



# BOLLETTINO

SALA STAMPA DELLA SANTA SEDE

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## NOTA DELLA SANTA SEDE AL CONSIGLIO PER GLI ASPETTI DEL DIRITTO DELLA PROPRIETÀ INTELLETTUALE RELATIVI AL COMMERCIO (ADPIC/TRIPS) DELL'ORGANIZZAZIONE MONDIALE DEL COMMERCIO (OMC/WTO)

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Dal 18 al 22 giugno si è riunito a Ginevra il Consiglio per gli aspetti della Proprietà Intellettuale relativi al Commercio ADPIC/TRIPS (*Trade-Related Aspects of Intellectual Property Rights*) dell'Organizzazione Mondiale del Commercio (OMC/WTO). I lavori di mercoledì 20 giugno sono stati interamente dedicati al tema: "Proprietà Intellettuale e accesso ai medicinali essenziali".

Attesa l'importanza che la questione riveste per la lotta contro le malattie nei Paesi in via di sviluppo, la Santa Sede ha presentato una sua Nota, che è stata distribuita a tutti gli Stati Membri, ed illustrata nella plenaria del Consiglio dall'Osservatore Permanente della Santa Sede presso l'OMC/WTO, S.E. Mons. Diarmuid Martin:

### INTELLECTUAL PROPERTY AND ACCESS TO BASIC MEDICINES

1. The AIDS crisis, together with the worrying return and diffusion of older infectious diseases, such as malaria and tuberculosis, constitutes a global disaster of dramatic magnitude. Most poor people suffering from these diseases receive only very inadequate health care. In so many of the poorest countries, lack of basic medicines together with poor health infrastructures, prevents an appropriate response to urgent public health needs. A heavy burden of disease has considerable negative effects on economic development. A reduction in disease, on the other hand, promotes human well-being, with a consequent improvement in the quality of those human resources which are the essential driving force of the what should be the fundamentally pro-development stance of the WTO.

2. The Holy See is aware that the availability of medicines is not the only aspect of access to health. It is, however, an essential aspect. Without access to essential medicine, there is no cure at all! Access to basic medicines depends on a series of factors, such as efficient infrastructure and logistics, informed drug choice and use, adequately controlled production, research and development aimed at specific diseases. Accessible price, however, always remains a determinant factor.

3. The high price of new drugs seems to be determined both by the burden of research and development of the product itself and by the role each medicine plays in the maintenance of a complex research and development structure. It is not possible, however, ethically to justify a rationale of fixing the highest possible prices in order to attract investors and to maintain and strengthen research, while leaving aside consideration of fundamental social factors. To condition the international reaction to any other natural or human-made disaster (such as earthquakes, floods, accidents or terrorism) on the victims being able to pay for the treatment and to contribute to the research and development of new assistance devices, would rightly be considered a crime.

4. The legal protection of Intellectual property, especially through patents, gives to the patentees monopoly rights over the product or process, during the patent life-span. Such a right may indeed allow a patentee to produce and supply the product only when and where it is possible to recover, through pricing policies, the costs of the investments contained in its development, as well as the expected revenues, while disregarding those who cannot afford the product prices. Within an open free trade system, intellectual property rights constitute an exceptional monopoly regime. As an exception within a legal regime, its use must be narrowly interpreted and must take due account of and, where necessary be subordinated to, other important principles. IP legal theory and practice have, in fact, created regimes, such as compulsory licences, to curb social/patent abuses. Compulsory licenses have thus been included in the TRIPS framework, to be used as remedies in situations of national emergency or other circumstances of extreme urgency, provided that such mandatory uses respect the rule of law and preserve some essential rights of the patent owner.

5. It must, of course, be recognized that prices are not the only component contributing to the lack of access to health, and that IP protection is necessary for progress and for the just compensation of researchers and producers. But in order to cope with a world health emergency, IP regimes must be integrated into a broader framework. The unity of humankind and the universality of human rights (among which the right to health) requires that all the economic and political actors involved (international organizations, governments, private foundations, corporations and NGOs) work together, pooling their differentiated responsibility for resolving a global crisis, leaving aside narrow individual or sectorial interest.

6. In the case of medicines, the supply stakeholders (scientific institutions, pharmaceutical companies and the governments of developed countries) should work together to ensure an adequate supply of urgently needed drugs at prices adequate to the cost of living in a particular country, especially LDCs or HIPC countries. They should also be open and flexible in an equitable manner to the granting of voluntary licenses for import, production and distribution of basic drugs. They should not create obstacles to national production of drugs in third countries; they should where possible help them, rather, to develop such production in ways that are consistent with their IP duties. Compulsory licenses and other safeguards, as worded in TRIPS, should however be maintained, because they are a national safeguard against eventual imperfections of the IP enforcement.

7. Full and efficient universal access to basic medicines will most likely require the enactment of an innovative differential pricing system, which can still preserve the incentive for future research and development. Luxury and non essential pharmaceutical products, for example, such as cosmetics, could well share a greater part of the burden of research and development of essential medicines.

8. A broad-based commitment of solidarity is the best way to prevent poor countries from falling into the temptation of weakening the Intellectual Property rights framework.

9. The solution to the problem of access to basic medicines is far beyond the mandate and the means of the Council for TRIPS. It is the common responsibility of many other international organizations as well as national governments, and in an appropriate manner also of the private sector. However, the Council for TRIPS could make a fundamental contribution, by means of an authoritative interpretation of the TRIPS rules,

- consistent with a unified vision of law,

- based on respect for human rights,

- and applying those articles of the WTO treaty that call for a pro-development interpretation of the whole legal body.

10. Such a legal interpretation might affirm

- that any TRIPS clause should not be understood in a way that becomes a practical obstacle to rapid, efficient and universal access to basic medicines, for those who are the victims of the actual dramatic health emergency, and

- that nothing in the TRIPS should prevent countries, including small countries with limited domestic manufacturing ability, from implementing sound health policies.

This would contribute to a broad and not restrictive interpretation of articles 30 and 31, which allow that licensing fees may be fixed in accordance with the real purchasing capacity of the poorest countries, balanced with a system that blocks the re-exports of the licensed products to the original markets.

11. The Holy See, consistent with the traditions of Catholic social thought, underlines that there is a "social mortgage" on all private property, namely, that the reason for the very existence the institution of private property is to ensure that the basic needs of every man and woman are met and sustained. This "social mortgage" on private property must also be applied today to "intellectual property" and to "knowledge" (John Paul II, *Message to the "Jubilee 2000 Debt Campaign" Group*, September 23, 1999). The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty. Hence, whenever there is a conflict between property rights, on the one hand, and fundamental human rights and concerns of the common good, on the other, property rights should be moderated by an appropriate authority, in order to achieve a just balance of rights.

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