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**GLOBAL PUBLIC GOODS, PATENTS
PROTECTION AND THE FIGHT AGAINST
INFECTIOUS DISEASES**

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Introduction

The spread of infectious diseases such as HIV/AIDS, malaria and tuberculosis is having a profound economic and social impact world-wide. These epidemics are hitting with particular strength sub-Saharan Africa and South East Asia, but the rest of the world is not immune from their devastating consequences. As globalization deepens and the international movement of people is facilitated by lower transport costs and promoted by increased economic interdependence –with rising international trade and investment flows–, the risks of a cross-border spread of both known and potentially infectious diseases is on the increase. The SARS outbreak in 2002-03 showed that no country is fully protected from this kind of epidemic. Even an industrialized country like Canada, which has one of the most developed health systems world-wide, experienced problems in controlling the outbreak. As the US National Intelligence Council (2000) warns, the US stands at risk as a result of the uncontrolled spread of infectious diseases in poor countries and failed states. Other developed countries are equally at risk.

Most deaths from infectious diseases are the result of well-known ailments, particularly in developing countries. HIV/AIDS, tuberculosis and malaria are responsible for over 6 million deaths every year. According to Sachs and Carter (2002), 'nearly all of these deaths could be prevented or treated with existing drugs, if the resources and political commitment existed'. In order to understand why there is a lack of political will to tackle this global problem, we need to analyze the incentives faced by the different actors in the international system.

On the one hand, states –especially in the developed world– fail to recognize health as an international public good and are therefore reluctant to substantially increase either the financial or human resources necessary to tackle the problem. Governments in the industrialized world tend to underestimate the potential threat that infectious diseases pose for their societies based on the questionable assumption that they are protected from an outbreak within their borders. Governments in the developing world lack the financial and technical capacity to implement public policies that reduce the impact of existing diseases by preventing their spread and by treating infected citizens. In order to increase financial resources for health in these countries both the rationalization of public spending and greater resources channelled through official development assistance (ODA) are required. The levels of ODA, measured as a percentage of GDP of the donor countries, have been dropping since the end of the Cold War in 1989. This reduction has been particularly significant for countries that suffer most from epidemics –like those in Africa– because major donors divert their resources to regions that have a higher geopolitical and strategic importance. For example, Sachs (2003) has estimated that for every US\$ 1.00 that the US has committed to the Global Fund to fight AIDS, malaria and tuberculosis, it has committed US\$ 350 to the reconstruction of Iraq.

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On the other hand, the international regulatory framework, embodied in the WTO TRIPS accord (Agreement on Trade-Related Aspects of Intellectual Property Rights) signed in 1994, protects patents for pharmaceutical products and makes it difficult for developing countries to import drugs at affordable prices. Although the agreement was partially reformed in August 2003 to facilitate trade in specific drugs to treat patients with infectious diseases in developing countries, there is still a suboptimal supply of medical treatment in the countries that need it most. Of the 42 million people world-wide with HIV/AIDS in 2002 (30 million in Africa and over 7 million in South-East Asia), less than 4 million had access to palliative care or treatment for opportunistic infections. Moreover, less than 4% of people in need of antiretroviral treatment in low- and middle-income countries were receiving the drugs at the end of 2001 (1). The situation is similar as regards tuberculosis, a disease that kills 2 million people every year, with 95% of deaths occurring in developing countries. A highly effective cure for tuberculosis exists and a course of treatment costs as little as 11 euros. However, only a small number of infected people have access to the treatment.

This paper focuses on the global fight against infectious diseases from the perspective of international political economy. It explores the difficulties arising at the international level when trying to supply simultaneously two global public goods: health, on the one hand, and investment in R&D to develop drugs to combat infectious diseases, on the other. This conflict can be solved only through international cooperation. The paper focuses on the negative impact that the international regulatory framework for property rights protection (the TRIPS agreement of the WTO) is having on the eradication of infectious diseases. It shows how narrow economic interest in the developed world have undermined the prospects of access to cheap generic drugs for millions of infected people world-wide. It also assesses the August 2003 TRIPS reform, which constitutes a first promising step towards enhanced international cooperation and health protection in developing countries. However, we argue that a greater effort at the global level, especially by increasing foreign aid to combat infectious diseases, is required in order to minimize the risks of a world-wide spread of epidemics and to take full advantage of the new international legal framework for the protection of property rights.

The paper is organized in five sections. Section II explains why both health and investment in R&D are global public goods and explores the problems faced by the international community for their optimal supply. Section III critically assesses the evolution of the TRIPS agreement and its impact on the fight against infectious diseases. Section IV discusses the role of ODA in improving health conditions in developing countries. Finally, section V reviews the main findings and proposes policy recommendations.

Global Public Goods

The pure theory of public goods, formulated by Samuelson (1954) states that public goods have two key characteristics that make them essentially different from private goods: *nonrivalrousness* and *nonexcludability*. They are non-rival in consumption because there is a zero marginal cost from an additional individual enjoying their benefits and they are not excludable because once they are provided it is impossible to discriminate those consumers that are not contributing monetarily to their supply. Standard examples of public goods include national defence and streetlights. These are goods that fit the definition perfectly, but they are limited geographically to a particular country. In addition, there are a number of goods that are neither purely public goods nor purely private goods, such as club goods or global commons (2).

To develop the notion of a global public good, we need to combine the definition of public good with that of an externality. An externality exists when an individual or firm takes an

action but does not bear all its costs (negative externalities) or all its benefits (positive externalities). This implies that the social cost of an action differs from its private cost because individual actions have a spill-over to the rest of society. For example, if a factory pours pollutants into a river, it is generating a negative externality to society. Conversely, increasing the educational level of women in developing countries has a positive indirect effect on child survival and on controlling population growth. Therefore, as Cornes and Sandler (1996:6) point out, 'pure public goods can be thought of as special cases of externalities'. If we take this idea to the international level, there are a number of goods that clearly have positive effects to everyone in the world.

Global public goods differ from public goods in the sense that their benefits go beyond national borders. They can be defined as goods that are non-excludable, non-rival in consumption and that have significant positive externalities, not only domestically but also internationally.

All public goods suffer from insufficient provision. The theory of collective action and the behaviour of free riders explain why there will be a suboptimal level of global investment in public goods (3). Since private individuals and firms find it difficult to fully enjoy the profits from the supply of public goods, they will have an insufficient incentive to invest in them. The rational action for every individual or for every state in the international system will be to free ride and not to contribute to the supply of a public good, expecting that others will do so. Finally, only a few altruists will contribute, and the provision of the public good will be insufficient to satisfy demand.

For global public goods, achieving an optimal supply is even more difficult than in the case of domestic public goods. Since there is no such thing as a world government, it is impossible to legally enforce their optimal supply. Therefore, international cooperation is required. The realist approach to international relations argues that states living in an anarchic world find it difficult to sustain cooperation over time because they are driven primarily by security concerns. Nevertheless, as Keohane (1984) has shown, it is possible to establish political institutions and international regimes that facilitate cooperation even in the absence of a hegemonic power that imposes it (4). Such regimes reduce the states' incentives to cheat on each other and help to develop trust, dialogue and a set of rules that all players recognize as useful. Obviously, cooperation is more likely to arise in areas where mutual gains are easier to identify, such as in the case of trade or financial stability. As we will see, cooperation in health issues has the potential to be achieved because an efficient supply of health at the global level reduces the long-term losses for the international community as a whole. The emergence of a global scientific community able to indicate to policy-makers the best course of action to reduce the impact of infectious diseases is also an important factor that facilitates cooperation. Finally, we must recognize that globalization is increasing the impact of cross border externalities. Therefore, interstate cooperation has become more necessary than in previous historical periods, both to reduce the rising cost associated with the underprovision of global public goods and to increase the global benefits that the world would enjoy if they were better supplied.

Health and Investment in R&D as Global Public Goods

Stiglitz (1995) has argued that international economic stability, international security (political stability), the international environment, international humanitarian assistance and knowledge are examples of global public goods. Would it be problematic to include health and investment in R&D under this category?

If we distinguish between communicable diseases and non-communicable diseases, it would be reasonable to assume that the control of communicable diseases is a global public good because all the world's citizens would benefit from their eradication.

On the other hand, the treatment of non-communicable diseases and injuries has traditionally been considered a private good because it was assumed that many of these diseases originated in voluntary decisions on lifestyle, such as tobacco consumption, unsafe habits or inadequate diet. However, as Chen *et al.* (1999: 286) point out, 'globalization is blurring the traditional line between public and private health (...) we are witnessing the emergence of an unprecedented wave of health threats –emerging infections, new environmental threats and behavioural pathologies'. First, globalization has increased economic and social interdependence, accelerating the transmission of information and the flows of goods and migrants world-wide, thereby accelerating the cross-border transmission of diseases and generalized lifestyle and cultural habits that have an impact on health. Secondly, globalization is putting more pressure on common-pool natural resources, which generates increasing environmental threats that affect the health of all citizens equally. Thirdly, aging populations in the developed world are increasing health costs associated with the treatment of non-communicable diseases. This is constraining public budgets and thus reducing the resources to invest in the eradication of both existing and new infectious diseases that have a world-wide negative impact. Therefore, as globalization advances, the responsibility for facing the risks associated with global health is becoming global and requires the coordinated action of all nation states.

The eradication of smallpox in 1977, a cooperative effort coordinated by the WHO, shows that if states recognize the global long-term gains of eliminating an infectious disease and work together to reduce collective problems under the supervision of a supranational organism, it is possible to intervene successfully.

Smallpox was an endemic disease in Europe in the eighteenth century. It is estimated that in 1775, 95% of Europeans had contracted the disease and one out of seven died from it. During the nineteenth and twentieth centuries, vaccination reduced smallpox, but the disease was not eradicated and its incidence grew, especially in South Asia. In 1965 the USSR presented to the World Health Assembly a proposal to eradicate smallpox because of the increased risk that the expansion of the disease in its Asian neighbours represented for its own population. The proposal was accepted because the international medical community considered it feasible and smallpox eradication become one of the WHO's main goals. Mass vaccination, extensive training of health services in the most affected countries and a strategy to isolate the disease in order to break the transmission chain led to its complete eradication in 1977. There were two factors that made smallpox eradication possible. First, there was a consensus among the scientific community on the correct course of action that should be undertaken and on its feasibility. Secondly, a cost-benefit analysis indicated that the investment required to eradicate the disease was several times lower than the cost of ongoing vaccination and care of infected persons (5). Therefore, as Cooper (1989:235) argues: 'eradication of smallpox was not only an international public good in terms of the alleviation of suffering, but it also offered a handsome return on investment by reducing precautionary expenditures worldwide'.

This case of smallpox, which has important similarities with other infectious diseases that are still endemic, illustrates that it is possible to reach an international consensus and to successfully implement eradication programmes. We now turn our attention to knowledge and investment in R&D as global public goods and analyze the problems associated with their suboptimal supply levels and the solutions that have been implemented to tackle this problem.

Knowledge has the characteristics of a global public good. When a mathematician discovers a new theorem or when a scientist develops a new vaccine, world knowledge increases because theorems and scientific laws are applicable under any circumstance. Since the results of pure scientific research are usually published in international academic journals, they rapidly become global public goods and can be applied to produce goods and services that are subsequently sold in private markets.

The problem, however, arises because pure scientific research is usually not sufficient to produce goods that can be sold in the marketplace. Companies build on basic research to develop such goods, but they also have to invest in R&D. Therefore, these companies, for example pharmaceutical companies that produce new drugs, face an incentive problem. They will not invest large sums in R&D if they know that they will not be able to extract monopoly profits from designing a new product, as these products can be easily copied by competitors and sold at a lower price.

To avoid this problem, states can either directly finance R&D investment or introduce domestic regulations to protect copyrights and patents. Direct financing is problematic because it is unclear up to which level a government would be able to discriminate between useful and useless R&D projects. Since public resources are limited, in practice, intervention through the regulation of property rights has been considered a better strategy except for the case of fundamental basic research.

Copyrights and patent protection give firms an incentive to invest in R&D to develop new products using the available scientific knowledge. If the expected net present value of the monopoly profits that a firm will earn from a patent outweighs the expected investment costs in R&D, the firm will have an incentive to devote resources to develop the new product. Although the fact that private companies sell their product at a price which is considerably higher than its marginal cost generates inefficiency, this is the most effective mechanism for compensating the risks associated with the uncertain returns for investing in R&D. As Stiglitz (1999a:321) argues, 'the patent system provides an effective self-selection mechanism: those who are convinced that they have a good idea invest their own money (...). Such selection mechanism may not be more effective than, say, government bureaucrats attempting to assess various applications, but the costs of mistakes are borne by those making the misjudgment, not by the public at large'. As a result, states approve and enforce strong regulatory frameworks for the protection of property rights. Patents are protected for an approximate period of ten years, depending on the country. Even though this protection is imperfect and new products can still be replicated by competitors, these legal systems have partially solved the problem of underinvestment in R&D, especially in industrialized countries, where 99% of the technological discoveries take place.

International Patent Protection: The TRIPS Agreement

As we have seen, there is a strong economic case for protecting technological innovations domestically through a patent system. Since high value-added new products tend to be produced in industrialized countries –which are also the countries that have the most advanced and trustworthy legal systems– these are the nations that have designed the most efficient and balanced property rights protection systems. Industrialized countries tend to have a comparative advantage in innovation because they are abundant in high skilled labour and capital, they invest high levels of their GNP in R&D and their markets are better prepared to absorb and test innovations due to their high relative income levels. These innovations include all kinds of products, from computer software to medical drugs to combat communicable and non-communicable diseases. Moreover, these goods tend to be produced by multinational corporations, which are the only firms capable of making substantial investments to develop innovations and to take advantage of economies of

scale and scope. As Raymond Vernon showed in his product cycle theory (1966), products tend to be developed and sold in industrialized countries in a first stage and exported to the rest of the world in a second stage. Finally, once they become commodities and their prices fall, multinational corporations relocate their production in countries where costs are lower.

With globalization and the expansion of world trade, multinational corporations saw Vernon's product cycle accelerate. Some of the products they developed were copied quickly by companies in developing countries, including those that had required high investments in R&D and that were protected by copyrights and patents domestically. Books, compact discs, computer programs, videotapes and textiles from prestigious firms were pirated and sold below cost in many developing countries, especially in China and South East Asia. In the pharmaceutical sector, US multinational companies saw laboratories in India, Brazil and South Africa produce generics of patented drugs without being persecuted. These drugs were later exported to both developed and developing countries and sold at lower prices. Since patent protection was a domestic regulation, they had no way to stop a process that posed a potential threat to their monopolistic profits and that was reducing their incentives to invest in R&D.

The Reagan Administration was afraid that if American companies substantially reduced their R&D investment, the US would be at risk of losing its comparative advantage in developing technological innovations, thereby reducing US economic growth in the long term. Therefore, after negotiations with companies and trade unions, the US Congress approved the Omnibus Trade and Competitiveness Act in 1988. This law authorized the government to impose unilateral trade sanctions (ie, trade retaliation in the form of higher tariffs) to countries that did not make reasonable efforts to enforce US patents and copyrights within their borders.

As part of the Trade Act, the US trade representative would have the task of annually identifying countries applying what the US considered to be 'unfair trade practices' and would list them under 'section super 301,' which was a first step to impose unilateral trade sanctions. Since the US is the most important exporter and importer of goods and services in the world, countries listed under 'section super 301' complained, arguing that American unilateralism was undermining the rule-based multilateral trading system and was being abused as an instrument to raise tariffs indiscriminately (Bhagwati 1991). This uncomfortable situation led the United States to press for the inclusion of property rights protection under international trade law during the Uruguay Round of world trade talks, negotiated from 1986 to 1994 (6).

In January 1995, TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) became one of the pillars of international trade law. The agreement covered copyright and related rights, trademarks (including service marks), geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and undisclosed information, including trade secrets (7). It was agreed that patent protection had to last at least 20 years from the date the patent application was filed. It was also established that the least developed countries would have until 2006 to implement TRIPS and developing countries until 1996. Finally, the TRIPS agreement allowed the violation of patent rights under specific circumstances. First, it authorized 'compulsory licensing,' which takes place when a government allows someone to produce a patented product –for example a drug– without the consent of the patent owner. This practice can be used only if the patent holder receives compensation, if it is done in a non-discriminatory way and if it is used to supply the domestic market (ie, drugs produced violating patents cannot be traded). Secondly, TRIPS allows parallel imports. This practice takes place when a product is sold by a patent holder in two countries at different prices and someone buys the product where it is cheaper and imports it to the country where it is

more expensive without the patent holder's permission. This practice does not solve the problem of lack of pharmaceutical products in countries where there is no local production of patented drugs.

Industrialized countries were assured the TRIPS agreement would be enforced because the Uruguay Round led to the creation of the WTO in 1995, which had the status of an international organization and included a dispute-settlement mechanism responsible for enforcing all WTO agreements. This meant that if a WTO member was found guilty of not protecting international patents within its borders, it was subject to a fine and, more importantly, the country that had brought the case to the dispute settlement mechanism would be allowed to retaliate by raising tariffs.

Developing countries strongly opposed TRIPS. They argued that trade liberalization was about reducing protectionism 'at the border' and not about creating new regulations that had effects 'behind the border' (ie, that 'imposed' changes in their domestic institutional and legal infrastructure). They also argued that they lacked the institutional capacity to implement these kinds of agreements. However, the Uruguay Round was not only about TRIPS. It included a variety of trade agreements that were considered beneficial by most developing countries. First, agriculture and textile liberalization, the two sectors in which most developing countries have a comparative advantage and in which protection in industrialized countries is most pronounced, was negotiated for the first time. Secondly, the creation of the WTO as an international organization was perceived by developing countries as a positive and important institutional development. This perception was based on the idea that they would be able to gain bargaining power vis-à-vis industrialized countries by forming coalitions and progressing in multilateral liberalization instead of being subject to bilateral negotiations with big and rich countries that had more bargaining power. Finally, the creation of the dispute-settlement mechanism within the WTO implied that there would be a supranational 'legal court' to which they could present cases if industrialized countries decided to break trading rules unilaterally. This was particularly important because 'section super 301' was considered an illegal mechanism for imposing trade sanctions because it was unilateral. In addition, the Uruguay Round created a new GATT (General Agreement on Tariffs and Trade) to further reduce tariffs in industrial products and a new agreement to regulate trade in services (GATS) (8).

Finally, it should be pointed out that the Uruguay Round, like the Doha Round that is currently being negotiated, introduced the 'single undertaking' clause, which implied that all WTO agreements had to be signed by all countries. For the first time in multilateral trade negotiations there were no opt-out clauses for specific agreements. Therefore, developing countries accepted TRIPS as part of the negotiating package because they perceived that the other agreements compensated making concessions in the area of property rights and because rejecting TRIPS would have implied losing all the trade concessions in other areas. In addition, several developing countries negotiated transition periods of up to ten years to implement TRIPS because it was clear that it would be virtually impossible for their weak political and institutional regimes to start enforcing property rights domestically overnight.

The TRIPS agreement became effective in 1995. It was clear that it had been the product of interest group pressure from multinational corporations based in rich countries and that its effect was a net transfer of wealth from developing to developed countries caused by the rise in prices for patented products (9). According to Oxfam (2003), quoting a World Bank study, the annual increase in income for the US, Germany, the UK and Japan as a result of the TRIPS agreement represented approximately US\$35 billion, of which almost US\$20 billion would go to the United States (10). However, since developing countries had signed TRIPS, it could be argued that the gains that developing countries had obtained from other WTO agreements had justified concessions in the area of property

rights. After all, the distribution of power in the international system is unequal and cooperation only takes place when there are overlapping national interest that can be exchanged in regional or multilateral forums.

The Perverse Effects of TRIPS: The Global Sanitary Emergency

The most important –and probably unexpected– consequence of the TRIPS agreement was to generate a sanitary emergency in developing countries, especially in Africa and South East Asia. The prohibition of trading generic cheap drugs made it impossible for developing countries to stop the rise in a variety of infectious diseases, especially HIV/AIDS. Thousands of lives were lost as a consequence of the enforcement of property right protection (ie, the protection of profits for pharmaceutical multinationals). This tragic situation generated a global debate on the perverse effects of the TRIPS agreement, which forced its reform in August 2003.

Since the second half of the nineties the HIV/AIDS epidemic expanded rapidly. In 1995 there were approximately 20 million people world-wide living with HIV/AIDS. This figure has doubled in less than a decade. The impact of other infectious diseases also widened during the same period. Between 1995 and 1999 the number of new tuberculosis cases increased by 500,000 in Africa and by 250,000 in South East Asia, and they are expected to rise at a faster pace between 2000 and 2005 (De la Dehesa 2003: 90).

The most important factor behind the rapid spread of HIV/AIDS in developing countries, especially in Africa, was that governments did not recognize the problem soon enough and did not implement appropriate policies to disseminate information and the necessary means among the population to stop contagion. The consequences of the diseases have been devastating. In Botswana, for instance, where approximately 40% of the adult population is HIV positive –the highest prevalence rate in the world– life expectancy has dropped from 65 years in 1990-95 to 40 years in 2003 because of AIDS-related deaths. Since only 1% of infected people in Africa receive medical treatment, there will be approximately 68 million deaths caused by HIV/AIDS in the next 20 years (De la Dehesa 2003:91).

As shown in Table 1, the impact of infectious diseases in developing countries is devastating. AIDS kills over 2.6 million people per year, 80% in Africa. Diarrhoea, a curable diseases caused primarily by lack of access to safe water and by precarious sanitary conditions, is responsible for over 2 million deaths per year. Tuberculosis and malaria are responsible for over 2.6 million deaths per year. These diseases caused over 7.5 million deaths in 2002, which meant that developing countries lost more than 230,000 years of productive life. Estimates conducted by the United Nations show that this reduction in the labour force reduces GDP growth from 2 to 4 percentage points per year (UNAIDS 2003: xii-xv).

Table 1. Diseases, deaths per year and lost productive years (figures in thousands for 2002)

	Total Deaths	Number of Productive Years Lost	Africa	America	South East Asia
Aids	2,673	89,819	2,154	81	360
Diarrhoea	2,089	62,670	–	–	–
Tuberculosis	1,669	33,287	357	59	723
Malaria	1,086	44,998	953	2	69
Total	7,517	230,774	3,464	142	1,152

Source: World Bank, World Development Report 2002.

Moreover, the HIV/AIDS epidemic is likely to increase income inequalities and poverty because the highest prevalence rates are found among the most vulnerable groups, especially women in rural areas and children that either contract the disease or become orphaned (11).

Besides the inaction of the political authorities to tackle the problem when it emerged in the early and mid nineties, the TRIPS agreement had an important impact on the spread of the diseases and on the reduction of potential economic growth in developing countries. HIV/AIDS is not a curable disease. However, an HIV-positive individual does not necessarily develop the disease in the short term. If treated with antiretroviral drugs, the infected individual can live and work for a relatively long period of time. However, these drugs are expensive because they are protected by patents, which means that their price is above their marginal cost of production. In 2000, the annual expenditure required for treating one person with patented drugs was between US\$10,000-US\$12,000 worldwide (UNAIDS 2003: 74). The TRIPS agreement did not allow trading in such drugs if they had been produced violating patents, which meant that countries like India or Brazil, which were capable of producing cheap generics, did not have an incentive to do so because they could be sanctioned by the WTO. UNAIDS has estimated that the annual cost of the treatment had been reduced to US\$350 per person by 2001 and it is likely to drop even more in the short term. Therefore, any cost below this threshold represents extraordinary profits for pharmaceutical companies. Drugs to treat other infectious diseases are also affected by TRIPS. According to Oxfam (2002: 213): 'Indian generic companies market Ciprofloxacin, an important anti-infective drug used in the treatment of Shigella (bloody diarrhoea), at one fifth of the price charged for the brand name equivalent'.

Developing countries were concerned, not only about patent protection for existing drugs, but also because new drugs capable of fighting diseases more effectively –and even vaccines if they were discovered– would be protected by patents. This would have implied that their prices would have skyrocketed, especially after 2006, date after which all transition periods for adopting the TRIPS agreement were supposed to end. The increase in prices for medical treatment has more important effects in developing country households than in industrialized country households for two reasons. First, because poverty levels are higher in developing countries. Secondly –and more importantly– because in developing countries out of pocket payments for drugs represent a higher proportion than in rich countries because the public health systems have less capacity and resources (12).

The sanitary emergency led to a wide recognition by the international community that the TRIPS agreement, as it stood in 2001, was fundamentally incompatible with the promotion of public health at a global scale. Therefore, the Doha Round of trade talks, which started in November 2001, included in paragraph 6 a 'Declaration on the TRIPS agreement and Public Health,' which was signed by all WTO members. The declaration represented a commitment to reform the TRIPS agreement to help poorer countries, unable to make medicines domestically, have access to cheaper generics made under 'compulsory licensing'.

TRIPS Reform and the Way Forward

The reform process has not been easy. It took almost two years to reach an agreement. In late August 2003, only a week before the Cancún meeting took place, a compromise solution was negotiated. If the agreement on TRIPS reform had not been achieved, it was expected that the Cancún meeting would have been a failure –as it actually was, but for differences over agriculture and the so-called 'Singapore issues'– (13). Therefore, there

was great pressure to obtain some kind of deal to remove one of the key obstacles for the Cancún meeting and for the Doha Round (Economist 2003).

Negotiations were difficult from the start. Pharmaceutical companies were concerned that 'compulsory licensing' could be used to produce pirated generic drugs unrelated to the treatment of infectious diseases and that these cheap generics could enter developed markets and drive prices down. Therefore, the US position was inflexible. On the other hand, developing country governments argued that they could offer no guarantee that the drugs would not be diverted into the wrong markets, but that inaction and maintenance of the *status quo* was not acceptable because the sanitary emergency was a growing reality. In June 2002 it was agreed to extend the transition period to implement TRIPS until 2016 for least-developed countries. In December 2002, WTO members approved a waiver to last until the TRIPS agreement was finally amended. This waiver allowed countries that could produce drugs to export them under compulsory licence to countries that could not manufacture them.

Finally, an agreement was reached. From August 30, 2003 developing countries are allowed to choose freely the drugs they need to license compulsory and these drugs will be tradable if they are required for public health purposes, but not in other cases. This means that the provision that stated that compulsory licensing was only allowed to produce for the domestic market is no longer applicable. However, countries importing generic drugs under this formula have to comply with certain requirements. First, they have to notify the WTO of the amounts and prices at which they will be buying the drugs and the exporting country should also notify the WTO that a domestic company will produce a generic to export it to a developing country that is not able to produce it domestically. Secondly, importing countries have to take reasonable measures within their means to prevent the re-export of the products that have actually been imported into their territories. This second requirement is intended to avoid a reduction in the prices of pharmaceutical products that are unrelated to epidemics in the industrialized countries, which are the markets where companies make most of their profits.

The amended TRIPS agreement is clearly more balanced than the original. However, it is still unclear if it will really solve the problem of access to cheap drugs for poor countries. Under the new provisions, developing countries that cannot produce drugs domestically have to ask another country's government to suspend the relevant patent and license a domestic company to produce the drug and export it. Therefore, for the deal to be effective, countries with the capacity to produce generics have to be willing to suspend the patents. Since the US still takes unilateral action against countries that do not protect patents using section 'super 301' of its trade act, it is still unclear which countries will take the risk of becoming a target of US retaliation to promote health in distant developing countries. Moreover, in the negotiations for the Free Trade Area of the Americas (FTAA) – a regional trading bloc that is expected to become effective in 2005– the US is trying to impose property rights protection that goes beyond the original TRIPS agreement in order to protect its pharmaceutical industry (Herranz 2003) (14).

As of November 2003, only Canada –a developed country with excellent trade relations with the US and that suffered the SARS outbreak– has notified the WTO that it is willing to license local companies to produce generic drugs and export them to developing countries. Developing countries like India and Brazil and other industrialized countries capable of producing generics, have not yet notified the WTO that they will do so, which means that in practice the new TRIPS agreement might be difficult to implement. A key issue will be the final price at which drugs will be sold in developing countries and the financial resources that these countries will have to purchase them, which will determine the profit margin for the producing companies. If the margin is high enough, there will be a greater incentive to produce the drugs. However, the financial resources available will

crucially depend on the level of foreign direct assistance that they receive from rich countries. We now turn to this issue.

Beyond Patents: Health Spending and Foreign Development Assistance

Flexibilization of the original TRIPS agreement was a necessary condition for allowing citizens in poor countries to have access to generic drugs. It was also a prerequisite for implementing a global strategy that would eventually eradicate infectious diseases worldwide. However, TRIPS reform is not a sufficient condition for achieving these goals. Countries have to have the resources to buy the medicines and distribute them to the population. Even if drug prices fall as a result of the new TRIPS agreement, which remains to be seen, developing country governments need both greater financial resources and their more effective use. More ODA, implementation of better management systems to track spending and efforts to reduce corruption levels are required. Otherwise, it will be virtually impossible for these countries to control pandemics within their borders and the world will be exposed to the spread of infectious diseases.

ODA levels, measured in constant 1999 US dollars, dropped in real terms from US\$70 billion in 1992 to US\$45 billion in 1999. This means that, even though the economies of developed countries have been growing fast, ODA has dropped by 29% in relative terms and by 50% in absolute terms from 1990 to 2000 (Dehesa 2003: 242). This dramatic reduction has been driven by the relative decrease in the need to influence policies in recipient countries as a result of the end of the Cold War. It also shows a lack of political commitment with the global fight against poverty, which has important implications in the global fight against infectious diseases. Some OECD countries, like the US –which only devotes 0.11% of its GNP to ODA–, have argued that ODA should not be increased because there is no correlation between ODA levels and economic growth. They point out that governments in corrupt developing countries do not allow ODA to reach the sectors that require it the most (health, infrastructure and education), and that aid ends up in private pockets and provides the wrong incentives, making it difficult for developing countries to implement sound development policies. However, in the case of health spending, better management of domestic resources is simply not sufficient to provide adequate sanitation. Even governments with relatively low levels of corruption need foreign assistance.

Moreover, several studies have shown that health spending and economic development are highly correlated. In a study based on a sample of seventy countries, Gupta, Verhoeven and Tiongson (2001) show that health spending has a greater impact (in terms of economic growth) in low-income countries than in middle- and high-income countries. They estimate that an increase in health investment of 1% reduces infant mortality by 2%. When health systems are appropriate, workers are more productive, children are much more likely to finish school and foreign investors are attracted. However, as shown in Table 2, health spending –both public and private– is significantly lower in least-developed and developing countries than in industrialized countries. This means that an increase in health-related ODA is required to stop the spread of infectious diseases.

Table 2. Health expenditure in US\$ per capita

	Public	Total
Least-developed countries	5	10
Developing countries	15	25
Middle-income countries	50	90
Middle/high-income countries	130	240
High-income countries	1.350	1.900

Source: World Bank: World Development Report 2002.

Countries with a GNP below US\$1,200 per capita suffer the most from infectious diseases, child malnutrition and high infant mortality rates. A group of health experts directed by Jeffrey Sachs has estimated that an expenditure of US\$42 per person per year is required to put in place well-functioning health systems in these countries, that would save over 7 million lives per year. The current level of expenditure is below US\$25 per person per year, which means that donors are called to provide US\$27 billion annually by 2007 and US\$38 billion annually by 2015, the target date to achieve the Millenium Development Goals (in 2001 they only spent US\$6 billion per year) (15). This amount represents only 0.1% of the GNP of the donor countries, which in 1970 made the commitment to devote 0.7% of their GNP to overseas development assistance, but are – on average– only devoting around 0.3%. This means that the required increase in health spending to reduce the impact of infectious diseases and infant mortality rates world-wide is perfectly attainable if there is a political commitment to move in the right direction (Sachs *et al*, 2002) (16).

If we focus specifically on HIV/AIDS, the need for ODA is even more crucial. UNAIDS (2002) has estimated that, as of 2001, annual spending on HIV/AIDS in low- and middle-income countries from all sources was US\$1.8 billion, but that annual resource requirements amounted to US\$3.2 billion in 2002 and would rise to US\$9.2 billion by 2005. While the countries involved might be able to provide one-third to one-half of the necessary resources, the remainder will need to be provided by the international community.

Aside from ODA, the most important international initiative to provide financial resources to poor countries that experience health emergencies has been the creation of the Global Fund to fight AIDS, tuberculosis and malaria in 2001. This public-private partnership, established following a proposal by Kofi Annan, has the status of a foundation and its secretariat is located in Geneva. It operates by financing specific projects that recipient countries present to its 23-member Board, which includes donor and recipient governments, non-governmental organizations, corporations, foundations, multilateral partners and affected communities. The projects presented have to be owned by the recipient countries according to the World Bank's Comprehensive Development Framework, which includes country ownership of development strategies as one of its core principles. This ensures that the Global Fund acts as a financing mechanism and not as an implementation agency. The Fund has already been able to mobilize almost US\$5 billion through 2008. Forty countries have provided 98% of this amount and private individuals or foundations the remaining 2%. It has already committed US\$ 1.5 billion in funding to support 154 projects in over ninety countries (Global Fund 2003).

However, the Global Fund needs a substantial increase in resources in order to effectively comply with its mandate. Developed countries, especially the US, EU member states, Canada and Japan should make a greater effort to finance the Global Fund without detracting resources from other development projects. As Sachs (2002) argues: 'There is a way out. To empower the United Nations to do what it can truly do: organize a global response to the global challenges of disease control, hunger, lack of schooling and environmental destruction, an effort in which the United States would be a major participant and indeed financier, in exactly the manner that it has repeatedly pledged'.

Conclusions

It is in the economic long-term best interests of both the developed and the developing world to increase the financial and human capacity to combat the spread of infectious diseases and to design a legal framework for patent protection that ensures that citizens in poor countries have access to drugs at affordable prices. The fight against infectious diseases is a challenging task because it requires finding an appropriate balance between

the provision of two global public goods: health and investment in R&D. This problem can only be solved through interstate cooperation, time-consuming negotiation and the recognition that the spread of infectious diseases is a long-term global problem for all states.

First, the international community has to ensure that poor countries that are unable to produce drugs to combat infectious diseases have access to them through imports. International protection of property rights is important because it provides companies with incentives to invest in R&D, which ultimately drives technological progress. However, this protection cannot prevent citizens of undeveloped countries that suffer from infectious diseases from having access to medicines. As we have seen, the original WTO TRIPS agreement placed a disproportionate emphasis on patent protection –which primarily benefits pharmaceutical corporations– over global health issues. This imbalance made it virtually impossible for developing countries to obtain generic drugs at affordable prices. The August 2003 TRIPS reform, which fulfils the Doha mandate that required the WTO to find a balance between property rights protection and the promotion of global health, removed some of the existing obstacles by allowing imports through ‘compulsory licensing’. If the agreement is implemented as planned, we should see a dramatic reduction in drug prices. Nevertheless, it remains to be seen if, in practice, countries capable of producing drugs are willing to violate patents and export drugs given that the US has warned that it will retaliate unilaterally against nations that do not enforce property rights protection domestically, even if the new TRIPS agreement allows them to do so.

Secondly, it is essential to increase the financial resources directed to poor countries so that they can implement appropriate health systems to control the impact of infectious diseases. This will not only benefit them, but will also reduce the possibilities of both existing and new diseases spreading world wide. TRIPS reform is not enough to ensure that citizens will have access to drugs. An effort to increase health coverage, vaccinations and access to drugs has to be coordinated by the United Nations and other supranational organizations. It requires financing from industrialized countries, which should substantially increase their levels of ODA to developing countries, at least until they reach the committed level of 0.7% of GNP. Health systems in developing countries also need improved management and a reduction in corrupt practices to ensure that health coverage reaches those citizens who need it the most. However, this is not enough. It is clear that without further financial assistance from the industrialized world, the impact of infectious diseases will only grow, making it more difficult to reduce poverty, promote economic growth and, ultimately, protect citizens from rich countries citizens from outbreaks of disease in the future.

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Notes:

- (1) For further details see UNAIDS/WHO (2002: 4).
- (2) For a detailed analysis of the difference between private goods, public goods, global commons and club goods see Rosen (2002) and Stiglitz (1999b) or Cornes and Sandler (1996).
- (3) See Olson (1965) for a detailed exposition of the logic of collective action.
- (4) See the volume edited by Krasner (1983) for a discussion of the role of international regimes in facilitating cooperation at the global level.
- (5) According to WHO (1979) estimates, the total cost of the smallpox eradication programme was approximately a US\$310 million one-off expense and it saved at least US\$1 billion in costs associated with vaccination programmes, care of infected persons and cost associated with quarantine.

- (6) The World Intellectual Property Organization (WIPO) has existed as a United Nations agency since 1974. However, it has never had the capacity to enforce property right protection internationally.
- (7) For a detailed and technical explanation of the TRIPS agreement see annex 1C of the Uruguay Round Agreement, available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs.
- (8) For a detailed discussion of the Uruguay Round and the creation of the WTO see Hoekman and Kosteki 1995 and Krueger (editor) 1998.
- (9) The US was the country that had been benefiting the most from transfers of technological innovation since the late eighties, ‘with royalty and licence payments increasing five-fold to US\$33 billion in the decade to 1997’ (Oxfam 2002: 211). TRIPS ensured that the US would continue to obtain substantial benefits.
- (10) See Oxfam 2002 for a critical assessment of the world trading system. Chapter 8 includes a detailed analysis of the TRIPS agreement and its consequences for developing countries.
- (11) For a detailed description of the economic, political and social implications of HIV/AIDS see UNAIDS/WHO 2002.
- (12) Oxfam (2002: 214) estimates that out-of-pocket payments in countries like the US represent less than one fifth of total expenditure on health. In countries like India or Vietnam this figure represents approximately four fifths, and in sub Saharan Africa more than three fifths.
- (13) See Steinberg (2003) for an analysis of the Cancún ministerial meeting and the reasons behind its failure.
- (14) Due to strong opposition by South American countries –especially Brazil– to the property rights framework proposed by the US at the November 2003 ALCA ministerial meeting in Miami, led to the decision that property rights protection would be temporarily excluded from the negotiations.
- (15) The Millennium Development Goals, established by the United Nations in 2000, set as targets (among others) the halting and reversal of the impact of HIV/AIDS and malaria, the halving of extreme poverty and hunger and the reduction by two thirds of infant mortality rates. These goals should be achieved by the year 2015. For further details see <http://www.un.org/millenniumgoals/>.
- (16) See also World Health Organization (2001) for similar estimates, for a detailed analysis of the links between health and development and for specific policy recommendations to reduce the impact of infectious diseases.

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