includes the right of everyone to be consulted and participate in significant decision-making processes that affect them. The right to participate is reflected in numerous international instruments, including the Covenant⁸ and the International Covenant on Civil and Political Rights,⁹ as well as the Declaration on the Right to Development.¹⁰ Accordingly, the Committee supports the active and informed participation of all those affected by intellectual property regimes.

Accountability

10. The Committee reiterates its position set out in its statement on poverty, “rights and obligations demand accountability: unless supported by a system of accountability, they can become no more than window-dressing.”¹¹ While the State holds the primary duty to respect, protect and fulfil human rights, other actors, including non-State actors and international organizations, carry obligations, which must be subject to scrutiny. Accordingly, the adequate protection of human rights needs accessible, transparent and effective accountability mechanisms to ensure that rights are respected, and where they are not, that victims can find redress. A human rights approach to intellectual property requires that all actors are held to account for their obligations under international human rights law, specifically with regard to the adoption, interpretation and implementation of intellectual property systems.

General legal obligations

11. In the context of intellectual property, it should be noted that while the Covenant provides for progressive realization and acknowledges the constraints due to limits on available resources, it also imposes on States parties various obligations which have immediate effect, including core obligations.¹² Progressive realization over a period of time should not be interpreted as depriving States parties’ obligations of all meaningful content. Rather, progressive realization means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of all the rights enshrined in the Covenant. Accordingly, the Committee wishes to emphasize that national and international intellectual property regimes must be consistent with the obligation of States parties to ensure the progressive realization of full enjoyment of all the rights in the Covenant. Furthermore, all parties are urged to ensure that intellectual property regimes contribute, in a practical and substantive way, to the full realization of all the Covenant rights.

Core obligations

12. In this regard, it should also be recalled that the Committee's General Comment No. 3, adopted in 1990, confirms that States parties have a "core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights" enunciated in the Covenant. As the Committee observes, without such a core obligation, the Covenant "would be largely deprived of its *raison d'être*".¹³ More recently, the Committee has begun to identify the core obligations arising from the "minimum essential levels in relation to the rights to health, food and education".¹⁴ The Committee wishes to emphasize that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.

International cooperation and assistance

13. As the Committee confirmed in its General Comment No. 14 on the right to health, it is particularly incumbent on all those in a position to assist, to provide "international assistance and cooperation, especially economic and technical", in order to enable developing countries to fulfil their core obligations under the Covenant.¹⁵ Accordingly, it is incumbent upon developed States, and other actors in a position to assist, to develop international intellectual property regimes that enable developing States to fulfil at least their core obligations to individuals and groups within their jurisdictions. In this regard and so as to avoid repetition, the Committee reaffirms paragraphs 15 to 18 of its statement on poverty.¹⁶

14. The Charter of the United Nations commits all nations to the development of an equitable and just international order that encourages peace, solidarity, social progress and better standards of life for all nations large and small. Article 28 of the Universal Declaration of Human Rights declares that everyone has the right to a social and international order in which the rights and freedoms in the Declaration can be enjoyed. Articles 2.1 and 23 of the Covenant further state that States parties should engage in international cooperation in order to achieve progressively the rights enshrined in the Covenant. Article 15.4 of the Covenant further recognizes the benefits to be derived from encouraging and developing international contacts and cooperation in the scientific and cultural fields.¹⁷

15. The Committee observes that countries enjoy different levels of development, resulting in different technological needs. While some countries might focus on the protection of technology, others may focus more on facilitating access. It is essential that intellectual property regimes facilitate and promote development cooperation, technology transfer and scientific and cultural collaboration. International rules concerning intellectual property should not necessarily be uniform if this might lead to forms of intellectual property protection inappropriate for development goals. The Committee encourages the adoption and implementation of effective international mechanisms for special and differential treatment for developing countries concerning intellectual property protection.

Self-determination

16. Article 1.2 of the Covenant states that “[a]ll peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic cooperation ...”. National sovereignty over wealth and resources is an important prerequisite for the effective promotion and protection of human rights. In negotiating, and adhering to, international treaties on intellectual property, States should consider how this will affect their sovereignty over wealth and resources and ultimately their capacity to ensure the rights enshrined in the Covenant.

Balance

17. Article 15 of the Covenant sets out the need to balance the protection of public and private interests in knowledge. On the one hand, article 15.1 (a) and (b) recognizes the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. On the other hand, article 15.1 (c) recognizes the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. When adopting and reviewing intellectual property systems, States should bear in mind the need to strike a balance between those concurrent Covenant provisions. In an effort to provide incentives for creation and innovation, private interests should not be unduly advantaged and the public interest in enjoying broad access to new knowledge should be given due consideration. The Committee notes that an example of this need to strike a balance can be found in the recent Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property protection is important for the development of new medicines, but at the same time also recognizes the concerns about its effect on prices.¹⁸

Conclusion

18. The Committee considers of fundamental importance the integration of international human rights norms into the enactment and interpretation of intellectual property law. Consequently, States parties should guarantee the social dimensions of intellectual property, in accordance with international human rights obligations to which they have committed themselves. An explicit commitment to do so and the establishment of a mechanism for a human rights review of intellectual property systems are important steps towards that goal.

19. There is a similar need for intergovernmental organizations to integrate international human rights obligations and principles into their policies, practices and operations. Conscious of the far-reaching importance and complexity of integrating human rights into the development of intellectual property regimes, the Committee confirms its willingness to discuss the issues identified in this statement with relevant actors and its availability to assist States parties and intergovernmental organizations in this process.

Notes

- ¹ On 27 November 2000, the Committee held a day of general discussion on article 15.1 (c) of the Covenant, the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author, which formed a basis for the Committee's drafting of a general comment.
- ² Statement of the Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization, 26 November 1999 (E/C.12/1999/9).
- ³ Article 15.1 (a) of the Covenant.
- ⁴ Article 15.1 (b) of the Covenant.
- ⁵ See e.g. the Preambles to the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights. See also article 5 of the 1993 Vienna Declaration and Programme of Action.
- ⁶ Report of the High Commissioner on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13, 27 June 2001, paragraph 14.
- ⁷ Statement by the Committee on Economic, Social and Cultural Rights on "Poverty and the International Covenant on Economic, Social and Cultural Rights", E/C.12/2001/10, 4 May 2001, paragraph 11.
- ⁸ Article 25.
- ⁹ Article 13.1.
- ¹⁰ Article 2.3.
- ¹¹ See note 7, paragraph 14.
- ¹² See, for example, the Committee's General Comments No. 3 (on the nature of States parties' obligations, article 2.1 of the Covenant) and 9 (the domestic application of the Covenant), No. 13 (on the right to education, paras. 43-44) and No. 14 (on the right to health, paras. 30-32), in HRI/GEN/1/Rev.5, 26 April 2001.
- ¹³ General Comment No. 3, paragraph 10, see note 12.
- ¹⁴ General Comments Nos. 11, 13 and 14, see note 12.
- ¹⁵ General Comment No. 14, paragraph 45, see note 12.
- ¹⁶ See note 7.

¹⁷ The Covenant refers to “international assistance and cooperation”, or similar formulations, in articles 2.1, 11.2, 15.4, 22 and 23.

¹⁸ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Qatar, adopted on 14 November 2001, WT/MIN(01)/DEC/2, paragraph 3.



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GENERAL COMMENT No. 17 (2005)

The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant)

I. INTRODUCTION AND BASIC PREMISES

1. The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author is a human right, which derives from the inherent dignity and worth of all persons. This fact distinguishes article 15, paragraph 1 (c), and other human rights from most legal entitlements recognized in intellectual property systems. Human rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities. Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.

2. In contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas the human right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.¹

3. It is therefore important not to equate intellectual property rights with the human right recognized in article 15, paragraph 1 (c). The human right to benefit from the protection of the moral and material interests of the author is recognized in a number of international instruments. In identical language, article 27, paragraph 2, of the Universal Declaration of Human Rights provides: "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." Similarly, this right is recognized in regional human rights instruments, such as article 13, paragraph 2, of the American Declaration of the Rights and Duties of Man of 1948, article 14, paragraph 1 (c), of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 ("Protocol of San Salvador") and, albeit not explicitly, in article 1 of Protocol No. 1 to the Convention for the Protection of Human Rights and Fundamental Freedoms of 1952 (European Convention on Human Rights).

4. The right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions seeks to encourage the active contribution of creators to the arts and sciences and to the progress of society as a whole. As such, it is intrinsically linked to the other rights recognized in article 15 of the Covenant, i.e. the right to

take part in cultural life (art. 15, para. 1 (a)), the right to enjoy the benefits of scientific progress and its applications (art. 15, para. 1 (b)), and the freedom indispensable for scientific research and creative activity (art. 15, para. 3). The relationship between these rights and article 15, paragraph 1 (c), is at the same time mutually reinforcing and reciprocally limitative. The limitations imposed on the right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions by virtue of these rights will partly be explored in this general comment, partly in separate general comments on article 15, paragraphs 1 (a) and (b) and 3, of the Covenant. As a material safeguard for the freedom of scientific research and creative activity, guaranteed under article 15, paragraph 3 and article 15, paragraph 1 (c), also has an economic dimension and is, therefore, closely linked to the rights to the opportunity to gain one's living by work which one freely chooses (art. 6, para. 1) and to adequate remuneration (art. 7 (a)), and to the human right to an adequate standard of living (art. 11, para. 1). Moreover, the realization of article 15, paragraph 1 (c), is dependent on the enjoyment of other human rights guaranteed in the International Bill of Human Rights and other international and regional instruments, such as the right to own property alone as well as in association with others,² the freedom of expression including the freedom to seek, receive and impart information and ideas of all kinds,³ the right to the full development of the human personality,⁴ and rights of cultural participation,⁵ including cultural rights of specific groups.⁶

5. With a view to assisting States parties' implementation of the Covenant and fulfilment of their reporting obligations, this general comment focuses on the normative content of article 15, paragraph 1 (c) (Part I), States parties' obligations (Part II), violations (Part III) and implementation at the national level (Part IV), while the obligations of actors other than States parties are addressed in Part V.

II. NORMATIVE CONTENT OF ARTICLE 15, PARAGRAPH 1 (c)

6. Article 15, paragraph 1, enumerates, in three paragraphs, three rights covering different aspects of cultural participation, including the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (art. 15, para. 1 (c)), without explicitly defining the content and scope of this right. Therefore, each of the elements of article 15, paragraph 1 (c), requires interpretation.

Elements of article 15, paragraph 1 (c)

“Author”

7. The Committee considers that only the “author”, namely the creator, whether man or woman, individual or group of individuals,⁷ of scientific, literary or artistic productions, such as, inter alia, writers and artists, can be the beneficiary of the protection of article 15, paragraph 1 (c). This follows from the words “everyone”, “he” and “author”, which indicate that the drafters of that article seemed to have believed authors of scientific, literary or artistic productions to be natural persons,⁸ without at that time realizing that they could also be groups of individuals. Under the existing international treaty protection regimes, legal entities are included among the holders of intellectual property rights. However, as noted above, their entitlements, because of their different nature, are not protected at the level of human rights.⁹

8. Although the wording of article 15, paragraph 1 (c), generally refers to the individual creator (“everyone”, “he”, “author”), the right to benefit from the protection of the moral and material interests resulting from one’s scientific, literary or artistic productions can, under certain circumstances, also be enjoyed by groups of individuals or by communities.¹⁰

“Any scientific, literary or artistic production”

9. The Committee considers that “any scientific, literary or artistic production”, within the meaning of article 15, paragraph 1 (c), refers to creations of the human mind, that is to “scientific productions”, such as scientific publications and innovations, including knowledge, innovations and practices of indigenous and local communities, and “literary and artistic productions”, such as, inter alia, poems, novels, paintings, sculptures, musical compositions, theatrical and cinematographic works, performances and oral traditions.

“Benefit from the protection”

10. The Committee considers that article 15, paragraph 1 (c), recognizes the right of authors to benefit from some kind of protection of the moral and material interests resulting from their scientific, literary or artistic productions, without specifying the modalities of such protection. In order not to render this provision devoid of any meaning, the protection afforded needs to be effective in securing for authors the moral and material interests resulting from their productions. However, the protection under article 15, paragraph 1 (c), need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes, as long as the protection available is suited to secure for authors the moral and material interests resulting from their productions, as defined in paragraphs 12 to 16 below.

11. The Committee observes that, by recognizing the right of everyone to “benefit from the protection” of the moral and material interests resulting from one’s scientific, literary or artistic productions, article 15, paragraph 1 (c), by no means prevents States parties from adopting higher protection standards in international treaties on the protection of the moral and material interests of authors or in their domestic laws,¹¹ provided that these standards do not unjustifiably limit the enjoyment by others of their rights under the Covenant.¹²

“Moral interests”

12. The protection of the “moral interests” of authors was one of the main concerns of the drafters of article 27, paragraph 2, of the Universal Declaration of Human Rights: “Authors of all artistic, literary, scientific works and inventors shall retain, in addition to just remuneration of their labour, a moral right on their work and/or discovery which shall not disappear, even after such a work shall have become the common property of mankind.”¹³ Their intention was to proclaim the intrinsically personal character of every creation of the human mind and the ensuing durable link between creators and their creations.

13. In line with the drafting history of article 27, paragraph 2, of the Universal Declaration of Human Rights and article 15, paragraph 1 (c), of the Covenant, the Committee considers that “moral interests” in article 15, paragraph 1 (c), include the right of authors to be recognized as

the creators of their scientific, literary and artistic productions and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, such productions, which would be prejudicial to their honour and reputation.¹⁴

14. The Committee stresses the importance of recognizing the value of scientific, literary and artistic productions as expressions of the personality of their creator, and notes that protection of moral interests can be found, although to a varying extent, in most States, regardless of the legal system in force.

“Material interests”

15. The protection of “material interests” of authors in article 15, paragraph 1 (c), reflects the close linkage of this provision with the right to own property, as recognized in article 17 of the Universal Declaration of Human Rights and in regional human rights instruments, as well as with the right of any worker to adequate remuneration (art. 7 (a)). Unlike other human rights, the material interests of authors are not directly linked to the personality of the creator, but contribute to the enjoyment of the right to an adequate standard of living (art. 11, para. 1).

16. The term of protection of material interests under article 15, paragraph 1 (c), need not extend over the entire lifespan of an author. Rather, the purpose of enabling authors to enjoy an adequate standard of living can also be achieved through one-time payments or by vesting an author, for a limited period of time, with the exclusive right to exploit his scientific, literary or artistic production.

“Resulting”

17. The word “resulting” stresses that authors only benefit from the protection of such moral and material interests which are directly generated by their scientific, literary or artistic productions.

Conditions for States parties’ compliance with article 15, paragraph 1 (c)

18. The right to the protection of the moral and material interests of authors contains the following essential and interrelated elements, the precise application of which will depend on the economic, social and cultural conditions prevailing in a particular State party:

(a) *Availability*. Adequate legislation and regulations, as well as effective administrative, judicial or other appropriate remedies, for the protection of the moral and material interests of authors must be available within the jurisdiction of the States parties;

(b) *Accessibility*. Administrative, judicial or other appropriate remedies for the protection of the moral and material interests resulting from scientific, literary or artistic productions must be accessible to all authors. Accessibility has four overlapping dimensions:

(i) **Physical accessibility**: national courts and agencies responsible for the protection of the moral and material interests resulting from the scientific, literary or artistic productions of authors must be at the disposal of all segments of society, including authors with disabilities;

- (ii) Economic accessibility (affordability): access to such remedies must be affordable for all, including disadvantaged and marginalized groups. For example, where a State party decides to meet the requirements of article 15, paragraph 1 (c), through traditional forms of intellectual property protection, related administrative and legal costs must be based on the principle of equity, ensuring that these remedies are affordable for all;
- (iii) Accessibility of information: accessibility includes the right to seek, receive and impart information on the structure and functioning of the legal or policy regime to protect the moral and material interests of authors resulting from their scientific, literary and artistic productions, including information on relevant legislation and procedures. Such information should be understandable to everyone and should be published also in the languages of linguistic minorities and indigenous peoples;

(c) *Quality of protection.* Procedures for the protection of the moral and material interests of authors should be administered competently and expeditiously by judges and other relevant authorities.

Special topics of broad application

Non-discrimination and equal treatment

19. Article 2, paragraph 2, and article 3 of the Covenant prohibit any discrimination in the access to an effective protection of the moral and material interests of authors, including administrative, judicial and other remedies, on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right as recognized in article 15, paragraph 1 (c).¹⁵

20. The Committee stresses that the elimination of discrimination to ensure equal access to an effective protection of the moral and material interests of authors can often be achieved with limited resources through the adoption or amendment or abrogation of legislation or through the dissemination of information. The Committee recalls general comment No. 3 (1990) on the nature of States parties' obligations, paragraph 12, which states that even in times of severe resource constraints, the disadvantaged and marginalized individuals and groups of society must be protected by the adoption of relatively low-cost targeted programmes.

21. The adoption of temporary special measures taken for the sole purpose of securing de facto equality for disadvantaged or marginalized individuals or groups, as well as those subjected to discrimination is not a violation of the right to benefit from the protection of the moral and material interests of the author, provided that such measures do not perpetuate unequal or separate protection standards for different individuals or groups and are discontinued once the objectives for which they were adopted are achieved.

Limitations

22. The right to the protection of the moral and material interests resulting from one's scientific, literary and artistic productions is subject to limitations and must be balanced with the other rights recognized in the Covenant.¹⁶ However, limitations on the rights protected under article 15, paragraph 1 (c), must be determined by law in a manner compatible with the nature of these rights, must pursue a legitimate aim, and must be strictly necessary for the promotion of the general welfare in a democratic society, in accordance with article 4 of the Covenant.

23. Limitations must therefore be proportionate, meaning that the least restrictive measures must be adopted when several types of limitations may be imposed. Limitations must be compatible with the very nature of the rights protected in article 15, paragraph 1 (c), which lies in the protection of the personal link between the author and his/her creation and of the means which are necessary to enable authors to enjoy an adequate standard of living.

24. The imposition of limitations may, under certain circumstances, require compensatory measures, such as payment of adequate compensation¹⁷ for the use of scientific, literary or artistic productions in the public interest.

III. STATES PARTIES' OBLIGATIONS

General legal obligations

25. While the Covenant provides for progressive realization and acknowledges constraints based on limits of available resources (art. 2, para. 1), it also imposes on States parties various obligations that are of an immediate effect, including core obligations. Steps taken to fulfil obligations must be deliberate, concrete and targeted towards the full realization of the right of everyone to benefit from the protection of the moral and material benefits resulting from any scientific, literary or artistic production of which he or she is the author.¹⁸

26. The progressive realization of that right over a period of time means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 15, paragraph 1 (c).¹⁹

27. As in the case of all other rights contained in the Covenant, there is a strong presumption that retrogressive measures taken in relation to the right to the protection of the moral and material interests of authors are not permissible. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after careful consideration of all alternatives and that they are duly justified in the light of the totality of the rights recognized in the Covenant.²⁰

28. The right of everyone to benefit from the protection of the moral and material benefits resulting from any scientific, literary or artistic production of which he or she is the author, like all human rights, imposes three types or levels of obligations on States parties: the obligations to *respect*, *protect* and *fulfil*. The obligation to *respect* requires States parties to refrain from interfering directly or indirectly with the enjoyment of the right to benefit from the protection of the moral and material interests of the author. The obligation to *protect* requires States parties to

take measures that prevent third parties from interfering with the moral and material interests of authors. Finally, the obligation to *fulfil* requires States parties to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of article 15, paragraph 1 (c).²¹

29. The full realization of article 15, paragraph 1 (c), requires measures necessary for the conservation, development and diffusion of science and culture. This follows from article 15, paragraph 2, of the Covenant, which defines obligations that apply to each aspect of the rights recognized in article 15, paragraph 1, including the right of authors to benefit from the protection of their moral and material interests.

Specific legal obligations

30. States parties are under an obligation to *respect* the human right to benefit from the protection of the moral and material interests of authors by, inter alia, abstaining from infringing the right of authors to be recognized as the creators of their scientific, literary or artistic productions and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, their productions that would be prejudicial to their honour or reputation. States parties must abstain from unjustifiably interfering with the material interests of authors, which are necessary to enable those authors to enjoy an adequate standard of living.

31. Obligations to *protect* include the duty of States parties to ensure the effective protection of the moral and material interests of authors against infringement by third parties. In particular, States parties must prevent third parties from infringing the right of authors to claim authorship of their scientific, literary or artistic productions, and from distorting, mutilating or otherwise modifying, or taking any derogatory action in relation to such productions in a manner that would be prejudicial to the author's honour or reputation. Similarly, States parties are obliged to prevent third parties from infringing the material interests of authors resulting from their productions. To that effect, States parties must prevent the unauthorized use of scientific, literary and artistic productions that are easily accessible or reproducible through modern communication and reproduction technologies, e.g. by establishing systems of collective administration of authors' rights or by adopting legislation requiring users to inform authors of any use made of their productions and to remunerate them adequately. States parties must ensure that third parties adequately compensate authors for any unreasonable prejudice suffered as a consequence of the unauthorized use of their productions.

32. With regard to the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of indigenous peoples, States parties should adopt measures to ensure the effective protection of the interests of indigenous peoples relating to their productions, which are often expressions of their cultural heritage and traditional knowledge. In adopting measures to protect scientific, literary and artistic productions of indigenous peoples, States parties should take into account their preferences. Such protection might include the adoption of measures to recognize, register and protect the individual or collective authorship of indigenous peoples under national intellectual property rights regimes and should prevent the unauthorized use of scientific, literary and artistic productions of indigenous peoples by third parties. In implementing these protection measures, States parties should respect the principle of free, prior and informed consent of the indigenous authors

concerned and the oral or other customary forms of transmission of scientific, literary or artistic production; where appropriate, they should provide for the collective administration by indigenous peoples of the benefits derived from their productions.

33. States parties in which ethnic, religious or linguistic minorities exist are under an obligation to protect the moral and material interests of authors belonging to these minorities through special measures to preserve the distinctive character of minority cultures.²²

34. The obligation to *fulfil* (provide) requires States parties to provide administrative, judicial or other appropriate remedies in order to enable authors to claim the moral and material interests resulting from their scientific, literary or artistic productions and to seek and obtain effective redress in cases of violation of these interests.²³ States parties are also required to *fulfil* (facilitate) the right in article 15, paragraph 1 (c), e.g. by taking financial and other positive measures which facilitate the formation of professional and other associations representing the moral and material interests of authors, including disadvantaged and marginalized authors, in line with article 8, paragraph 1 (a), of the Covenant.²⁴ The obligation to *fulfil* (promote) requires States parties to ensure the right of authors of scientific, literary and artistic productions to take part in the conduct of public affairs and in any significant decision-making processes that have an impact on their rights and legitimate interests, and to consult these individuals or groups or their elected representatives prior to the adoption of any significant decisions affecting their rights under article 15, paragraph 1 (c).²⁵

Related obligations

35. The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions cannot be isolated from the other rights recognized in the Covenant. States parties are therefore obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant. In striking this balance, the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration.²⁶ States parties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to food, health and education, as well as to take part in cultural life and to enjoy the benefits of scientific progress and its applications, or any other right enshrined in the Covenant.²⁷ Ultimately, intellectual property is a social product and has a social function.²⁸ States parties thus have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education. Moreover, States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights.²⁹ States parties should, in particular, consider to what extent the patenting of the human body and its parts would affect their obligations under the Covenant or under other relevant international human rights instruments.³⁰

States parties should also consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions.

International obligations

36. In its general comment No. 3 (1990), the Committee drew attention to the obligation of all States parties to take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realization of the rights recognized in the Covenant. In the spirit of Article 56 of the Charter of the United Nations, as well as the specific provisions of the Covenant (arts. 2, para. 1, 15, para. 44 and 23), States parties should recognize the essential role of international cooperation for the achievement of the rights recognized in the Covenant, including the right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions, and should comply with their commitment to take joint and separate action to that effect. International cultural and scientific cooperation should be carried out in the common interest of all peoples.

37. The Committee recalls that, in accordance with Articles 55 and 56 of the Charter of the United Nations, well-established principles of international law, and the provisions of the Covenant itself, international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States parties and, in particular, of States which are in a position to assist.³¹

38. Bearing in mind the different levels of development of States parties, it is essential that any system for the protection of the moral and material interests resulting from one's scientific, literary and artistic productions facilitates and promotes development cooperation, technology transfer, and scientific and cultural cooperation,³² while at the same time taking due account of the need to preserve biological diversity.³³

Core obligations

39. In general comment No. 3 (1990), the Committee confirmed that States parties have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights enunciated in the Covenant. In conformity with other human rights instruments, as well as international agreements on the protection of the moral and material interests resulting from one's scientific, literary or artistic productions, the Committee considers that article 15, paragraph 1 (c), of the Covenant entails at least the following core obligations, which are of immediate effect:

(a) To take legislative and other necessary steps to ensure the effective protection of the moral and material interests of authors;

(b) To protect the rights of authors to be recognized as the creators of their scientific, literary and artistic productions and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, their productions that would be prejudicial to their honour or reputation;

(c) To respect and protect the basic material interests of authors resulting from their scientific, literary or artistic productions, which are necessary to enable those authors to enjoy an adequate standard of living;

(d) To ensure equal access, particularly for authors belonging to disadvantaged and marginalized groups, to administrative, judicial or other appropriate remedies enabling authors to seek and obtain redress in case their moral and material interests have been infringed;

(e) To strike an adequate balance between the effective protection of the moral and material interests of authors and States parties' obligations in relation to the rights to food, health and education, as well as the rights to take part in cultural life and to enjoy the benefits of scientific progress and its applications, or any other right recognized in the Covenant.

40. The Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide "international assistance and cooperation, especially economic and technical", which enable developing countries to fulfil their obligations indicated in paragraph 36 above.

IV. VIOLATIONS

41. In determining which actions or omissions by States parties amount to a violation of the right to the protection of the moral and material interests of authors, it is important to distinguish the inability from the unwillingness of a State party to comply with its obligations under article 15, paragraph 1 (c). This follows from article 2, paragraph 1, of the Covenant, which obliges each State party to take the necessary steps to the maximum of its available resources. A State which is unwilling to use the maximum of its available resources for the realization of the right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions is in violation of its obligations under article 15, paragraph 1 (c). If resource constraints render it impossible for a State to comply fully with its obligations under the Covenant, it has the burden of justifying that every effort has been made to use all available resources at its disposal to satisfy, as a matter of priority, the core obligations outlined above.

42. Violations of the right to benefit from the protection of the moral and material interests of authors can occur through the direct action of States parties or of other entities insufficiently regulated by States parties. The adoption of any retrogressive measures incompatible with the core obligations under article 15, paragraph 1 (c), outlined in paragraph 39 above, constitutes a violation of that right. Violations through acts of commission include the formal repeal or unjustifiable suspension of legislation protecting the moral and material interests resulting from one's scientific, literary and artistic productions.

43. Violations of article 15, paragraph 1 (c), can also occur through the omission or failure of States parties to take necessary measures to comply with its legal obligations under that provision. Violations through omission include the failure to take appropriate steps towards the full realization of the right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary or artistic productions and the failure to enforce relevant laws or to provide administrative, judicial or other appropriate remedies enabling authors to assert their rights under article 15, paragraph 1 (c).

Violations of the obligation to respect

44. Violations of the obligation to *respect* include State actions, policies or laws which have the effect of infringing the right of authors to be recognized as the creators of their scientific, literary and artistic productions and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, their productions that would be prejudicial to their honour or reputation; unjustifiably interfering with the material interests of authors, which are necessary to enable those authors to enjoy an adequate standard of living; denying authors access to administrative, judicial or other appropriate remedies to seek redress in case their moral and material interests have been violated; and discriminating against individual authors in relation to the protection of their moral and material interests.

Violations of the obligation to protect

45. Violations of the obligation to *protect* follow from the failure of a State to take all necessary measures to safeguard authors within their jurisdiction from infringements of their moral and material interests by third parties. This category includes such omissions as the failure to enact and/or enforce legislation prohibiting any use of scientific, literary or artistic productions that is incompatible with the right of authors to be recognized as the creator of their productions or that distorts, mutilates or otherwise modifies, or is derogatory towards, such productions in a manner that would be prejudicial to their honour or reputation or that unjustifiably interferes with those material interests that are necessary to enable authors to enjoy an adequate standard of living; and the failure to ensure that third parties adequately compensate authors, including indigenous authors, for any unreasonable prejudice suffered as a consequence of the unauthorized use of their scientific, literary and artistic productions.

Violations of the obligation to fulfil

46. Violations of the obligation to *fulfil* occur when States parties fail to take all necessary steps within their available resources to promote the realization of the right to benefit from the protection of the moral and material interests resulting from one's scientific, literary or artistic productions. Examples include the failure to provide administrative, judicial or other appropriate remedies enabling authors, especially those belonging to disadvantaged and marginalized groups, to seek and obtain redress in case their moral and material interests have been infringed, or the failure to provide adequate opportunities for the active and informed participation of authors and groups of authors in any decision-making process that has an impact on their right to benefit from the protection of the moral and material interests resulting from their scientific, literary or artistic productions.

V. IMPLEMENTATION AT THE NATIONAL LEVEL

National legislation

47. The most appropriate measures to implement the right to the protection of the moral and material interests of the author will vary significantly from one State to another. Every State has a considerable margin of discretion in assessing which measures are most suitable to meet its specific needs and circumstances. The Covenant, however, clearly imposes a duty on each State

to take whatever steps are necessary to ensure that everyone has equal access to effective mechanisms for the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author.

48. National laws and regulations for the protection of the moral and material interests of the author should be based on the principles of accountability, transparency and independence of the judiciary, since these principles are essential to the effective implementation of all human rights, including article 15, paragraph 1 (c). In order to create a favourable climate for the realization of that right, States parties should take appropriate steps to ensure that the private business sector and civil society are aware of, and consider the effects on the enjoyment of other human rights of the right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions. In monitoring progress towards the realization of article 15, paragraph 1 (c), States parties should identify the factors and difficulties affecting implementation of their obligations.

Indicators and benchmarks

49. States parties should identify appropriate indicators and benchmarks designed to monitor, at the national and international levels, States parties' obligations under article 15, paragraph 1 (c). States parties may obtain guidance on appropriate indicators, which should address different aspects of the right to the protection of the moral and material interests of the author, from the World Intellectual Property Organization (WIPO), the United Nations Educational, Scientific and Cultural Organization (UNESCO) and other specialized agencies and programmes within the United Nations system that are concerned with the protection of scientific, literary and artistic productions. Such indicators must be disaggregated on the basis of the prohibited grounds of discrimination, and cover a specified time frame.

50. Having identified appropriate indicators in relation to article 15, paragraph 1 (c), States parties are invited to set appropriate national benchmarks in relation to each indicator. During the periodic reporting procedure, the Committee will engage in a process of scoping with the State party. Scoping involves the joint consideration by the State party and the Committee of the indicators and national benchmarks, which will then provide the targets to be achieved by the State party during the next reporting cycle. During that period, the State party will use these national benchmarks to monitor its implementation of article 15, paragraph 1 (c). Thereafter, in the subsequent reporting process, the State party and the Committee will consider whether or not the benchmarks have been achieved, and any difficulties that may have been encountered.

Remedies and accountability

51. The human right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author should be adjudicated by competent judicial and administrative bodies. Indeed, effective protection of the moral and material interests of authors resulting from their scientific, literary and artistic productions would be hardly conceivable without the possibility of availing oneself of administrative, judicial or other appropriate remedies.³⁴

52. All authors who are victims of a violation of the protected moral and material interests resulting from their scientific, literary or artistic productions should, consequently, have access to effective administrative, judicial or other appropriate remedies at the national level. Such remedies should not be unreasonably complicated or costly, or entail unreasonable time limits or unwarranted delays.³⁵ Parties to legal proceedings should have the right to have these proceedings reviewed by a judicial or other competent authority.³⁶

53. All victims of violations of the rights protected under article 15, paragraph 1 (c), should be entitled to adequate compensation or satisfaction.

54. National ombudsmen, human rights commissions, where they exist, and professional associations of authors or similar institutions should address violations of article 15, paragraph 1 (c).

VI. OBLIGATIONS OF ACTORS OTHER THAN STATES PARTIES

55. While only States parties to the Covenant are held accountable for compliance with its provisions, they are nevertheless urged to consider regulating the responsibility resting on the private business sector, private research institutions and other non-State actors to respect the rights recognized in article 15, paragraph 1 (c), of the Covenant.

56. The Committee notes that, as members of international organizations such as WIPO, UNESCO, the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), and the World Trade Organization (WTO), States parties have an obligation to take whatever measures they can to ensure that the policies and decisions of those organizations are in conformity with their obligations under the Covenant, in particular the obligations contained in articles 2, paragraph 1, 15, paragraph 4, 22 and 23 concerning international assistance and cooperation.³⁷

57. United Nations organs, as well as specialized agencies, should, within their fields of competence and in accordance with articles 22 and 23 of the Covenant, take international measures likely to contribute to the effective implementation of article 15, paragraph 1 (c). In particular, WIPO, UNESCO, FAO, WHO and other relevant agencies, organs and mechanisms of the United Nations are called upon to intensify their efforts to take into account human rights principles and obligations in their work concerning the protection of the moral and material benefits resulting from one's scientific, literary and artistic productions, in cooperation with the Office of the High Commissioner for Human Rights.

Notes

¹ Relevant international instruments include, inter alia, the Paris Convention for the Protection of Industrial Property, as last revised in 1967; the Berne Convention for the Protection of Literary and Artistic Works, as last revised in 1979; the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention); the WIPO Copyright Treaty; the WIPO Performances and Phonograms Treaty (which, inter alia, provides international protection for performers of "expressions of folklore"),

the Convention on Biological Diversity; the Universal Copyright Convention, as last revised in 1971; and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) of WTO.

² See article 17 of the Universal Declaration of Human Rights; article 5 (d) (v) of the International Convention on the Elimination of All Forms of Racial Discrimination; article 1 of Protocol No. 1 to the Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights); article 21 of the American Convention on Human Rights; and article 4 of the African Charter on Human and Peoples' Rights (Banjul Charter).

³ See article 19 of the Universal Declaration of Human Rights; article 19, paragraph 2, of the International Covenant on Civil and Political Rights; article 5 of the European Convention on Human Rights; article 13 of the American Declaration on Human Rights and article 9 of the African Charter on Human and Peoples' Rights.

⁴ See article 26, paragraph 2, of the Universal Declaration of Human Rights. See also article 13, paragraph 1, of the Covenant.

⁵ See article 5 (e) (vi) of the Convention on the Elimination of All Forms of Racial Discrimination; article 14 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) and article 17, paragraph 2, of the African Charter on Human and Peoples' Rights.

⁶ See article 27 of the International Covenant on Civil and Political Rights; article 13 (c) of the Convention on the Elimination of all Forms of Discrimination against Women; article 31 of the Convention on the Rights of the Child and article 31 of the International Convention on the Rights of All Migrant Workers and Members of their Families.

⁷ See also paragraph 32 below.

⁸ See Maria Green, International Anti-Poverty Law Centre, "Drafting history of article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights", E/C.12/2000/15, paragraph 45.

⁹ Committee on Economic, Social and Cultural Rights, twenty-seventh session (2001), "Human Rights and Intellectual Property", Statement by the Committee on Economic, Social and Cultural Rights, 29 November 2001, E/C.12/2001/15, at paragraph 6.

¹⁰ See also paragraph 32 below.

¹¹ See article 5, paragraph 2 of the Covenant.

¹² See below, at paragraphs 22, 23 and 35. See also articles 4 and 5 of the Covenant.

¹³ Commission on Human Rights, second session, Report of the Working Group on the Declaration on Human Rights, E/CN.4/57, 10 December 1947, page 15.

¹⁴ See article 6 bis of the Berne Convention for the Protection of Literary and Artistic Works.

¹⁵ This prohibition, to some extent, duplicates the national treatment provisions contained in international conventions for the protection of intellectual property, the main difference being that articles 2, paragraph 2 and 3 of the Covenant apply not only to foreigners but also to a State party's own nationals (see articles 6 to 15 of the Covenant: "everyone"). See also Committee on Economic, Social and Cultural Rights, thirty-fourth session, general comment No. 16 (2005) on the equal right of men and women to the enjoyment of all economic, social and cultural rights, 13 May 2005.

¹⁶ See paragraph 35 below. The need to strike an adequate balance between article 15, paragraph 1 (c), and other rights under the Covenant applies, in particular, to the rights to take part in cultural life (art. 15, para. 1 (a)) and to enjoy the benefits of scientific progress and its applications (art. 15, para. 1 (b)), as well as the rights to food (art. 11), health (art. 12) and education (art. 13).

¹⁷ See article 17, paragraph 2, of the Universal Declaration of Human Rights; article 21, paragraph 2, of the American Convention on Human Rights and article 1 of Protocol No. 1 to the Convention for the Protection of Human Rights and Fundamental Freedoms.

¹⁸ See general comment No. 3 (1990), at paragraph 9; general comment No. 13 (1999) on the right to education, at paragraph 43 and general comment No. 14 (2000) on the right to the highest attainable standard of health, at paragraph 30. See also the Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights (Limburg Principles), at paragraphs 16 and 22, Maastricht, 2-6 June 1986.

¹⁹ See general comment No. 3 (1990), paragraph 9; general comment No. 13 (1999), paragraph 44; general comment No. 14 (2000), paragraph 31. See also Limburg Principles, paragraph 21.

²⁰ See general comment No. 3 (1990), at paragraph 9; general comment No. 13 (1999), at paragraph 45 and general comment No. 14 (2000), at paragraph 32.

²¹ See general comment No. 13 (1999), at paragraphs 46 and 47, and general comment No. 14 (2000), at paragraph 33. See also Maastricht Guidelines on Violations of Economic, Social and Cultural Rights (Maastricht Guidelines), paragraph 6, Maastricht, 22-26 January 1997.

²² See article 15, paragraph 1 (c), of the Covenant, read in conjunction with article 27 of the International Covenant on Civil and Political Rights. See also UNESCO, General Conference, nineteenth session, Recommendation on Participation by the People at Large in Cultural Life and Their Contribution to It, adopted on 26 November 1976, at paragraph I (2) (f).

- ²³ See Committee on Economic, Social and Cultural Rights, nineteenth session, general comment No. 9 (1998) on the domestic application of the Covenant, at paragraph 9. See also article 8 of the Universal Declaration of Human Rights and article 2, paragraph 3, of the International Covenant on Civil and Political Rights.
- ²⁴ See also article 22, paragraph 1, of the International Covenant on Civil and Political Rights.
- ²⁵ See Committee on Economic, Social and Cultural Rights, twenty-seventh session (2001), “Human Rights and Intellectual Property”, Statement by the Committee on Economic, Social and Cultural Rights, 29 November 2001, E/C.12/2001/15, at paragraph 9.
- ²⁶ Ibid., at paragraph 17.
- ²⁷ Ibid., at paragraph 12.
- ²⁸ Ibid., at paragraph 4.
- ²⁹ Cf. article 27, paragraph 2, of the WTO TRIPS Agreement.
- ³⁰ See article 4 of the UNESCO Universal Declaration on the Human Genome and Human Rights, although this instrument is not as such legally binding.
- ³¹ Committee on Economic, Social and Cultural Rights, fifth session, general comment No. 3 (1990), at paragraph 14.
- ³² Committee on Economic, Social and Cultural Rights, twenty-seventh session, Human Rights and Intellectual Property, Statement by the Committee on Economic, Social and Cultural Rights, 29 November 2001, E/C.12/2001/15, at paragraph 15.
- ³³ See article 8 (j) of the Convention on Biological Diversity. See also Sub-Commission on the Promotion and Protection of Human Rights, 26th meeting, Resolution 2001/21, E/CN.4/Sub.2/Res/2001/21.
- ³⁴ Cf. Universal Declaration of Human Rights, article 8; general comment No. 9 (1998), at paragraphs 3 and 9; Limburg Principles, at paragraph 19; Maastricht Guidelines, at paragraph 22.
- ³⁵ See general comment No. 9 (1998), at paragraph 9 (with regard to administrative remedies). See further article 14 (1) of the International Covenant on Civil and Political Rights.
- ³⁶ See general comment No. 9, at paragraph 9.
- ³⁷ Cf. Committee on Economic, Social and Cultural Rights, eighteenth session, Globalization and Economic, Social and Cultural Rights, Statement by the Committee on Economic, Social and Cultural Rights, 11 May 1998, at paragraph 5.



WTO OMC

FACT SHEET

September 2006

TRIPS and pharmaceutical patents

CONTENTS

Philosophy: TRIPS attempts to strike a balance	1
What is the basic patent right?	2
A patent is not a permit to put a product on the market	2
Under TRIPS, what are member governments' obligations on pharmaceutical patents?	2
IN GENERAL (see also "exceptions")	2
ELIGIBILITY FOR PATENTING	3
RESEARCH EXCEPTION AND "BOLAR" PROVISION	3
ANTI-COMPETITIVE PRACTICES, ETC	4
COMPULSORY LICENSING	4
WHAT ARE THE GROUNDS FOR USING COMPULSORY LICENSING?	4
PARALLEL IMPORTS, GREY IMPORTS AND 'EXHAUSTION' OF RIGHTS	5
THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH	5
IMPORTING UNDER COMPULSORY LICENSING ('PAR.6')	6
What does 'generic' mean?	7
Developing countries' transition periods	7
GENERAL	7
PHARMACEUTICALS AND AGRICULTURAL CHEMICALS	7
For more information	8

Philosophy: TRIPS attempts to strike a balance

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes

The TRIPS Agreement

Article 7 *Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 *Principles*

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.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids “re-inventing the wheel”.
- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory licence. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

What is the basic patent right?

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market

A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

Under TRIPS, what are member governments’ obligations on pharmaceutical patents?

IN GENERAL (see also “exceptions”)

Patenting: WTO members have to provide patent protection for any invention, whether a **product** (such as a medicine) or a **process** (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. *Article 27.1*. Patent protection has to last at least 20 years from the date the patent application was filed.

The TRIPS Agreement

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application⁽⁵⁾. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

- diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

(5) For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

Article 33

Non-discrimination: Members cannot discriminate between **different fields of technology** in their patent regimes. Nor can they discriminate between the **place of invention** and whether products are **imported or locally produced**. *Article 27.1*

Three criteria: To qualify for a patent, an invention has to be new (“novelty”), it must be an “inventive step” (i.e. it must not be obvious) and it must have “industrial applicability” (it must be useful). *Article 27.1*

Disclosure: Details of the invention have to be described in the application and therefore have to be made public. Member governments have to require the patent applicant to disclose details of the invention and they may also require the applicant to reveal the best method for carrying it out. *Article 29.1*

ELIGIBILITY FOR PATENTING

Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health – *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals – *Article 27.3a*
- certain plant and animal inventions – *Article 27.3b*.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not “unreasonably” conflict with the “normal” exploitation of the patent. *Article 30*.

RESEARCH EXCEPTION AND “BOLAR” PROVISION

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval – for example from public health authorities – without the patent owner’s permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the “regulatory exception” or “Bolar” provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled “Canada – Patent Protection for Pharmaceutical Products”)

The TRIPS Agreement

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The TRIPS Agreement

Article 8

Principles

[...]

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

[...]

ANTI-COMPETITIVE PRACTICES, ETC

The TRIPS Agreement says governments can also act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, “unreasonably” restraining trade, or hampering the international transfer of technology. *Articles 8 and 40*

COMPULSORY LICENSING

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field.

The agreement allows compulsory licensing as part of the agreement’s overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term “compulsory licensing” does not appear in the TRIPS Agreement. Instead, the phrase “**other use without authorization of the right holder**” appears in the title of **Article 31**. Compulsory licensing is only part of this since “other use” includes use by governments for their own purposes.

Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

For example: Normally, the person or company applying for a licence must have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms – *Article 31b*. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder – *Article 31h*.

However, for “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial use” (or “government use”) or anti-competitive practices, there is no need to try for a voluntary licence – *Article 31b*.

Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market.

WHAT ARE THE GROUNDS FOR USING COMPULSORY LICENSING?

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices – but only as grounds when some of the normal requirements for compulsory

The TRIPS Agreement

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

[...]

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

[...]

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

[...]

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[...]

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

[...]

licensing do not apply, such as the need to try for a voluntary licence first. *Doha declaration 5(b) and (c)*

PARALLEL IMPORTS, GREY IMPORTS AND 'EXHAUSTION' OF RIGHTS

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

For example, suppose company A has a drug patented in the Republic of Belladonna and the Kingdom of Calamine, which it sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A's price, that would be a parallel or grey import.

The legal principle here is "exhaustion", the idea that once company A has sold a batch of its product (in this case, in Calamine), its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch.

The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies that this means that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives. *Article 6 and Doha declaration 5(d)*

THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

Some governments were unsure of how these TRIPS flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) were among the members pushing for clarification.

A large part of this was settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health – by promoting both access to existing medicines and the creation of new medicines.

They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

On one remaining question, they assigned further work to the TRIPS Council – to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and public health.)

The TRIPS Agreement

Article 6

Exhaustion

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 Doha declaration

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

[...]

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

[...]

IMPORTING UNDER COMPULSORY LICENSING ('PAR.6')

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be “predominantly for the supply of the domestic market”. This applies to countries that can manufacture drugs – it limits the amount they can export when the drug is made under compulsory licence. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members’ shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.

The decision actually contains **three** waivers:

- Exporting countries’ obligations under Article 31(f) are waived – any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.
- Importing countries’ obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.
- 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, developing countries can make use of economies of scale.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as “reasonable measures within their means” and “proportionate to their administrative capacities” are included to prevent the conditions becoming burdensome and impractical for the importing countries.

All WTO member countries are eligible to import under this decision. But 23 developed countries have announced voluntarily that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US.

After they joined the EU in 2004, another 10 countries have been added to the list: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

And 11 more said they would only use the system to import in national emergencies or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

After that, several potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under compulsory licence. At the time of writing (September 2006) Norway, Canada, India and the EU have formally informed the TRIPS Council that they have done so.

The 2003 waivers are interim; the ultimate goal is to amend the TRIPS Agreement itself, and a decision to do this was reached in December 2005, accompanied again by a chairperson’s statement. The amendment – a direct translation of the waivers – enters into force when two thirds of members accept it.

What does 'generic' mean?

Dictionaries tend to define a "generic" as a product — particularly a drug — that does not have a trademark. For example, "paracetamol" is a chemical ingredient that is found in many brandname painkillers and is often sold as a (generic) medicine in its own right, without a brandname. This is "generic from a trademark point of view".

Sometimes "generic" is also used to mean copies of patented drugs or drugs whose patents have expired — "generic from a patent point of view". This is not necessarily different since patented drugs are almost always sold under a brandname or trademark. When copies of patent drugs are made by other manufactures, they are either sold under the name of the chemical ingredient (making them clearly generic), or under another brandname (which means they are still generics from the point of view of patents).

Whether a drug is generic is one question. Whether it infringes intellectual property rights and is pirated or counterfeit is a separate question. Generic copies are legal from the patent point of view when they are made after the patent has expired or under voluntary or compulsory licence — but pirated and counterfeit products are by definition illegal.

Developing countries' transition periods

GENERAL

Developing countries and economies in transition from central planning did not have to apply most provisions of the TRIPS Agreement until 1 January 2000. The provisions they did have to apply deal with non-discrimination. *Article 65.2 and 65.3*

Least-developed countries were given until 1 January 2006. *Article 66.1*. On 30 November 2005, members agreed to extend the deadline to 1 July 2013, or to the date a country is no longer "least-developed", if that is earlier.

For pharmaceutical patents this is extended to 2016 under the Doha Declaration on TRIPS and Public Health.

Most **new members** who joined after the WTO was created in 1995 have agreed to apply the TRIPS Agreement as soon as they joined. *Determined by each new member's terms of accession*

PHARMACEUTICALS AND AGRICULTURAL CHEMICALS

Some developing countries delayed patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005.

This was allowed under provisions that say a developing country that did not provide product patent protection in a particular area of technology

The TRIPS Agreement

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

[...]

when the TRIPS Agreement came into force (on 1 January 1995), has up to 10 years to introduce the protection. *Article 65.4*

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations.

They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period – *Article 70.8*. This is sometimes called the “**mailbox**” provision (a metaphorical “mailbox” is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty (“newness”).

And if the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it had to – subject to certain conditions – provide the patent applicant an **exclusive marketing right** for the product for five years, or until a decision on a product patent was taken, whichever was shorter. *Article 70.9*

Which countries used the extra transition period under Article 65.4, wholly or partially? The answer is not entirely straightforward. Thirteen WTO members – Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay – notified “mailbox” systems to the TRIPS Council, indicating that at the time they did not grant patent protection to pharmaceutical products. It is possible that a few other members should have notified the WTO but did not do so.

The TRIPS Agreement

Article 70

Protection of Existing Subject Matter

[...]

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

For more information

The WTO website's gateway to TRIPS:

http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

TRIPS, pharmaceuticals and public health:

http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

The Doha Declaration on TRIPS and Public Health:

http://www.wto.org/english/tratop_e/trips_e/healthdecexpln_e.htm

The 30 August 2003 decision on importing and exporting under compulsory licence:

http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

*WTO NEWS: * SPEECHES ? DG PASCAL LAMY

14 July 2009

Lamy urges multilateral cooperation to advance public health ?in the real world?

Director-General Pascal Lamy, in his address to the WIPO Conference on Intellectual Property and Public Policy Issues on 14 July 2009, said ?the international intellectual property system cannot operate in isolation from broader public policy questions such as how to meet human needs as basic health, food and a clean environment.? He said the objective of the Doha Declaration on the TRIPS Agreement and Public Health ?was and remains cheaper medicines for the poor.? This is what he said:

Strengthening Multilateral Cooperation on IP and Public Health?

Ladies and Gentlemen,

Let me first applaud the timely initiative taken by the World Intellectual Property Organisation (WIPO) to set public health together with the issues of climate change, biodiversity and food security at the heart of its ambitious new program on intellectual property (IP) and global challenges.

This initiative reaffirms that the international IP system cannot operate in isolation from broader public policy questions such as how to meet basic human needs for health, food and a clean environment.

The conference, and the work program that it carries forward, show that IP has moved to the centre of cross-cutting debates that defy traditional boundaries between separate policy domains, and between distinct areas of technical expertise. Coherence, cooperation and practical dialogue within the international system is indispensable, if we are to address these fundamental policy questions in a sustainable manner. At once open minded and thoughtful, it is an initiative that bears the trademark of Director General Francis Gurry.

I?m honoured, also, to share the podium with our colleague Dr Margaret Chan, Director General of WHO. From our past dialogue, I know that Margaret, Francis and I share a strong personal commitment to intensifying the cooperation between our three organizations. Such partnership and goodwill will be crucial for an effective international response to the ever evolving challenges posed for public health, and to ensure the IP system is balance, fair and effective.

However ? and this news may come as a surprise to some of you ? there are limits to what Directors-General can achieve in what are member-driven organisations, even when they join forces in partnership. Margaret?s gifts as a vocal performer have been known to rescue a

difficult meeting, but there is no truth in the rumour that the Three Directors-General will seek to emulate the Three Tenors. But whatever harmony we are able to produce ? however imperfect to the purist's ear ? will be vastly preferable to silence ? or even discord and dissonance ? between our three organizations.

Effective partnership also means we have to recognize that we have complementary roles, different areas of expertise, and distinct mandates ? we will make most progress if we each play to our strengths and recognise the strengths of our partners.

As Margaret Chan just said, we see our work on IP and public health as a way to ensure that each agency contributes its core expertise to a collective effort, and respects the competences of others. We accept that health policy, the IP system, and the framework for legitimate trade relations are inevitably intertwined and must be managed harmoniously.

Infectious diseases certainly do not respect borders, and prey upon our common physiology, blind to political boundaries. Health represents the most compelling case for international cooperation. Interdependence is not a mere policy option; it is quite literally a matter of life and death.

Consider the international dimension of confronting the HIV-AIDS pandemic, the continuing devastation wrought by neglected diseases, suffered mostly by the world's poorest communities, the resurgence of resistant strains of TB, and the current H1N1 flu pandemic. Climate change will likely have a severe impact on disease patterns and on agriculture: so health, food security and adaptation to climate change are fundamentally interlinked. To retreat behind borders ? whether they are national borders, or formal boundaries between our institutions ? is not an option.

For the WTO, this realization came into sharp focus in 2001, when ministers issued the Doha Declaration on the TRIPS Agreement and Public Health. While fundamentally important for the WTO and for the application of the TRIPS Agreement, the Doha Declaration has also helped to shape the framework for multilateral cooperation on IP and public health through the course of this decade.

It has helped governments make use of TRIPS flexibilities and contributed to lower prices for certain medicines, especially first-line ARVs. It has strengthened public understanding of TRIPS as supporting a balanced and flexible framework for IP protection and enforcement that is responsive to the broader policy agenda. And the Declaration stressed the need for TRIPS to be viewed as part of the wider national and international action to address public health-related problems. For health activists, who had been among the WTO's severest critics, it has served as both a landmark and a benchmark.

The Declaration has often been referred to in many Resolutions of the World Health Assembly, including the WHO's Global Strategy and Plan of Action, and in WIPO's Development Agenda. Just last week, ECOSOC

Ministers reaffirmed the Doha Declaration's provisions on flexibilities for protecting public health and promoting access to medicines. The Declaration finds resonance in the human rights and bioethics domains. Taken together, these various instruments form a powerful tool for cooperation, which we are actively pursuing at a practical level with WIPO and WHO, along with other key players such as UNAIDS, UNCTAD, UNDP and UNITAID. We need to draw on the entire spectrum of expertise and join forces to support our Members to meet their public health needs in a coherent and effective way.

Between 2001 to 2005 the WTO negotiated the first, and still the only, amendment to the package of trade agreements concluded by the Uruguay Round in 1994: the so-called "Paragraph 6 System" to enhance the supply of medicines to countries with limited capacity to manufacture their own medicines. This process was driven by a deep concern that these countries could not use TRIPS flexibilities effectively; that a specific legal obstacle had to be removed.

Now that action has been taken, a debate has continued over whether the solution really works, or whether it continues to throw up obstacles. WTO Members who negotiated this instrument have continued to look closely at its effective functioning in the annual reviews we, in the WTO, have undertaken every year since 2005. Last week's ECOSOC Ministerial Declaration significantly called for "a broad and timely acceptance" of the amendment to TRIPS that would embed this mechanism securely within international law, an important call which we warmly welcome and indeed redouble.

So far, the system has been put into practice once. In part this flows from the limited patent coverage of needed medicines in key exporting countries. This pattern may change in the future as procurement efforts turn towards a new generation of medicines. In any case, the very availability of this mechanism, together with the changing climate among the health community and drug companies, may help drug procurement programs to bargain down prices – just as the prospect of compulsory licensing can be used in general to exert leverage in negotiations on voluntary access to technologies. Voluntary licensing often emerges as an operationally more effective tool in many cases.

The objective was never to issue lots of compulsory licenses as an end in itself. The objective was and remains cheaper medicines for the poor. The system, therefore, has to be judged in terms of prices and access. A simple headcount of notifications under the paragraph 6 system is a poor indicator of public health outcomes.

The paragraph 6 system is one additional flexibility within TRIPS, alongside a number of other health policy safeguards; and TRIPS itself in turn forms just one element of wider national and international action to ensure enhanced access to medicines.

That said, we should not have a blind faith in the system's success. That is why it is subject to an annual review by WTO members. But it may be important, also, to consider how procurement programs can make more effective use of the system as it stands. It creates a legal avenue for

access, but that does not itself generate a commercially viable level of demand.

Indeed, the system explicitly recognizes the need to create economies of scale for procurement initiatives in regions with a significant proportion of least-developed countries (LDCs). The system is open more generally to the coordination of import needs and source countries so as to ensure the necessary economies of scale. We also need to assess the operation of this system against a stronger empirical base ? put simply, where are relevant patents in force, and where are they not?

These deceptively simple questions can be hard to answer with confidence. WIPO has made great strides to improve access to and intelligent use of patent information, and to facilitate international cooperation to establish the patent status of key medicines in developing countries. Here again, multilateral cooperation is essential to ensure that this mechanism operates effectively, along with the full range of policy tools, within and beyond the field of IP, to step up the flow of essential medicines to the most needy.

The WTO aims to serve as an active and constructive partner on public health within the multilateral system, and not merely concerning the TRIPS Agreement, given the other areas of interaction between trade and health where the WTO can offer unique expertise.

Since the Doha Declaration was adopted in 2001, we have established much closer cooperation between international organizations with primary competences bearing on IP and public health. Actively promoting and sustaining the carefully negotiated and crucial balance between the development of new medicines and their accessibility has been a shared goal of all partners.

The WTO offers technical input and advice as requested by its international partners, but also runs an active and collaborative program of capacity building with WHO and WIPO as partners, contributing to each other parallel activities.

Our capacity building activities do not advocate policy positions or push for any particular choices. The goal is help policy makers and senior government officials explore the full range of options they have available, so that they can choose for themselves how to exercise those options in practice.

The effective use of the IP system and of TRIPS flexibilities is important, but does not stand alone: IP law and policy must be harnessed with drug procurement policies, pro-competition safeguards, and regulation of drugs for safety and quality. Again, no one international agency has a monopoly on these diverse areas of expertise, and the challenge of ensuring practical access to medicines requires a comprehensive, multidisciplinary effort.

There will always be scope to improve how we work with our international partners. Partnership is hollow if we do not try to learn from each other; cooperation is wasteful of resources if we fail to coordinate on

practical program delivery and the sharing of vital information; and coherence ? which is probably the backbone of how we work with each other ? is impossible if we do not respect and build on each other?s distinct competences and policy settings. Above all, we must heed and respond to the concerns and practical needs of our Members and the communities they serve.

Multilateral cooperation can be an empty gesture if it does not deliver actual, tangible results at the national level ? in short, if it does not advance public health in what a WTO Appellate Body decision termed ?the real world where people live and work and die.?

I thank you for your attention.

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Public Policy Position

COMPULSORY LICENSING

- Merck's profits fund the development of innovative pharmaceuticals and vaccines which meet unmet medical needs. Merck does not expect low income countries to pay prices that incorporate the cost of product development (especially for HIV therapies); middle-income countries should support technological innovation by paying higher prices than the poorest countries.
- Merck respects that international trade agreements, especially the World Trade Organization's TRIPs agreement (trade-related aspects of intellectual property rights) and subsequent Declaration on TRIPs and Public Health agreements, provide countries with the authority, in limited circumstances, to use compulsory licensing. In the case of medicines, we further respect that compulsory licenses may be issued, under limited and specified circumstances, to meet a health crisis or emergency.
- However, both the letter and spirit of international trade rules suggest that such authority should be used only in the most extraordinary and limited circumstances in order to foster a global environment that supports all forms of innovation. Merck will work vigorously in the interests of meeting health needs to discourage the compulsory licensing of Merck medicines.
- In the case of medicines, global diseases such as HIV/AIDS present challenges for all involved, including pharmaceutical companies, to observe and respect intellectual property rights in a manner that supports prevention and treatment of disease as well as creates incentives for research into new medicines and vaccines.
- Merck understands that access to medicines is a particularly complex issue in the world's least developed countries, and to ensure that patents are not singled out as a cause for lack of access, Merck does not file for patents for its products in those countries.
- Merck can offer a range of value-added services, such as training healthcare workers, as appropriate, and technology transfer and manufacturing, as long as recipients share Merck's commitment to the highest standards of quality. Developing countries will benefit from such value because our investments generate far-reaching public health and economic benefits. For example, current methods for screening and treatment of AIDS patients can reduce the risk of the development of drug-resistant strains of the disease.
- The price of medicine is not the only barrier to treatment in the developing world. A crippling lack of healthcare workers, poor healthcare delivery systems, a brain drain, and other factors also impede access to care.
- Adopting strong intellectual property protections is an important condition for foreign direct investment in developing countries. Minimizing the use of compulsory licenses will promote economic growth for middle income countries and enhance these countries' ability to nurture the technological and commercial capabilities that are essential for the development of a high-value, knowledge-intensive life sciences sector.

Merck and Schering-Plough are now one company. We are working to update our public policy position statements to reflect our new global organization.

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