

TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond

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Abstract

The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and the multinational pharmaceutical industry.

The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. While TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPS safeguards. But the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health. The recent failure at the WTO to resolve the outstanding issue to ensure production and export of generic

medicines to countries that do not produce may even indicate that the optimism felt at Doha was premature.

Résumé

Parmi les différentes raisons de l'absence d'accès aux médicaments essentiels dans les pays en développement, leur prix élevé constitue un obstacle majeur. Ces prix prohibitifs sont souvent le résultat de la protection très forte de la propriété intellectuelle. Les gouvernements des pays en développement qui tentent de réduire ces prix sont l'objet de fortes pressions de la part des pays industrialisés et de l'industrie pharmaceutique multinationale. Les accords ADPIC (Accords sur les Droits de Propriété Intellectuelle qui touchent au Commerce) de l'Organisation Mondiale du Commerce (OMC) définissent des normes minimales pour la protection de la propriété intellectuelle, incluant les brevets pour les médicaments. Si ces accords offrent des mécanismes de sauvegarde pour compenser les effets négatifs de la protection ou des abus liés aux brevets, en pratique, l'utilisation appropriée de ces mécanismes, lorsque les brevets constituent des obstacles majeurs à l'accès aux médicaments, n'est pas claire.

Les défenseurs de la santé publique ont considéré la Déclaration de Doha comme une étape importante parce qu'elle donnait la primauté aux considérations de santé publique sur celles de propriété privée intellectuelle et clarifiait les modalités d'utilisation des clauses de sauvegarde des ADPIC pour les membres de l'OMC. Mais la Déclaration de Doha n'a pas résolu les problèmes associés à la protection de la propriété intellectuelle et à la santé publique. L'échec récent à l'OMC des tentatives pour résoudre la question relative à la production et à l'exportation de médicaments génériques vers les pays qui n'en produisent pas confirme que l'optimisme post-Doha était prématuré.

Introduction

Infectious diseases kill over 10 million people each year, more than 90% of whom are in the developing world [1]. The leading causes of illness and death in Africa, Asia, and South America—regions that account for four-fifths of the world's population—are HIV/AIDS, respiratory infections, malaria, and tuberculosis.

In particular, the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Each day,

close to eight thousand people die of AIDS in the developing world [2]. The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and the multinational pharmaceutical industry.

The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS or "Agreement"), which sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals, has come under fierce criticism because of the effects that increased levels of patent protection will have on drug prices. While TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

The Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, adopted a Declaration on TRIPS and Public Health ("Doha Declaration" or "Declaration") which affirmed the sovereign right of governments to take measures to protect public health. Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPS safeguards. Although the Doha Declaration broke new ground in guaranteeing Members' access to medical products, it did not solve all of the problems associated with intellectual property protection and public health. The recent failure at the WTO to resolve the outstanding issue to ensure production and export of generic medicines to countries that do not produce may even indicate that the optimism felt at Doha was premature.

I

THE ACCESS PROBLEM AND INTELLECTUAL PROPERTY

A number of new medicines that are vital for the survival of millions are already too costly for the vast majority of people in poor countries. In addition, investment in Research and Development (R&D) towards the health needs of people in developing countries has almost come to a standstill. Developing countries, where three-quarters of the world population lives, account for less than 10% of the global pharmaceutical market. The implementation of TRIPS is

expected to have a further upward effect on drug prices, while increased R&D investment that aims at addressing health needs in developing countries, despite higher levels of intellectual property protection, is not expected [3].

One-third of the world population lacks access to the most basic essential drugs and, in the poorest parts of Africa and Asia, this figure climbs to one half. Access to treatment for diseases in developing countries is problematic either because the medicines are unaffordable, have become ineffective due to resistance, or are not sufficiently adapted to specific local conditions and constraints.

Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices. Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has virtually ground to a standstill because drug companies in developed and developing nations simply cannot recoup the cost of R&D for products to treat diseases that abound in developing countries [4]. Of the 1,223 new drugs approved between 1975 and 1997, approximately 1% (13 drugs) specifically treat tropical diseases [5].

TRIPS sets out minimum standards and requirements for the protection of intellectual property rights, including trademarks, copyrights, and patents. The implementation of TRIPS, initially scheduled for 2006 by all WTO Members, is expected to impact the possibility of obtaining new essential medicines at affordable prices.

Médecins sans Frontières (MSF), together with other non-governmental organizations (NGOs), formulated the following concerns related to TRIPS:

- Increased patent protection leads to higher drug prices [6]. The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices. As a result, the access gap between developed and developing countries will widen.
- Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend.

It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry.

Developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond

the obligations of TRIPS. This is often referred to as “TRIPS plus.” TRIPS plus is a non-technical term which refers to efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics [7].

Industrialized countries and World Intellectual Property Organization (WIPO) offer expert assistance to help countries become TRIPS-compliant. This technical assistance, however, does not take into account the health needs of the populations of developing countries. Both of these institutions are under strong pressure to advance the interests of large companies that own patents and other intellectual property rights.

II IMPORTANT DEVELOPMENTS IN THE DEBATE ON ACCESS TO DRUGS AND INTELLECTUAL PROPERTY

A number of factors have shaped the debate on TRIPS and access to medicines, directly or indirectly impacting the content of the Doha Declaration.

Big Pharma vs. Nelson Mandela: trade dispute in South Africa

In February 1998, the South African Pharmaceutical Manufacturers Association and 40 (later 39, as a result of a merger) mostly multinational pharmaceutical manufacturers brought a suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act No. 90 of 1997 (“Amendment Act”) violated TRIPS and the South African constitution [8].

The Amendment Act introduces a legal framework to increase the availability of affordable medicines in South Africa. Provisions included in the Amendment Act are generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines¹ [9].

At the start of the litigation, the drug companies could rely on the support of their home governments. For its part, the United States had put pressure on

1. Parallel imports are cross-border trade in a patented product, without the permission of the manufacturer or publisher. Parallel imports take place when there are significant price differences for the same good in different markets.

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South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the Amendment Act [10]. In 1998, the European Commission joined the United States in pressuring South Africa to repeal the legislation [11]. AIDS activists effectively highlighted these policies, profoundly embarrassing then-presidential candidate Al Gore. Confronted at election campaign rallies about his personal involvement in the dispute, demonstrators accused him of killing babies in Africa [12]. As a result of increasing public pressure, the United States changed its policies at the end of 1999. By the time the case finally reached the courtroom in May 2000, the drug companies could no longer count on the support of their home governments.

Demonstrators in major cities asked the companies to drop the case; several governments and parliaments around the world, including the European Parliament, demanded that the companies withdraw from the case. The legal action turned into a public relations disaster for the drug companies [13].

During the course of the trial it became clear that the most contentious section of the Amendment Act was based on a draft legal text produced by the WIPO Committee of Experts [14], a fact that made it difficult for the drug companies to maintain the position that the Amendment Act violated South Africa's obligations under international law. Eventually, the strong international public outrage over the companies' legal challenge of a developing country's medicines law and the companies' weak legal position caused the companies to unconditionally drop the case in April 2001.

The widely publicized South African court case brought two key issues out into the international arena. First, the interpretation of the flexibilities of TRIPS and their use for public health purposes needed clarification to ensure that developing countries could use its provisions without the threat of legal or political challenge. Second, it became clear that industrialized countries that exercised trade pressures to defend the interest of their multinational industries could no longer exert pressure without repercussions at home.

United States vs. Brazil: The Brazilian AIDS Programme

Since the mid-1990s, Brazil has offered comprehensive AIDS care, including universal access to antiretroviral (ARV) treatment. An estimated 536,000 people are infected with HIV in Brazil, with 203,353 cases of AIDS reported to the Ministry of Health from 1980 through December 2000. In 2001, 105,000 people with HIV/AIDS received ARV treatment. The Brazilian AIDS programme

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reduced AIDS-related mortality by more than 50% between 1996 and 1999 [15]. In two years, Brazil saved US\$472 million in hospital costs and treatment costs for AIDS-related infections.

At the core of the success of Brazil's AIDS programme is the ability to produce medicines locally. Brazil has also been able to negotiate lower prices for patented drugs by using the threat of production under a compulsory license [16]. Article 68 of the Brazilian patent law allows for compulsory licensing, which allows a patent to be used without the consent of the patent holder [17]. The Brazil AIDS programme serves as a model for some developing countries that are able to produce medicines locally, and Brazil has offered a cooperation agreement, including technology transfer, to developing countries for the production of generic ARV drugs [18]. In February 2001, the United States took action against Brazil at the WTO Dispute Settlement Body (DSB) over Article 68 of the Brazilian intellectual property law. Under that provision, Brazil requires holders of Brazilian patents to manufacture the product in question within Brazil – a so-called “local working” requirement. If the company does not fulfil this requirement, the patent shall be subject to compulsory licensing after three years, unless the patent holder can show that it is not economically feasible to produce in Brazil or can otherwise show that the requirement to produce locally is not reasonable. If the company is allowed to work its patent by importation instead of manufacturing in Brazil, parallel import by others will be permitted.

The United States argued that the Brazilian law discriminated against United States owners of Brazilian patents and that it curtailed patent holders' rights. The United States claimed that the Brazilian law violated Article 27.1 and Article 28.1 of TRIPS [19]. Brazil argued that Article 68 was in line with the text and the spirit of TRIPS, including Article 5.4 of the Paris Convention, which allows for compulsory licensing if there is a failure to work a patent. Article 2.1 of TRIPS incorporates relevant articles of the Paris Convention.

The United States action came under fierce pressure from the international NGO community, which feared it would have a detrimental effect on Brazil's successful AIDS programme [20]. Brazil has been vocal internationally in the debates on access to medicines, and on several occasions, including the G-8, the Roundtable of the European Commission, and WHO meetings, Brazil has offered support to developing countries to help them increase manufacturing capacity by transferring technology and know-how. NGOs feared that the United States action could have a negative effect on other countries' ability to accept Brazil's offer of assistance. On June 25, 2001, in a joint statement with

Brazil, the United States announced that it would withdraw the WTO panel against Brazil [21].

The role of NGOs

NGOs have played a key role in drawing attention to provisions of TRIPS that can be used to increase access to medicines. One such provision pertains to compulsory licensing, which enables a competent government authority to license the use of an invention to a third-party or government agency without the consent of the patent-holder. The patent holder, however, according to Article 31 of TRIPS, retains intellectual property rights and “shall be paid adequate remuneration” according to the circumstances of the case. The first international meeting specifically on the use of compulsory licensing to increase access to AIDS medicines took place in March 1999 at the Palais des Nations in Geneva and was organized by Consumer Project on Technology, Health Action International, and MSF. Later that year, the same group of NGOs organized the Amsterdam Conference on Increasing Access to Essential Drugs in a Globalized Economy, which brought together 350 participants from 50 countries on the eve of the Seattle WTO ministerial conference. The statement drawn up at this conference (“Amsterdam Statement”) focused on establishing a working group in the WTO on TRIPS and access to medicines, considering the impact of trade policies on people in developing and least-developed countries, and providing a public health framework for the interpretation of key features of WTO agreements. The working group was to address questions related to the use of compulsory licensing to increase access to medicines, mechanisms to allow production of medicines for export markets to a country with no or insufficient production capacity, patent barriers to research, and overly restrictive and anti-competitive interpretations of TRIPS rules regarding protection of health registration data. In addition, the working group was to examine “burden sharing” approaches for R&D that permit countries to consider a wider range of policy instruments to promote R&D and to consider the practical burdens on poor countries of administering patent systems. The Amsterdam Statement also urged national governments to develop new and innovative mechanisms to ensure funding for R&D for neglected diseases.

The Amsterdam Statement has served as a guide for the work of NGOs and other advocates on TRIPS and public health. Many international and national NGOs, such as the OXFAM campaign, “Cut the Cost,” the South African Treatment Action Campaign, Act Up Paris, and the Health Gap

Coalition in the United States, are now involved in campaigning for access to medicines.

The WTO Ministerial 1999 in Seattle

Though public health and access to medicines did not form part of the official agenda in Seattle in the way it would two years later in Doha, the issue did receive attention for a number of reasons. First, in Seattle a Common Working Paper section on TRIPS contained the following proposal: “to issue... compulsory licenses for drugs appearing on the list of essential drugs of the World Health Organization.” [22] Since only about 11 of the 306 products on the WHO Model List of Essential Drugs are patented drugs in certain countries² this proposal could have limited the use of compulsory licensing, rather than making sure it became a useful tool to overcome access barriers, such as prohibitive pricing, caused by patent abuse.

Then-United States President Clinton chose Seattle as the venue to declare a change in United States policy with regard to intellectual property rights and access to medicines. The United States government had come under fierce attack from AIDS activists because of its policies in South Africa. Under the new policy, the United States Trade Representative and the Department of Health and Human Services would together establish a process to analyse health issues that arise in the application of United States trade-related intellectual property law and policy. In his speech, President Clinton referred specifically to the situation in South Africa and the HIV/AIDS crisis, saying that “the United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won’t have to go without medicine they so desperately need.” [23]

In May 2000, President Clinton confirmed the change in United States policy by issuing an Executive Order on Access to HIV/AIDS Pharmaceuticals and Medical Technologies, supporting the use of compulsory licenses to increase access to HIV/AIDS medication in sub-Saharan Africa [24]. Although this policy change contributed to breaking the taboo on the use of compulsory licensing in the health field, attention to TRIPS and medicines at the WTO was diverted by the collapse of the WTO conference in Seattle [25]. However, outside the WTO, the debate on access to medicines, TRIPS, and compulsory licensing became more intense.

2. High cost or price of a drug in general used to exclude a drug from the WHO Essential Drug List.

Changing attitudes among global players

A number of international institutions and UN agencies contributed to the debate on access to medicines and looked into the consequences of stronger intellectual property protection as a result of TRIPS for developing countries.

The World Health Organization

The public health community first raised concerns about the consequences of globalization and international trade agreements with respect to drug access during the 1996 World Health Assembly. A resolution on the Revised Drug Strategy (RDS) set out the WHO's medicines policy [26]. The WHO resolution on the RDS requested the WHO in paragraph 2 (10) "to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate." This resolution gave the WHO the mandate to publish, in 1998, the first guide with recommendations to Member States for implementing TRIPS while limiting the negative effects of higher levels of patent protection on drug availability [27]. The United States and a number of European countries unsuccessfully pressured the WHO in an attempt to prevent publication of the guide [28].

At that time, the WHO's involvement in trade issues was highly controversial. The emphasis on public health needs versus trade interest was seen as a threat to the commercial sector of the industrialized world. For example, in 1998, in response to the draft World Health Assembly's resolution on the RDS and in reference to "considerable concern among the pharmaceutical industry," the European Directorate General for Trade (DG Trade) of the European Commission concluded: "No priority should be given to health over intellectual property considerations." [29]

However, subsequent resolutions of the World Health Assembly have strengthened the WHO's mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

- the need to strengthen policies to increase the availability of generic drugs;
- and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs.

As a result, the WHO's work programme on pharmaceuticals and trade now includes the provision of policy guidance and information on intellectual

property and health to countries for monitoring and analyzing the effects of TRIPS on access to medicines [31].

The European Union

In February 2001, the EU adopted the Programme for Action, a programme which accelerates action on HIV/AIDS, malaria, and tuberculosis in the context of poverty reduction. The EU programme recognized the potential problems of TRIPS and the need to rebalance its priorities. In addition, several European Parliament resolutions reflected a shift in support of a pro-public health approach to TRIPS [32]. As part of this approach, DG Trade changed its policy to acknowledge the concerns of developing countries. Reflecting this change, DG Trade dropped its objections to the use of compulsory licensing to overcome patent barriers to medicine access and became an advocate for a global tiered pricing system for pharmaceuticals [33]. These policy changes are in stark contrast to previous European Commission policies, which closely track the pharmaceutical industry's agenda.

Other Organizations

Other organizations, such as UNAIDS, the World Bank, the Group of 77, and regional organizations such as the Organization of African Unity, added their voice to the debate on TRIPS and access to medicines. The UN Sub-Commission for the Protection and Promotion of Human Rights passed a resolution, pointing out the negative consequences for human rights to food, health, and self-determination if TRIPS is implemented in its current form. Referring specifically to pharmaceutical patents, the resolution stresses the need for intellectual property rights to serve social welfare needs [34]. In 1999, the United Nations Development Programme's (UNDP's) Human Development Report made a plea for re-writing the rules of globalization to make them work "for people – not just profits." [35]

Unable to turn a deaf ear to the growing chorus of critics of TRIPS and its effects on access to medicines, the WTO changed course. In April 2001, when proposing a special TRIPS Council session on access to medicines, Zimbabwe – chair of TRIPS Council – said that the WTO could no longer ignore the access to medicines issue, an issue that was being actively debated outside the WTO but not within it [36]. The voices had been heard; public health would be featured as a key subject at the Doha Conference.

III
A BRIEF HISTORY OF THE DOHA DECLARATION
ON TRIPS AND PUBLIC HEALTH

The Fourth Ministerial Conference of the WTO took place in Doha in 2001 and was a breakthrough in international discussions on TRIPS and access to medicines. The WTO Ministerial adopted a Declaration on TRIPS and Public Health, which put public health before commercial interests and offered much needed clarification in the field of TRIPS and public health.

The African proposal for a special TRIPS Council meeting in June

The “African Group” statement to the TRIPS Council about the need to confront the access to medicines issue initiated preparations for the Declaration. Just two months later, in June 2001, the TRIPS Council held its first session devoted to TRIPS and access to medicines. It was the first time that the TRIPS Council discussed intellectual property issues in the context of public health. At that meeting, the African Group proposed issuing separate declarations on access to medicines [37]. Referring to the devastating AIDS crisis in Africa and mounting public concern, Zimbabwe as head of the Africa Group stated: “We propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health.” [38]

In September 2001, the TRIPS Council devoted another full day of discussion to the topic of access to medicines. At this meeting, the African Group, joined by nineteen other countries, presented a draft text for a ministerial declaration on TRIPS and Public Health. A comprehensive text, this proposal addressed political principles to ensure that TRIPS did not undermine the legitimate right of WTO Members to formulate their own public health policies. The text also provided practical clarifications for provisions related to compulsory licensing, parallel import, data protection, and production for export to a country with insufficient production capacity. In addition, the draft included a proposal for evaluating the effects of TRIPS on public health, with particular emphasis on access to medicines and R&D for the prevention and treatment of diseases predominantly affecting people in developing and least-developed countries.

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At the meeting, the United States, Japan, Switzerland, Australia, and Canada circulated an alternate draft, stressing the importance of intellectual property protection for R&D, arguing that intellectual property contributes to public health objectives globally. The text was aimed at limiting the flexibilities of TRIPS during crisis and emergency situations. The EU circulated its own draft, which proposed a solution to the problem of production for exports to fulfil a compulsory license in a country with insufficient or no production capacity by allowing production under the TRIPS Article 30 exception.

From the onset of the pre-Doha negotiations, the main point of contention was the text proposed by the developing countries: "Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health." [39] Some developed countries saw this wording as a new rule that would override the present rules of TRIPS, which do not allow for health exceptions that are inconsistent with TRIPS [40].

The text drafted by the chair of the WTO General Council, Mr. Stuart Harbinson, that was the basis for the negotiations in Doha, left the issue unresolved and instead offered two options for Paragraph 4. The first option read:

Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement shall be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to ensure access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose.

Whereas the second option offered was:

We affirm a Member's ability to use, to the full, the provisions in the TRIPS Agreement which provide flexibility to address public health crises such as HIV/AIDS and other pandemics, and to that end, that a Member is able to take measures necessary to address these public health crises, in particular to secure affordable access to medicines.

Further, we agree that this Declaration does not add to or diminish the rights and obligations of Members provided in the TRIPS Agreement. With a view to facilitating the use of this flexibility by providing greater certainty, we agree on the following clarifications.

Negotiations in Doha

In Doha, for three days the discussions on TRIPS and public health dominated the trade talks. Early on in the meeting it became clear that a majority of Members preferred the first option of the Harbinson draft, making it the basis for further negotiation. The reason for this was that option one recognises that measures can be taken for health in general and not only in cases of health crisis. Furthermore the text in option 2 implies that the Declaration would not create new rights or alter existing rights. This would have weakened the significance of the Declaration for example in WTO dispute settlement procedures. The core supporters of the second option included the United States, Japan, Australia, Switzerland, Canada, and Korea. The EU, at this stage, did not take a clear position and claimed it was playing the role of “honest broker.” After three days of negotiation among the participating Members, a compromise was reached. The compromise text, which resulted from negotiations primarily between Brazil and the US, read:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all [41].

This text acknowledges the unmitigated right of countries to take measures to protect public health. Thus, if intellectual property rules should stand in the way of doing so (for example, in the case of high prices associated with patented medicines), countries are allowed to override the patent.

In Paragraph 5, the Declaration lays out the key measures and flexibilities within TRIPS that can be used to overcome intellectual property barriers to access to medicines. The discussions at Doha and the Doha Declaration itself make it unambiguously clear that the use of compulsory licenses is in no way confined to cases of emergency or urgency; in fact, the grounds for issuing a compulsory license are unlimited. Members who proposed language that would have limited measures like compulsory licensing to emergency situations, pandemics, or specified diseases such as HIV/AIDS were unsuccessful. In addition, the Declaration leaves Members free to determine for themselves what constitutes a national emergency or urgency, in which cases the procedure for issuing a compulsory license becomes easier and faster. The Declaration

also resolves the question of whether TRIPS authorizes parallel trade once and for all by noting: “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.” [42]

In addition, the Declaration grants Least Developed Country (LDC) Members an extra ten-year extension – until 2016, instead of 2006 – to the implementation deadline for pharmaceutical product patent protection. The negotiating history illustrates that this outcome was not predetermined. Pre-Doha, the United States proposed two operative paragraphs, which included this extension of transition periods until 2016 for patents on pharmaceutical products, as well as offering a moratorium on dispute settlement action to sub-Saharan African countries, which do not fall within the LDC grouping. The moratorium covered laws, regulations and other measures that improve access to patented medicines for HIV/AIDS and other pandemics. These proposals were viewed as a “divide and conquer” strategy employed by the United States to break the cohesion of the developing countries [43] and the proposal for a moratorium on dispute settlement actions was rejected at Doha. The proposal to extend the deadlines for LDCs were accepted. The extended deadlines are important because they extend the timeframe (until 2016) in which countries may rethink the kind of pharmaceutical intellectual property law they want while still being able to import and produce generic medicines.

The Declaration also refers to the as-yet unfulfilled commitment of developed-country Members to provide incentives to their enterprises and institutions to promote technology transfer to LDCs pursuant to Article 66.2. The ten-year extension might be of limited value because only LDCs will be able to benefit from this provision. Of the 143 WTO members, only 30 are LDCs, representing 10% of the world’s population. The ten-year extension is limited to Sections 5 (patents) and 7 (undisclosed information) of TRIPS; the extension does not apply to other provisions of the Agreement relevant to pharmaceuticals, notably Article 70 (“exclusive marketing rights”). Though there seemed to be an understanding among the negotiators in Doha that Paragraph 7 implied that LDCs are not required to provide “mail box” protection or “exclusive marketing rights,” this is not clear from the text of the declaration. Paragraph 7 of the declaration refers to pharmaceutical products, which means that LDCs are still under the obligation to provide process patents.

A key issue that remained unresolved in Doha is how to ensure that production for export to a country that has issued a compulsory license, but does not have manufacturing capacity, can take place within a country that provides

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pharmaceutical patents. Since Article 31 (f) of TRIPS limits compulsory licensing to uses which are predominantly for the supply of the domestic market, countries agreed that further action was necessary to ensure that countries without production capacity can make use of compulsory licensing provisions to the same extent that countries with manufacturing capacity can use these provisions. The Doha Declaration acknowledges the problem in Paragraph 6:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

However to date no progress has been made to resolve this issue.

Other areas of debate in Doha

Public Health

Most of the language aimed at narrowing the scope of the Declaration to health crisis and pandemics³ was replaced with language that referred generally to public health. Indeed, the title itself – Doha Declaration on Public Health – reflects this shift.

Access for All

Some countries objected to the text that countries have the right “to ensure access to medicines for all” [44]. In particular, Switzerland objected to the wording, but had difficulty defending a position that advocated access to medicines for some but not for others.

Scope

A point of strong contention was how far-reaching the Declaration would be. Some WTO Members feared that the negotiations could lead to changes in TRIPS and wanted to include a confirmation that the Declaration was purely a clarifying exercise. They borrowed language from the WTO Dispute Settlement Process Rules to indicate that the Ministerial Declaration would have no formal legal effect to change the rights and obligations TRIPS established.

3. Pandemics refer to diseases, mostly of infectious nature, that travel across borders.

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The text did not, however, make it into the final version of the Declaration. As a result, one could argue that the Declaration actually does go beyond clarifying the already existing rules. A Member can appeal to the Declaration and its negotiating history in the event that a Member's legislation, particularly relating to patents in the health field, is challenged on the grounds that it is incompatible with TRIPS.

Why Doha came to pass

Why was it possible to achieve a declaration on such a contentious issue considering that public health hardly played a part in the trade talks two years ago? Mike Moore, WTO Director-General, made it clear on the opening day of the conference that the TRIPS and health issue could be the deal-breaker for a new trade round. Observers point to a number of factors that contributed to the success of the negotiations [45]. First, the developing country Members were extremely well prepared and operated as one bloc. Second, the uncompromising positions of western countries such as the United States and Canada were hard to maintain in light of the anthrax crisis and the threat that a shortage of ciprofloxacin (Cipro™) might occur. Both the United States and Canada rapidly expressed their willingness to set aside the patent held by the German company Bayer if other solutions could not be found [46]. The anthrax scare and the threatened shortage of Cipro forced all WTO Members to ask how much of a prisoner they wanted to be of their own patent systems. Third, a growing and active international NGO movement ensured the issue would be high profile, and that NGOs would monitor different countries' positions.

IV

DRUG INDUSTRY RESPONSE TO THE WTO DECLARATION
ON TRIPS AND PUBLIC HEALTH

The multinational pharmaceutical industry argued from the beginning that a declaration was not necessary because:

- a) patents are not a problem [47];
- b) weakening patent protection would have devastating effects on the R&D capabilities of the research-based industry.

Although the International Federation of Pharmaceutical Manufacturers (IFPMA) officially welcomed the Declaration on TRIPS and Public Health,

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individuals in the industry expressed their concerns. Indeed, the United States pharmaceutical companies asked the United States Trade Representation (USTR) to re-open the negotiations even after an agreement on the text of the Declaration was reached.

For more than two years, IFPMA has warned against the dangers of compulsory licensing-ever since NGOs started to propose compulsory licensing systems to overcome patent barriers. IFPMA's position has not changed. "Compulsory licensing is a threat to good public health by denying patients around the world the future benefits of R&D capabilities of the research-based industry from which new therapies come." [48]

The generic drug industry welcomed the Declaration, in particular the freedom of countries to decide the grounds for compulsory licensing. It did however express concern about possible unilateral pressure to influence countries not to make full use of the Declaration. The industry suggested that the advanced WTO Members should commit themselves to the Declaration in practice by refraining from exerting unilateral pressure. The generic drug contingent expressed disappointment that there was no resolution of the issue that arises when a country with limited production capacity that issues a compulsory license for a medicine cannot find an efficient, affordable, and reliable source of medicines, due to TRIPS restrictions on production and export of medicines. After 2005, production of affordable medicine will increasingly become dependent on compulsory licensing. However production under a compulsory license is restricted to production "predominantly for the supply of the domestic market." [49] The problem is not the compulsory license itself, but the need to allow exports from a country where the drug is under patent to a country that has issued the compulsory license.

The generic drug industry expressed further disappointment that the Declaration did not offer an interpretation of the data protection issue addressed in Article 39.3 of TRIPS. The concern here is that an overly restrictive interpretation of Article 39.3 will lead to delays in introduction of generic medicines, may provide exclusive marketing rights beyond the patent protection term and increase barriers to the registration of generic medicines including those produced under a compulsory license.

V

THE POST-DOHA AGENDA

It is crucial that the Doha declaration “paragraph 6” issue of production for export be resolved. Implementation deadlines for some important producing countries are quickly approaching, thus further limiting the possibilities of producing generic versions of medicines that are protected by patent elsewhere.

Another flaw of the Doha Declaration is that it does not resolve the problem of production for export from markets that provide patents to countries that do not grant pharmaceutical patents (and subsequently do not grant compulsory licenses). This is of particular importance now that the least-developed WTO Members can delay the granting of pharmaceutical product patents until 2016. These countries need to have access to sources of affordable medicines, which threaten to dry up as the 2005 deadline for TRIPS implementation is nearing for producing countries.

It will also be a challenge to find ways to make the Doha Declaration on TRIPS and Public Health operational at the regional and national levels. A classic example is the Bangui Agreement, the regional intellectual property agreement for francophone Africa, which was adopted in 1977 and revised in 1999 to ensure TRIPS compatibility, but includes typical TRIPS plus provisions that are not in line with the Doha Declaration.

At the national level, countries should be encouraged to make full use of the Doha Declaration in the process of adjusting national intellectual property laws to become compliant with TRIPS. This will require substantial advice and technical assistance from institutions like WIPO and WTO. While the spirit of the Doha Declaration is to tailor intellectual property laws to national needs, the practice has been to encourage developing countries to go beyond the minimum requirements and speed up the process to become TRIPS-compliant. It will require a “culture change” at WIPO and WTO to adjust the type of technical assistance to developing countries’ needs. In addition to increasing their interaction with countries, WIPO and WTO will have to increase their level of collaboration with the public health community, including the WHO, which has become heavily involved in trade discussions as a result of the process that led to the Doha Declaration.

A key requisite for the success of the Doha Declaration will be the political will of countries to take measures to offer access to medicines to their population. There is no excuse for the South African government’s lack of action at the moment.

VI
PRODUCTION AND EXPORT OF MEDICINES
– IS THE DOHA SPIRIT DWINDLING?

In grim contrast to the optimistic spirit in Doha in 2001, the WTO in the months that followed the Doha conference failed completely to deliver on the promise that a solution to allow production of medicines for export to countries that do not have production capacity would be found before the end of 2002.

The TRIPS Council discussed different proposals. The opening moves of the key players, the European Union, the United States, Africa group, India, Brazil and the WHO in the TRIPS Council were the following: the EC and their members submitted two possible options to address the paragraph 6 problem: an amendment to Article 31(f) of the TRIPS Agreement that would create an exception to the requirement that a compulsory license is predominantly for the domestic market, and the option of allowing production for export as a limited exception under Article 30 [51]. Both options would be subject to conditions with regard to eligible countries and scope of diseases. The United States proposed a dispute settlement moratorium whereby the Members would agree not to bring a WTO complaint against countries that export some drugs to countries in need. The United States insisted that any solution should apply to epidemics mentioned in the Doha declaration, namely HIV/AIDS, TB and Malaria. The Africa Group, joined by Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand, suggested as possible options an amendment to Article 31 in order to delete the paragraph that limits compulsory licensing to “predominantly for the domestic market”, or to develop an authoritative interpretation that would recognize the right of Members to allow the production for export without the consent of the patent holder to address public health needs in another country under Article 30 of the TRIPS Agreement.

The WHO favoured a solution that is based on Article 30 of TRIPS. In its statement to the TRIPS Council on September 17, 2002, the WHO set out the features of a solution to the Doha declaration “paragraph 6 problem” which are desirable from a public health perspective as follows: “a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country;

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facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines". The WHO concluded: "Thus, the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.

"Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs." [52]

A coalition of NGOs (Consumer Project on Technology, Essential Action, Médecins Sans Frontières, Oxfam International, Health GAP Coalition, and the Third World Network) wrote on December 19, 2002 to the WTO members calling for a solution that is based on Article 30. They made the following proposal:

Under Article 30 of the TRIPS agreement, Members may provide an exception to the exclusive rights conferred by a relevant patent to permit all acts associated with the production for export to a third country of a patented product or a product produced by a patented process; where the export addresses health needs in the third country; and the product and/or process is either (a) not patented; or (b) a compulsory license has been granted or government use made of the relevant patent in the third country.

They pointed out that the Article 30 approach to addressing the issue of exports of medicines passes the test of being administratively simple, workable and economically viable. They urged the WTO to reject proposals to tie Article 30 export exemptions to overly restrictive or complex conditions and procedures.

While negotiations went on in the TRIPS Council, the European Parliament on October 23, 2002 adopted Amendment 196 to the EU Directive 2001/83/EC relating to medicinal products for human use. This Amendment reads as follows:

Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that country.

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The approach taken by the European Parliament is consistent with the position of the WHO in the TRIPS Council. The revision of the EU rules on medicines is still under discussion and it is unclear at this stage whether the EP amendment will be maintained. The Parliament's amendment had no impact on the EU's position in the TRIPS Council which by then was advocating a solution solely based on Article 31f of TRIPS. However, the Parliament's move is significant for the discussions at the TRIPS Council because it can serve as a model for a paragraph 6 solution, and it shows that countries can formulate exceptions under Article 30 of the TRIPS Agreement without prior consent of the WTO.

The Motta Text

Unfortunately, the WTO negotiations took an entirely different direction. Months of discussions in the TRIPS Council showed a deep divide between the developing countries that were seeking a workable solution and the industrialised world that tried to limit the scope of any solution as much as possible. In an attempt to meet the 2002 deadline, most delegations were prepared to accept a far from ideal compromise text that became known as "the December 16 Motta text" named after the chair of the TRIPS Council. The Motta text is ambiguous on the scope of diseases through its reference to paragraph 1 of the Doha Declaration which mentions AIDS, TB and Malaria. A more appropriate basis for the scope of disease would have been paragraph 4 of the Doha declaration which refers to public health problems in general. On the eligibility for countries, the Motta text seems to be at odds with the Doha Declaration which requires implementing the TRIPS in a manner to "promote access to medicines for all". The Motta text provides for cumbersome procedures to determine eligibility of countries, and for measures to prevent diversion of medicines to rich country markets.

Even though the Motta text was seen as far from ideal, all countries were ready to agree to it. NGOs called upon the negotiators to reject the text [53]. In the end it was the United States that vetoed the proposal. The lobby of the drug companies to restrict the scope of diseases and eligible countries of any solution to paragraph 6 has been very fierce in particular in the United States. The United States considered the scope of diseases too broadly defined, rejected the proposal and announced a unilateral moratorium on disputes. In an attempt to break the deadlock, the European Commission followed up on an earlier United States proposal and listed diseases for which the solution could apply, and introduced an advisory role for the WHO in case a Member requested

this⁴ [54]. This proposal was rejected by the developing countries as backtracking on the Doha declaration and was met with a wave of objections from all over the world. In numerous letters, professional medical organizations, individual medical doctors, NGOs, consumer groups and human rights groups rejected any further narrowing of the scope of the Doha declaration [55]. Apart from HIV/AIDS, the list included only diseases for which there is either no treatment or where virtually all the recommended treatments are so old as to be off-patent [56]. The negotiations in the WTO became quite bizarre with trade negotiations trying to determine public health priorities for countries. The latest attempt to make the Motta text palatable for the United States came from the Chair of the TRIPS Council who proposed in January 2003 to adopt a statement that there is an understanding that the solution “under paragraph 6 of that Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency.” Again this proposal was rejected by the developing countries. MSF reacted fiercely in an open letter to the WTO members and called upon the Members to reject the proposal. The use of compulsory licensing was never meant to address only emergency situations and it would certainly be unacceptable to limit the use of compulsory licensing for countries without production capacity even further, while the entire purpose of the paragraph 6 discussions was to lift the barriers to use compulsory licensing non-producing countries face [57].

At this point it had become clear that there was little left of the spirit that led to the Doha declaration on TRIPS and Public Health. In particular the United States seemed to want to turn the clock back to the pre-Doha era.

Conclusion

The very fact that public health and access to medicines have been singled out as major issues needing special attention in TRIPS implementation indicates that health care and health care products need to be treated differently from other products. By giving countries broad discretion in deciding how to counter the negative effects of TRIPS, the Doha Declaration may stand for the proposition that public health concerns outweigh full protection of intellectual property.

4. The EC proposal read: “This covers at least HIV/AIDS, malaria, tuberculosis, yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, hemorrhagic fevers, and arboviruses. When requested by a Member, the World Health Organization shall give its advice as to the occurrence on an importing Member, or the likelihood thereof, of any other public health problem.”

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In fact, the Doha Declaration takes a large step toward ensuring that intellectual property protection actually serves the public interest, an interest broader than that of the commercial sector. In the years to come, it will be important to scrutinize closely whether the results of intellectual property protection serve the poor as well as the rich. The Doha Declaration lays out the options countries have available when prices of existing patented drugs are too high for their populations. But Doha did not solve every problem: the lack of R&D investment in new drugs for the particular health needs of the poor remains to be addressed [58].

In the Doha process, developing countries and NGOs pointed to commercial and public sector neglect of the R&D needs of developing countries.

Recent studies claim that the R&D cost of a commercial drug company per new pharmaceutical product is US\$802 million [59]. The Global Alliance for Tuberculosis Drug Development, a non-profit entity for R&D of tuberculosis drugs, estimated that the total R&D cost for a new tuberculosis drug, including the cost of failure, is between US\$115 million and US\$240 million [60]. These high R&D costs claimed by the commercial pharmaceutical sector pose some key questions that need to be resolved. Is the present system for funding R&D the most efficient, and is it sufficient to rely on the present intellectual property systems to fuel innovation? Clearly, in the area of neglected diseases, the answer is no.

In an increasingly globalized economy, additional international mechanisms need to be developed to address health needs in developing countries. MSF and others have proposed a radical shift in the way health R&D is financed, in particular for drugs for neglected diseases. For example, health R&D could be financed based on burden-sharing between countries, or obligating companies to complete essential medical research. Such a proposal might be incorporated into an international treaty on essential health R&D. In the end, the challenge for the coming years will be to encourage essential health R&D not only for the benefit of some, but for the benefit of all.

A major concern is the backtracking of rich countries on the promises made in Doha as was seen during the discussions on paragraph 6. The failure to reach an agreement to allow the production and export of generic medicines in the face of current health needs in developing countries gives little reason for optimism about the full implementation of the Doha Declaration. The implementation of the Doha declaration is a test for the TRIPS Agreement. Ultimately the following question will have to be answered: Is there a future for the TRIPS Agreement if in practice the flexibility to ensure that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” does not exist?

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