Public health versus intellectual property
Or how Members of the World Trade Organisation (WTO) without pharmaceutical production capacity could have access to affordable medicines in public health emergencies by using compulsory licenses

By Servaas van Thiel[1]

[1] Professor van Thiel works for the Council of Ministers of the European Union in Geneva. He teaches international law at the post-graduate Program on International Legal Co-operation of the Free University Brussels, Belgium, and serves as a Substitute Judge in the Regional Court of Appeal in Den Bosch, the Netherlands. The information contained in this article is in the public domain and any views expressed are purely personal and in no way a reflection of the official position of any of the institutions mentioned. The public sources consulted for this contribution include de-restricted WTO documents; WTO Press briefings; the international press; web-sites of the USTR, the European Commission, the Global Trade Negotiations Home Page of the Center for International Development of Harvard University, and civil society organisations (OXFAM, Médecins sans Frontières, Pharmaceutical Industry); Bulletin Quotidien Europe; Inside US Trade and the US Geneva Mission Daily Bulletin.

Table of contents

1. Patents versus patients: from a technical issue discussed in specialised international organisations to a societal issue negotiated in the WTO framework

The possible negative role of existing systems of patent protection on the availability of affordable medicines has for quite some time been discussed in the limited spheres of specialised international fora. In particular the World Health Organisation (WHO) has been preoccupied with access to and rational use of medicines. In 1977 its Executive Board (EB), following a request from the World Health Assembly (WHA), introduced a first model list of essential drugs[2] and the provision of these drugs was identified as one of the eight elements of primary health care in the 1978 WHO Alma-Ata Declaration. This drugs strategy was accompanied by an active stance on rational, including generic, prescribing which resulted in the WHO Guide to good prescribing[3]. It was only natural, therefore, that in 1996 the WHO started looking into the public health impact of certain WTO agreements and in particular of the agreement on Trade Related Intellectual Property Rights (TRIPS). The organisation sparked controversy, however, when it offered a comprehensive interpretation of key TRIPS provisions in 1999 which inter alia favoured parallel imports and compulsory licensing as price reducing devices[4]. In May 1999 the 52d World Health Assembly adopted an updated version of the "Revised Drug Strategy", which in more moderate wording urged states to use all options under international law to secure access to essential drugs. Since then the issue is regularly followed up in WHO governing bodies (WHA and EB) in an effort to maximise the potential of essential medicines to save life and improve health status[5].

In addition, on the basis of global UN human rights instruments, which recognise both the right to intellectual property protection and the right to health[6], human rights bodies have also been active in the international discussion on patents versus patients. The Geneva based Sub-Commission on Human Rights (consisting of a limited number of independent human rights experts), for instance, clearly assumes a conflict between the implementation of the TRIPS agreement and the realisation of economic, social and cultural rights[7]. In more modest terms, the intergovernmental Commission on Human Rights regularly calls upon states to pursue policies in accordance with international law

---

[2] The Executive Board acted (subsequent to the 1975 resolution of the World health Assembly (WHA28.66). The twelfth list of essential medicines was produced by the WHO expert Committee in April 2002, WHO Technical Report Series no 914.

[3] De Vries et.al (1994): "Guide to good prescribing: a practical manual", WHO Geneva document WHO/DAP/94.11 which inter alia concerns rational and generic prescribing.

[4] WHO (1999): "Globalisation and access to drugs: perspectives on the WTO Trips agreement", Health Economics and Drugs DAP series no 7 as revised.

[5] Following up on the revised drugs strategy in 2001 the 54th WHA adopted three intellectual property related resolutions: "Strengthening health systems in developing countries" (WHA 54.13 of 21 May 2001), "Scaling up the response to HIV/AIDS " (WHA 54.10 of 21 May 2001) and "WHO Medicines strategy" (WHA 54.11 of 21 May 2001). The latter provided a framework for action in essential drugs and medicines policy 2000-2003 (Document WHO/EDM/2000.1) with four main objectives: to promote rational use; to increase quality and safety of pharmaceuticals; to improve access to essential medicines; and to provide support for development and implementation of national medicines policies. For a progress report on these see WHO (2002): "WHO medicines strategy: a progress report", Report by the secretariat, document EB111/30 of 13 December 2002.

[6] Article 27 para 2 of the 1948 Universal Declaration on Human Rights, Article 15 of the 1967 International Covenant on Economic, Social and Cultural Rights and Article 29 of the Draft Declaration on rights of indigenous people recognise the right to protection of intellectual property. Article 25 of the Universal Declaration and Article 12 of the International Covenant on Economic, social and Cultural Rights refer to the right to health.

[7] Resolution 2000/7 of the Sub-Commission E/CN.4/Sub.2/RES/2000/7 of 17 August 2000 invited the High Commissioner to report on the issue which she did in June 2001 (E/CN.4/Sub.2/2001/13 of 27 June 2001). See also the progress report on globalisation in E/CN.4/Sub.2/2001/10 of 2 August 2001 and the even more strongly worded Sub Commission Resolution 2001/21 (E/CN.4/Sub.2/2001/L.11 dd.2 of 16 August 2001.

(including international agreements such as the TRIPS agreement) to promote the availability of pharmaceuticals and medical technologies to treat pandemics such as HIV/AIDS[8].

Unsurprisingly, the World Intellectual Property Organisation (WIPO) also addressed the issue of access to medicines and patents[9]. It commissioned a study from the Washington based International Intellectual Property Institute which concluded in 2000 that access to affordable drugs involves numerous and complex issues including health care infrastructure, international pricing mechanisms, financing and debt, tariffs and patents. The study found that patent protection, though an important issue that should be addressed in the context of public health and the Aids crisis, can not possibly be an important factor impeding access to AIDS medicines in Sub-Saharan Africa, because most anti-retroviral medications are not widely patented in Africa and most sub-Saharan countries are not obliged under the TRIPS agreement to provide patent protection until 2006 (a deadline that was extended in 2002 to 2016). It was, moreover, submitted that even if these drugs were available for free they would not reach more than 10 to 20 percent of the population because of the lack of health care infrastructure to conduct testing, to store and distribute medication and to monitor patient compliance. The study concluded that providing state-of-the-art HIV/AIDS therapies to patients in poor countries required two kinds of subsidies: the indirect subsidy which consumers in developed countries pay in the form of higher prices for patented drugs and direct funding of the treatment infrastructure and the purchase of drugs for patients in poor countries by developed countries and international programs such as UNAIDS[10]. Two years later WIPO itself stepped into the discussion in a more direct way when it published a flyer to identify what it considered the myths that misguided the international debate on access to patented pharmaceuticals[11]. In this publication WIPO underlines that patents stimulate the development of essential drugs, by making expensive and long-term research and development worthwhile, and contribute to society as a whole, by requiring the disclosure of key technical information that can be used by others (no need to reinvent the wheel). According to WIPO a proper balance between public health concerns and the interests of the patent owner exists within the patent system. Contrary to common misconceptions the patent system is not the key factor limiting access to drugs and health care[12] or causing high drug costs [13]. It neither favours corporate interests over the greater

---

[8] See Resolution 2001/33 on access to medication in the context of pandemics such as HIV/AIDS (E/CN.4/RES/2001/33 of 20 April 2001) adopted by the CHR at its 57th Session and Resolution 2002/32 on the same issue (E/CN.4/RES/2002/32) adopted by the CHR at its 58th Session in 2002.

[9] WIPO has a wide range of programs for establishing international legal and administrative intellectual property norms and standards. It supports the initiatives taken by the Secretary-General of the United Nations, and is co-operating with the World Health Organisation, UNAIDS, and the World Trade Organisation, in areas where it can offer its experience and expertise regarding the question of patents and health care. Whereas WIPO has no mandate to interpret the TRIPS Agreement, it provides legal and technical assistance to countries on the implementation of the TRIPS Agreement in accordance with the 1995 WIPO-WTO co-operation agreement. Since 1998, WIPO has provided more than 100 developing countries with a wide range of TRIPS related assistance and WIPO and WTO recently launched another joint initiative to assist least developed countries in implementing the TRIPS Agreement and in using intellectual property as a tool for technological advancement, economic growth, and knowledge and wealth creation. For a detailed overview see the Annual Reports which are available at http://www.wipo.int.

[10] IIPI (2000): "Patent protection and access to HIV/AIDS pharmaceuticals in sub-Saharan Africa: a report prepared for the WIPO", Washington DC (also published on http//wipo.org).

[11] In 2002 WIPO organised a Conference on Patents and Health Systems (25 to 27 March) and published a brochure to dispel a number of myths in the debate on patents and access to drugs ("Striking a balance: the patent system and access to drugs and health care", WIPO Publication 491(E) undated, ISBN 92.805.1066.3 (also published on http//wipo.org).

[12] WIPO notes that problems in access to health care and the availability of life-saving drugs are not primarily due to the patent system, but to socio-economic factors and national health infrastructures. In fact many drugs do not even fall under patent protection in many developing countries, and some 95 percent of the pharmaceutical products on the World Health Organisation's Essential Drug List are no longer protected by patents.

social good[14], nor deters sound competition[15]. Patent protection systems are not especially unfair to developing countries[16] and do not interfere with the basic human right to life-saving drugs.[17]

Towards the end of the 1990ies the trade off between patent protection and access to affordable medicines became an important societal issue attracting the attention of a broader public, when the gruesome pictures of the Sub-Saharan AIDS crisis appeared on western television screens. This caused a civil society controversy over "patents versus patients" in which developing countries and many NGO's increasingly held patent protection responsible for the non-availability of essential medicines to poor patients[18], whereas the pharmaceutical industry and the intellectual property community underlined the need for adequate patent protection to allow the recuperation of high investment costs and the continuation of pharmaceutical research and development[19]. High media attention to the issue was reinforced by several events including the ill fated attempts by the pharmaceutical industry to challenge the TRIPS compatibility of provisions in the South African Medicines Act[20], the US complaint brought under the WTO dispute settlement procedures against

---

[13] WIPO notes that the price of drugs depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing. Even reduced prices that reflect the cost of generic versions are still above the level that patients in some countries can afford.

[14] WIPO underlines that patent protection is available to any inventor, whether an individual, a research institution, or an enterprise in both developing and developed countries. It provides key incentives to inventive work and in return requires adequate disclosure of information which is thus shared with society adding to the general body of accessible technical knowledge in the world. This form of technology transfer is of prime importance in promoting and aiding further research and development in every country, especially in the case of health care products. Medical researchers rely heavily on previous work in developing better drugs to treat diseases.

[15] WIPO qualifies a patent as a form of social contract, administered by the government, that balances the interests of the inventor, by giving exclusive rights for 20 years, with the broader interests of society at large, by requiring disclosure of information. During the patent period, anyone can obtain a patent on an improved invention on the basis of the patent of others. When the patent expires the invention enters into the public domain so that anyone can freely use or reproduce it without having to ask for permission or make payments. The patent system is designed this way to allow new entrants to compete against existing patent holders. At the same time, patent laws often stipulate circumstances under which patent rights could be curtailed or limited, for example, by way of granting non-voluntary (compulsory) licenses, subject to certain conditions.

[16] WIPO stresses that adequate patent protection is an indispensable incentive to creative and inventive work and is crucial to establishing and maintaining an attractive commercial environment. It stimulates domestic innovation, fosters new industries, creates jobs and helps attract foreign investment. An adequate patent system can also help countries develop and strengthen their own research infrastructures and capacities and adequate intellectual property systems are a key factor in sustained economic development, which ultimately helps break the cycle of poverty and leads to better education, higher living standards, and better healthcare for the people.

[17] Both the right of any individual to enjoy the material and moral benefits as a creator of intellectual property, and the right of all human beings to a standard of living that affords adequate health and medical care, are set forth in the United Nations Universal Declaration of Human Rights (Articles 25 and 27). They are not contradictory but should be seen as complimentary because the former rights afford the enjoyment of the latter rights through progress and innovation in science. International intellectual property treaties, including those relating to patents, fully comply with the Declaration.

[18] For a list of OXFAM studies in the framework of its 2001 "Cut the cost campaign" see http://www.oxfam.org/eng/campaigns_camp_cutcost.htm:. See also http://www.accesssmed-msf.org.

[19] See for instance the web-site of the European Federation of Pharmaceutical Industries and Associations (EFPIA) http://www.efpia.org (which inter alia posts the EFPIA Position paper on the WTO Millennium Round (July 2001).

[20] See Financial Times of 5 March 2001 (The case was mutually settled on the basis of a joint statement on 20 April 2001). Industry complained that Section 15 c of ACT 90/97 gave the South African health Minister wide discretion in allowing parallel imports of medicines that were put on the market elsewhere (at lower prices) with the consent of the right-holder. The legal basis for the complaint was questioned, however,

the Brazilian compulsory licensing scheme[21] and the post September 11, 2001 discussion in the USA and Canada to grant compulsory licenses for the domestic production of the anti-biotic Cipro required to treat human beings exposed to anthrax[22].

In particular at the turn of the century the issue started figuring high on the international political agenda including at the June 2001 Special Session of the UN General Assembly on HIV/AIDS and the July 2001 G8 Heads of State and Government in Genoa which resulted in the establishment of the Global Fund to help finance the fight against HIV/AIDS, Tuberculosis and Malaria[23]. In none of these international fora, however, was there a possibility to come to a legally binding solution on the question to what extent public health considerations should be allowed to override existing rules on the protection of intellectual property rights, including those of the patent holders of pharmaceutical products. Negotiations on that question could in fact only take place within the framework of the World Trade Organisation's agreement on Trade Related Intellectual Property Rights (TRIPS), which sets a number of enforceable minimum standards of intellectual property protection while at the same time providing for a certain flexibility to override those patent rights for public health reasons.

It was the African Group which, in the run up to the Fourth WTO Ministerial Conference in Doha (November 2001), first brought the issue to the June 2001 TRIPS Council where it quickly gathered importance as Members almost unanimously agreed the need for a separate Ministerial Declaration on that issue at the DOHA Ministerial. In a very short period of time the WTO agreement on intellectual property rights had moved centre stage in the international political debate on the relation between the protection of intellectual property rights and access to affordable medicines.

The purpose of this contribution is to describe the attempts made within the World Trade Organisation to balance the need (and the right) of the disease stricken populations in the poorest developing countries (and in particular those in Sub-Saharan Africa suffering from epidemic diseases such as HIV/AIDS, Tuberculosis and Malaria), to have access to affordable medicines, with the need to ensure the continued incentive effect of patent protection on private sector research and development of new medicines. To that end some general remarks will first be made in para 2

---

because whereas the TRIPS agreement grants the right holder the exclusive right to produce and import (Article 28 para 1) it also leaves the issue of exhaustion to national jurisdiction (Article 6). Any country is thus free to assume that the rights of the patent holder are exhausted once the product is put on the market anywhere with his consent (regime of international exhaustion).

[21] See case WT/DS199 concerning the grounds on which a compulsory license can be granted under Article 31 TRIPS (mutually settled in July 2001). In this case the USA contested the WTO compatibility of Brazil's Industrial Property Law 9279 of May 1996 for allowing compulsory licensing if the subject matter of a patent is not locally worked. This means that the patent owner can, in derogation of his exclusive rights, be forced to share his invention if the patented product is imported rather than produced domestically in the country granting the compulsory license. The TRIPS agreement itself does not specify the grounds on which a compulsory license can be granted.

[22] See international press between 18 October and 3 November 2001. The Cipro case was important because it did not concern a supply shortage in the case of an epidemic, but it was a unique example of two developed countries (USA, Canada) considering compulsory licensing to reduce the price of the imported drug (as clarified by public health officials in the International Herald Tribune of 18 October 2001 at 2 and the Financial Times of 23 October 2001 at 19).

[23] Subsequent to the July 2000 G8 summit leaders in Okinawa which endorsed the International Development targets for HIV/AIDS, tuberculosis and malaria, the September 2000 European Commission new policy framework for tackling these three diseases, the April 2001 UN Secretary General call to create a Global Fund to fight HIV/AIDS, the April 2001 OAU Abuja Summit, the June 2001 UN General Assembly Special Session on HIV/AIDS and the July 2001 G8 Summit in Genoa, a Global Fund was established as a financial facility to help fight the spread of HIV/AIDS, Tuberculosis and Malaria. For information see http//globalfundatm.org.

on the broader interface between trade and public health[24] and on the more specific relation between patent protection and access to medicines under the TRIPS agreement, including the outcome of the November 2001 WTO Ministerial Conference in Doha. Para 3 will focus on the main issues that arose in the DOHA follow up negotiations in Geneva on the possibility to create additional flexibility for countries without pharmaceutical production capacity so as to allow them access to affordable medicines through compulsory licenses. The reasons for the failure of these follow up negotiations to produce a result by the agreed 20 December 2002 deadline and the repair efforts undertaken since then will be addressed in paragraph 4 together with some final observations.

2. International trade, public health and patent protection in the WTO: DOHA confirms the state of play, but calls for negotiations to create additional flexibility

The underlying assumption of the classical theory of international trade is that international division of labour will result in a more rational allocation of production factors, because it allows for specialisation (which again facilitates the acquisition of skills and know how and the formation of capital) and the realisation of economies of scale. As a result more output can be produced with less input which results in an overall raising of the standards of living. Free trade is the condition sine qua non for this beneficial process of economic integration or globalisation. Unsurprisingly therefore, the intermediate policy objective of the World Trade Organisation (WTO) is to liberalise trade[25] in the framework of an open, rules based, multilateral trading system which is dynamic in the sense that new rules can be added through regular multilateral trade negotiations, while existing rules are enforced through a multilateral and binding dispute settlement mechanism.

The process of trade liberalisation, however, is not an end in itself, but has the ultimate and fundamental objectives of raising standards of living, ensuring full employment and economic growth, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development[26]. Against the background of these more fundamental end-objectives there has traditionally been a clear recognition in international trade agreements that commercial considerations may in certain circumstances have to be sub-ordinated to legitimate and overriding public policy objectives.

The need to protect public health[27] is one of these policy objectives which may in certain circumstances justify restrictions on trade, and this is fully recognised by the World Health Organisation as well as the World Trade Organisation. The World Health Organisation's International Health Regulations, for instance, which are the legal framework for WHO's efforts to prevent the global spread of infectious epidemics, allow time-limited trade or travel restrictions that

[24] For an elaborate study into the relationship between trade and public health see: WHO/WTO (2002): "WTO agreements and public health, A joint study by the WHO and the WTO Secretariat", WTO Geneva (ISBN 92.870.1223.7 or 92.4.156214.5).

[25] The third pre-ambular paragraph to the Marrakech Agreement establishing the WTO reads: "Being desirous of contributing to these objectives by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations".

[26] The first pre-ambular paragraph to the Marrakech Agreement establishing the WTO reads: "Recognising that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development".

[27] The WHO defines health as a "state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". Public health refers to all organised measures (whether public or private) to prevent disease, promote health, and prolong life of the population as a whole. WHO/WTO (2002) at 23.

may be necessary to prevent the spread of infectious diseases, provided these cause minimal disruption of international trade flows[28]. Likewise several World Trade Organisation agreements seek to define a balance between public health protection and free trade. The 1947 General Agreement on Tariffs and Trade (GATT), with its overriding objective of eliminating trade barriers, already explicitly recognised the right of Members to restrict imports and exports if necessary to protect the health of humans, animals and plants[29]. Moreover, the WTO agreements on technical barriers to trade (TBT) and on sanitary measures (SPS) allow Members to take measures that restrict trade in the interest of protecting public health, but at the same time seek to ensure that those measures do not unnecessarily restrict trade.[30] The SPS agreement, which deals with specific health risks, allows Members to restrict trade to ensure food safety (measures concerning additives, contaminants, toxins and drug and pesticide residues) and the protection of human life from plant or animal carried diseases, but requires a scientific justification for such measures. The TBT agreement allows for the setting of domestic standards and technical regulations in a wider context than just public health, but requires that scientific information is taken into account. Furthermore the General Agreement on Trade in Services enables (but does not oblige) WTO Members to make market access and national treatment commitments as regards health services in the four modes of supply (cross border supply, cross border consumption, cross border establishment and cross border movement of natural persons). This could, in addition to (public) health care that is domestically available, allow supplementary access to highly skilled foreign medical specialists or inward foreign investment.

The need to protect intellectual and industrial property rights is another public interest objective that has traditionally been recognised as capable of overriding free trade principles. Though the international protection of those rights is guaranteed by a series of highly specialised international agreements which are partly administered by the World Intellectual Property Organisation (WIPO), the protection and enforcement[31] of several of these rights[32] was imported into the WTO legal system (and thus brought within the scope of its dispute settlement mechanism[33]) by means of the

---

[28] The 1951 International Sanitary Regulations (WHO Regulations No 2, adopted by the Fourth WHA in 1951 in accordance with Article 21 of the constitution) constituted the first single international code of measures for preventing the international spread of designated infectious diseases and contained reporting and notification requirements of outbreaks of these diseases. They were replaced in 1969 by the International Health Regulations which were revised in 1973 (cholera) and 1981 (smallpox). Another revision is underway since 1995 at the request of the WHA (Resolution WHA48.7). The Regulations serve as the framework for WHO's outbreak alert and response activities and the revision process is based on three challenges: ensuring that only public health risks that are of an urgent international importance are reported; avoiding stigmatisation and unnecessary impact on international travel and trade; ensuring the system is sensitive enough to detect new or re-emerging public health risks. It is expected that the revised Regulations will be ready for submission to the 58th WHA in 2005 (see document EB111/34 of 15 December 2002 at 3).

[29] Article XX (b) GATT reads: "Subject to the requirement that such measures are not applied in a manner which could constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (b) necessary to protect human, animal or plant life or health;".

[30] Both SPS and TBT favour the formulation of international standards and the SPS explicitly recognises the food safety standards agreed in the framework of the FAO/WHO Codex Alimentarius Commission.

[31] The Trips Preamble refers to the need to promote effective and adequate protection of intellectual property rights, which it recognises as private rights, and to ensure that measures and procedures to enforce those rights do not themselves become barriers to legitimate trade. The Preamble also recognises the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods.

[32] The Trips agreement more specifically relates to copyright, trademarks, geographical indications, industrial designs, patents, layout designs and integrated circuits.

[33] Article 64 Trips declares Articles XXII and XXIII GATT 1994, as elaborated and applied by the DSU, applicable to disputes under the Trips agreement, but a 5 year moratorium is provided for non violation complaints (Article XXIII paras 1b and 1c).

TRIPS agreement. This agreement essentially obliges WTO Members not only to provide protection for these rights[34] (and ensure national- and most favoured nation treatment as regards this protection), but also to adopt procedures that enable right holders to ban imports of counterfeit or pirate products[35]. The TRIPS agreement thus gives a response to the concern that trade liberalisation may expose developers of know how and technology to unfair competition from imports of unauthorised copies of their products, a concern that had already been recognised by the 1947 GATT[36]. At the same time, however, the TRIPS agreement stresses the need for transfer of technology to developing countries for the purposes of economic development.[37]

The TRIPS agreement, and in particular its Section 5 on patents[38], is relevant for the protection of public health as it obliges Members to protect pharmaceutical patents (with delays for developing countries[39]), while at the same time allowing them to make exceptions for public policy reasons such as the need to ensure affordable access to existing drugs. In fact TRIPS on the one hand provides exclusive rights to pharmaceutical inventions, thus allowing the pharmaceutical industry a period of twenty years to recuperate its costs of research and development and to earn a return on invested capital. On the other hand TRIPS sets out the conditions under which Members can provide limited exceptions to the exclusive rights conferred by a patent (Article 30 TRIPS)[40] and may authorise other use of the patent by the government or third parties, by obliging a patent holder to share his invention with others by means of compulsory licensing (Article 31 TRIPS)[41].

---

[34] Protection is widely defined as including matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights. Footnote 3 to Article 3 para 1 Trips.

[35] Articles 51 to 60 Trips oblige Members to establish procedures to enable right holders (subject to evidence, security and compensation requirements) to request the suspension of the release into free circulation for up to 10 days (20 if a legal procedure is started) of counterfeit trademark or pirated copyright goods and enable authorities to order destruction or disposal of infringing goods. Article 61 Trips obliges Members to provide for criminal procedures and penalties for wilful trademark counterfeiting or copyright piracy.

[36] Article XX d GATT provides that nothing in the agreement shall be construed to prevent the adoption or enforcement by any Contracting Party of measures necessary to secure compliance with laws or regulations relating to the protection of patents, trade marks and copyrights and the prevention of deceptive practices (provided such measures neither are contrary to the GATT, nor constitute a means of arbitrary or unjustifiable discrimination or disguised restriction on international trade).

[37] Many developing countries, however, have criticised TRIPS as an instrument to prolong the unfair global distribution of know how and technology by effectively giving high tech economies a protected monopoly position for relatively long production periods, without equally effective provisions on the sharing of protected technology. Developing countries also complained about the misuse of intellectual property rights by Western industry to usurp traditional know how that originated in developing countries and opposed the patentability of genetically engineered plants or animals by Western industry as this might disrupt the way agriculture has been conducted all over the world over many centuries. This perceived fundamental imbalance in the Trips agreement has lead to contentious discussions in the framework of the WTO debate on implementation issues, which was launched in particular after the 1998 Geneva Ministerial Conference, and in which developing countries insisted on full compliance with those Trips provisions that foresee transfer of technology as well as special and differential treatment for developing countries.

[38] Section 5 of the TRIPS agreement (Articles 27 to 34), relates more particular to patents and concerns respectively the patentable subject matter (essentially any new inventions capable of industrial application, Article 27), the rights conferred (essentially the exclusive right to produce and sell for a period of 20 years, Article 28 and 33), the conditions on patent application (essentially the disclosure requirement, Article 29), the exceptions (including the limited exception of Article 30, and the compulsory licenses of Article 31) and certain procedural and due process requirements (Articles 32 and 34).

[39] Articles 66 para 1 and 65 para 4 TRIPS.

[40] Article 30 TRIPS allows Members to provide limited exceptions to the exclusive rights conferred by a patent, provided, that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[41] Article 31 TRIPS does not mention the grounds on which a compulsory license may be granted, thus

In the run up to the DOHA Ministerial it was clear that negotiations on any text touching on this carefully crafted balance in the existing TRIPS provisions would be very difficult. There was, however, a strong push to come to a positive outcome in DOHA partly because of the high profile of the issue (no country could afford to fail), partly because it was one of the few development related issues on which a concrete result in the form of a high profile political declaration could be achieved, and partly also because of the impact of the anthrax episode on important players such as the USA and Canada[42]. And indeed in DOHA agreement was reached on a separate Ministerial Declaration on the TRIPS agreement and public health[43].

The DOHA Declaration essentially confirms the existing TRIPS balance between the preservation of patent rights and the need to promote the availability of affordable medicines to the poor. In a first part it starts with an introduction to the issue by recognising "the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (para 1), while at the same time stressing that the TRIPS agreement should be part of the solution (para 2). Similarly the Declaration recognises that intellectual property protection is important for the development of new medicines, while also recognising concerns about its effects on prices (para 3).

Subsequently, in a second part containing the more operative paragraphs 4 and 5, the Declaration reiterates that the TRIPS agreement does not and should not prevent WTO Members from taking measures to protect public health[44]. Consequently, while reiterating the commitment of all WTO Members to the TRIPS agreement, the Declaration affirms that interpretation and implementation of that agreement should be supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection Ministers reaffirmed the right of WTO Members to make full use of TRIPS flexibility to address public health issues[45] including in particular the right of each Member to grant compulsory licenses and determine the grounds upon which such licenses are granted (sub-paragraph 5b), and the right of each Member to determine what constitutes a national emergency or other circumstances of extreme urgency (sub-paragraph 5c).

Both these sub-paragraphs refer to Article 31 TRIPS which contains the conditions under which a WTO Member may force the owner of a patent to give up his exclusive rights and share his invention with others. More specifically, Article 31 recognises the right of Members to authorise the

---

leaving this decision to the full discretion of national authorities, but merely stipulates the conditions under which a compulsory license may be granted.

[42] In the fall of 2001letters with anthrax were circulated in the USA thus further increasing public insecurity after the September terrorist attacks in New York and Washington. Both the USA and Canada considered issuing compulsory licenses for the domestic production of the Bayer patented anti-biotic Cipro. See also Footnote 22.

[43] WT/MIN(01)/DEC/W/2 of 14 November 2001. For an excellent background analysis of the genesis and contents of the Declaration see Kampf R. (2002): "Patents versus Patients?", 40 Archiv des Völkerrechts of 2002 at 90 to 134, Mohr Siebeck (ISSN 0003-892-X).

[44] Article 8 TRIPS explicitly recognises that Members may adopt measures necessary to protect public health and nutrition, (and to promote the public interest in sectors of vital importance to their socio-economic and technological development), provided that such measures are consistent with the provisions of the TRIPS agreement.

[45] Para 5a provides that in applying the customary rules of interpretation of public international law, each provision of the TRIPS agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles. Article 7 TRIPS (Objectives) provides inter alia that intellectual property rights should be protected and enforced in a manner "conducive to social and economic welfare", and Article 8 (Principles) inter alia recognises the right of Members to adopt measures necessary to protect public health and nutrition. contribute to

use of a patent in derogation of the exclusive rights of the right holder (by means of a compulsory license), provided that every authorisation is considered on its individual merits (a), is preceded by efforts by the proposed user to obtain authorisation from the right holder on reasonable commercial terms (b), is granted for a limited duration (c), is non-exclusive (d), is non-assignable (e), is granted predominantly for the supply of the domestic market of the authorising Member (f), is terminated if no longer necessary (g), is accompanied by payment of adequate remuneration to the right holder (h), and subject to judicial review (i and j). Moreover, and in derogation of these conditions, Article 31 (b) provides that the compulsory requirement that the proposed user should first try to obtain authorisation from the right holder on reasonable commercial terms, may be waived inter alia "in the case of a national emergency or other circumstances of extreme urgency" (ex post notification of the right holder replaces ex ante efforts to obtain authorisation on reasonable commercial terms).

In brief the operative part of the DOHA Declaration thus reaffirms the right of WTO Members to use, to the full, the existing TRIPS flexibility including the right to grant compulsory licenses, even without prior attempt to contact the right holder, in case of a national emergency.

Finally, in a third part (paras 6 and 7), the Declaration reaffirms the existing commitment of developed Members to provide incentives to their private industry to encourage the transfer of technology to least developed Members[46] and instructs the TRIPS Council to undertake further work on two outstanding issues. First, after recognising that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing" it instructs the TRIPS Council "to find an expeditious solution to this problem and report to the General Council before the end of 2002". Second, while agreeing to waive the obligation of least developed countries to provide patent protection with respect to pharmaceutical products until 1 January 2016, it instructs the TRIPS Council to take the necessary action for that purpose.

Whereas the TRIPS Council has come to an agreed text on the second issue[47], negotiations on additional flexibility for countries without pharmaceutical production capacity have not (yet) resulted in a consensus text, although the compromise text that was proposed on 16 December 2002 by the TRIPS Council Chair, comes very close to a possible final solution, as will be clarified in the subsequent paragraphs.

3. The Geneva negotiations on additional flexibility for countries without pharmaceutical production capacity: five major issues on which a compromise solution could be found

In line with the DOHA mandate discussions took place in the framework of the WTO TRIPS Council on the possibility to allow certain countries in certain circumstances to import medicines

[46] Article 66 para 2 TRIPS provides that developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

[47] On 27 June 2002 the TRIPS Council formalised part of paragraph 7 of the Doha Declaration on TRIPS and public health by approving a decision extending until 2016 the transitional period during which least-developed countries do not have to provide patent protection for pharmaceuticals. It also approved a waiver that exempts least-developed countries from having to provide exclusive marketing rights for any new drugs in the period when they do not provide patent protection (approved by the General Council on 8 July 2002). This constitutes a double derogation to the TRIPS agreement which allows developing countries to postpone patent protection for pharmaceuticals for shorter periods and which obliges countries using that possibility to still allow inventors to file patent applications (mailbox provision of Article 70 para 8), and to grant them exclusive marketing rights for five years from the moment that country's health authority approves the new drug for sale. WTO (2002): "Intellectual property: TRIPS and public health - Council approves LDC decision with additional waiver", WTO DDA Press/301 of 28 June 2002.

that were produced under a compulsory license in another country, in spite of the Article 31f TRIPS obligation that the production under a compulsory license should predominantly be sold on the domestic market. The discussion was informed by five proposals, submitted by respectively the African Group, Brazil speaking for 14 Latin American and Asian countries (hereafter Brazil plus), the United Emirates, the EU and the USA[48], a Swiss and a South-African non-paper, several Secretariat background papers and an EU compromise proposal dated 7 November 2002[49].

It was already clear in DOHA that the Geneva follow up negotiations would be difficult. The main controversial issues throughout the discussions were which countries should be allowed to import, which products, for what diseases, from which possible exporters, and under what safeguards, and through which legal form this additional flexibility should be created[50]. Though in general terms all Members agreed on the need to stay as closely as possible to the DOHA declaration, there appeared to be much room for interpretation on all these issues. In spite of positive press reports on progress made at the November 2002 Sydney Mini-Ministerial meeting, the situation on the ground in Geneva remained problematic with wide divergences on all of the main issues[51].

In fact throughout the second part of November there seemed to be a hardening of positions of the extreme sides in the debate. Developing countries, rather than actively seeking the middle ground, reiterated their maximum positions on many crucial issues in order to obtain the largest possible flexibility to use compulsory licenses. This position was motivated partly by the need to have access to affordable medicines to combat major diseases, partly by commercial reasons of countries with a substantial generic industry, and perhaps even by more overall tactical considerations related to the DOHA negotiations and the upcoming Cancun Ministerial Conference (September 2003). Major producer countries, alarmed by their pharmaceutical industry, reiterated fears for trade diversion

[48] The five proposals include IP/C/W/351 Kenya on behalf of the African group, IP/C/W/352 European Communities and their Member States, IP/C/W/354 United Arab Emirates, IP/C/W/355 Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela (at the TRIPS Council meeting, the Philippines also associated itself with the proposal), IP/C/W/358 United States.

[49] Ever since DOHA the EU has tried to bridge opposite positions of developing countries who sought maximum additional flexibility to use compulsory licenses, and of reluctant producer countries who feared trade diversion and erosion of patent protection standards with adverse effects on their industry and on future pharmaceutical research and development. The EU compromise paper is posted on the web-site of the European Commission.

[50] The WTO Secretariat compiled Member's views on possible elements of the proposed mechanism which allowed an easy identification of the diverging positions on all key questions. IP/C/W/363 of 11 July 2002, IP/C/W/363/Add.1 of 23 July 2002.

[51] Other contentious issues that arose during the negotiations included an African proposal for a comprehensive moratorium on disputes against any Member that would take measures to address the international and national health concerns in countries with insufficient or no manufacturing capacity, for as long as it would take the international community to effectively combat the diseases, as determined by the World Health Organisation in accordance with its statutes, and another African proposal that non-violation complaints under Articles XXII and XXIII of GATT 1994 as incorporated in Article 64 of the TRIPS Agreement would not be exercised with respect to any non-discriminatory intellectual property measure adopted to address public health concerns in member countries with insufficient or no manufacturing capacity in the pharmaceutical sector. Controversial also was the Swiss/New Zealand proposal for public competitive tenders to ensure that the Member in need of pharmaceutical products would obtain the offer quickly and efficiently while ensuring transparency. Such members could be assisted by the WTO or the WHO. A proposal from Africa/UAE/Brazil plus to require concrete action from Developed Members to transfer know how and technology, including incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members, was opposed by the USA which insisted that a solution under paragraph 6 of the Declaration could only provide or facilitate technology transfer if developed country Members were not included as exporters. If developed country producers were included there would be no incentive for production capacity to shift to developing and least developed countries.

and erosion of patent protection standards with adverse effects on industry and on future pharmaceutical research and development. Their nervousness was increasing in particular on the potentially wide country and product scope of the proposed mechanism and the lack of legally binding safeguards leading to a lack of balance ("if the scope is wide, the safeguards must be tight").

In December the issue went backwards and forwards between the TRIPS Council, the General Council and the TNC. On 16 December the TRIPS Council Chair (Mexico) courageously submitted a text under his personal responsibility, and this text in fact bridged the opposite positions in the debate on five out of the six main outstanding issues.

First, on the question of **the beneficiary importing countries** the DOHA Declaration contained several contradictory indications. In para 1 it referred to "public health problems afflicting many developing and least-developed countries" suggesting that the Declaration itself only covered a limited number of countries. In para 6, however, it recognised the difficulty of "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector" of making effective use of compulsory licensing and instructed the TRIPS Council "to find an expeditious solution to this problem".

In the Geneva negotiations all WTO Members agreed that least developed countries should automatically qualify as potential beneficiaries of the proposed mechanism without any need for further examination as to eligibility. A major disagreement, however, arose over possible other beneficiaries. Most WTO Members relied on para 6 and believed that any WTO Member which considered that it had insufficient manufacturing capacity (including importing countries where the product is not patented[52]) should be able to benefit from the mechanism, but they indicated that they would respect the choice of developed countries not to be included (self-exclusion). Important producer countries, on the other hand, relied on para 1 of the DOHA Declaration, and recalled that the Sub-Saharan AIDS crisis had been at the origin of the entire discussion. They therefore believed that only least developed and low income developing countries (according to the World Bank classification) should benefit from the mechanism, thus excluding high-income developing countries and OECD countries (and with special conditions applying to requests from importing countries where the product is not patented[53]). A closely related issue was whether the DOHA eligibility condition of having "no or insufficient manufacturing capacity" should be self-assessed by each Member as a matter of discretion[54], or whether conditions and objective criteria should be formulated as regards such self-assessment by the TRIPS Council[55], possibly with some kind of oversight process providing for a case-by-case examination allowing rebuttal.

---

[52] There may be no patent in certain countries on the pharmaceutical products concerned either because the producer did not register a patent, or because the TRIPS Agreement or the provisions on pharmaceutical patents are not yet in force in certain countries.

[53] These conditions were suggested to take the form of either notification requirements to the WTO or a limitation of the circle of potential exporters to other developing or least-developed Members.

[54] Some members further specified that the assessment should be on a product by product basis i.e. the country's production capacity of a specific drug, taking account of production capabilities in active substances and not just in final pharmaceutical products. Others remarked that the assessment should not be limited to any one point in time as ability to manufacture is a dynamic concept, and that manufacturing capacity should not be viewed solely in terms of technological capability but should take into account economic feasibility and economies of scale.

[55] In its 7 November compromise the EU suggested two major steps in the self assessment process including the question whether the Member has manufacturing facility to make active ingredients (if not import to be allowed; if yes can ingredient be produced in sufficient quantities) and whether the member has a manufacturing facility which, once it has access to the active ingredients, can make the final product (if not import to be allowed; if yes can final product be produced in sufficient quantity). The result of these steps should be notified for review to the TRIPS Council on a regular basis.

The compromise solution suggested in the 16 December 2002 text of the Chair defines eligible importing Member in Article 1(b) as any least-developed Member and any other Member that notifies the TRIPS Council of its intention to use the system (no approval from any WTO body required). However, 23 WTO Members agreed up-front to be listed as non-user of the system[56] and some other WTO Members stated that they would use the system only in situations of national emergency or other circumstances of extreme urgency. In addition the Annex to the draft Decision specifies that eligible Members (other than least developed countries) may themselves establish that they have no or insufficient productive capacity in the pharmaceutical sector. Only in the latter case does the Annex provide in a more objective way that: "When it is established that such capacity has become sufficient to meet the Member's needs, the system shall cease to apply".

Secondly, on the question what products countries should be allowed to import under the special mechanism the DOHA Declaration was also ambiguous because in para 1 it seemed to refer to medicines required to address "public health problems" "especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics", whereas in para 4 it referred to "WTO Members' right to protect public health and, in particular, to promote access to medicines for all", and in para 6 it referred to "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector".

The question arose in Geneva whether the proposed mechanism should only cover end products i.e. patented medicines or also active ingredients or intermediate products and patented production processes. In general developing countries wanted a wide product coverage including not only end products or medicines but all public health-related products, including active pharmaceutical substances and diagnostic kits, as well as related technical processes and equipment. Most industrialised countries initially wanted to limit the product scope to patented pharmaceutical products and pharmaceutical products manufactured through a patented process, but many among them subsequently recognised the constructive ambiguity of the DOHA Declaration as regards the coverage of active ingredients and diagnostic kits. Others insisted, however, that the solution should be confined to patented pharmaceuticals and also believed that the proposed mechanism should only cover those patented pharmaceuticals needed for the diseases explicitly mentioned in para 1 of the DOHA Declaration (see below).

The compromise solution suggested in the 16 December 2002 text of the Chair refers to "pharmaceutical product" which it defines as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in para 1 of the DOHA Declaration. It adds that it is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included. That compromise therefore takes account of the wish of developing countries to have a product coverage that goes beyond patented pharmaceuticals, while also linking the product coverage to the type of diseases mentioned in para 1 of the DOHA Declaration.

Third, on the question of exporting countries the DOHA Declaration did not contain any direct reference, but contained very broad formulations (including in the negotiating mandate in para 6) that could be interpreted as referring to importing and exporting countries. As such para 4 provided that "the TRIPS agreement does not and should not prevent Members from taking measures to protect public health" and that the agreement "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". Moreover, para 5 b stipulated that "Each Member has the right to grant compulsory licenses" and the freedom to determine the grounds upon which such licenses are granted. Again para 5 c gave each Member the right "to determine what constitutes [a national

[56] Australia, 15 EU Member States, Canada, Iceland, Japan, New Zealand, Norway, Switzerland, and the USA.

emergency or] other circumstances of extreme urgency".

In the Geneva negotiations some industrialised countries initially noted that it would be best to limit this circle to developing countries only as this would stimulate transfer of technology and creation of local production capacity. They also voiced the concerns of their established pharmaceutical industry that inclusion of developed countries in the list of potential exporters risked distorting competition within developed countries between the patent holders and their generic competitors (who could benefit through stockpiling or economies of scale). Others suggested that developing countries should be the suppliers, at least in cases where the resources from the Global Fund were used to fight epidemics. Most Members[57], on the other hand, saw no reason to limit the circle of exporting countries. They argued that the specific product concerned might not be available in any developing country and that importing countries should in any case have the possibility to obtain the best product at the best price.

The compromise solution suggested in the 16 December 2002 text of the Chair refers to "exporting Member" which is defined as any Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member (Article 1c).

Fourth, on the question which **safeguards** should accompany the mechanism the DOHA Declaration was silent. Nevertheless the general position of many industrialised countries was that the wider the product scope and the circle of importing and exporting Members, the more safeguards would be required to prevent trade diversion and other abuses of the mechanism that would undermine the balance between access to affordable medicines and incentives for research into new vaccines and medicines. Developing countries, on the other hand, feared the administrative burden and costs involved in enforcing safeguards and insisted therefore that these should be proportional to available resources and development needs, while not undermining the practical use of the envisaged solution. Nor should these safeguards in any way limit existing flexibility under the TRIPS Agreement as clarified in DOHA or set stricter conditions than already foreseen (no TRIPS plus).

Specific safeguards discussed in Geneva included **transparency to the right holder,** on which producer countries insisted, essentially to allow the right holder a second chance to offer the medicines at low price (as required by Article 31 (b) TRIPS except in case of national emergencies or extreme urgencies) and to obtain adequate remuneration (as required by Article 31 (h) TRIPS). The EU was specific in demanding that both the importing and the exporting Member should promptly notify the right holder of their intention to issue or request the issue of a compulsory licence and that the right holder should be given the opportunity, within a short timeframe after notification, to make an offer to supply the relevant products at strongly reduced prices. In cases of a national emergency or of extreme urgency in the importing Member, the Member authorising the production should not be obliged to first await an offer from the right holder, who should however be promptly notified and be given a short period of time to make an offer.

Also discussed was the question of **transparency to the WTO.** For most industrialised countries compulsory transparency to the WTO by importing and exporting Members of all action under the proposed mechanism[58] was an essential part of the package in particular to allow other Members to monitor possible (re) importation of the products concerned. The USA, Switzerland and Japan submitted that in addition to the importing Members informing the TRIPS Council (transparency), there should be a system to allow interested Members to be responsive and the TRIPS Council to

[57] The EU took position rather late in the debate, but in its 7 November compromise proposal clearly opted for the broader solution of all Members qualifying as exporters.

[58] The intention of importing countries, including those where no patent exists on the relevant pharmaceutical product, to request another Member to issue a licence could be notified to the WTO on the basis of Article 63.1 of the TRIPS Agreement.

keep implementation of the mechanism and possible trade diversion under review. Many other WTO members could be open to compulsory transparency as this would ensure better competition and limit recourse to the mechanism. The African group, however, could only accept a possibility, but not an obligation, to notify intended use of the mechanism either to other Members directly or through the WTO Secretariat and to any relevant international organisations.

In general Members agreed on the need for **safeguards against trade diversion** but controversy arose whether it should be sufficient to give right holders access to legal remedies and provide for strict product-labelling, or whether all Members should be obliged to take the necessary regulatory and administrative measures against trade diversion[59]. Predictably, developing countries, who doubted whether diversion actually was a real problem, essentially sought to place the burden of safeguards against trade diversion on the patent owners, by referring to their right to seek remedies against re-exports out of the "domestic market", and by allowing them to label the exported products for consumption within designated domestic markets. It was also suggested that, before delivering the compulsory licences both for import and production, the producer could make a binding confirmation with respect to the price, quantity, quality and delivery conditions of the pharmaceutical in question as this could help in checking diversion. Industrialised countries, on the other hand, wanted a strong commitment from all WTO Members to take and support measures against trade diversion as already provided for by Articles 28 and 44.1 TRIPS. Exporting Members should ensure that the products manufactured under the compulsory license would, in their entirety, be exported to the requesting importing Member. The importing Member on its turn should ensure that the products were offered for sale, sold and distributed at home and not re-exported, inter alia by means of proper border controls, supervision over the distribution of pharmaceuticals concerned and the imposition of the necessary constraints on the distributor. Some insisted, moreover, that parallel imports should not be allowed as the product was not produced and marketed with the consent or license of the right holder.

A discussion also took place in Geneva on the **applicability of the other Article 31 conditions to both exporting and importing countries and in particular the one concerning remuneration.** According to that Article every authorisation must be considered on its individual merits (a), be preceded by efforts by the proposed user to obtain authorisation from the right holder on reasonable commercial terms (b)[60], be granted for a limited duration (c), be non-exclusive (d), be non-assignable (e), be granted predominantly for the supply of the domestic market of the authorising Member (f), be terminated if no longer necessary (g), **be accompanied by payment of adequate remuneration to the right holder** (h), and be subject to judicial review (i and j).

In general terms industrialised countries argued that all relevant requirements of Article 31, other than Article 31(f), would remain fully applicable, both to the Member granting the licence under the proposed exception and to the country of importation, which, in case the pharmaceutical product concerned were patented there, would also have to issue a compulsory licence for its import.

---

[59] At the time the international press reported a case of illegal diversion of not for profit products which were patented in the EU, delivered from one Member State to Africa at preferential prices under a pharmaceutical company program, and then routed back to another Member State through a number of African states, without the importing company holding the required import license. According to the license holder the total delivery seized by EU customs represented only 1/5 of the illegally diverted medicines, the rest having been delivered to parallel traders in- and outside the Community. The total import value of the product imported by the importing company was estimated at "dozens of millions of Euro".

[60] In derogation of this condition, Article 31 (b) provides that the compulsory requirement that the proposed user should first try to obtain authorisation from the right holder on reasonable commercial terms, may be waived inter alia "in the case of a national emergency or other circumstances of extreme urgency" (ex post notification of the right holder replaces ex ante efforts to obtain authorisation on reasonable commercial terms).

Developing countries on the other hand argued that not all the conditions needed to apply[61] and that a requirement on the importing Member to also issue a compulsory license under Article 31 would be administratively burdensome[62], while possibly resulting in double remuneration of the right holder.

More specifically as regards remuneration to right holder developing countries noted the importance of international mechanisms to assist in funding the compensation required on compulsory licences, and insisted that the patent holder should not in any case be entitled to double remuneration as both compulsory licences would be issued to address essentially the same problem. On the latter point there was broad agreement, but it triggered the question whether compensation should be determined in the country of export or the country where the product is consumed. Some countries argued that the importing Member would be in the best situation to assess the facts and that the amount of compensation would maintain some relationship with the ability of patients to afford the product. According to the USA, on the other hand, the burden should fall on the exporting country (which clearly has more resources than the importing country) and should be worked out taking into account the value of the licence. The amount of compensation payable by the importing Member to the right holder could take into account any compensation paid to the right holder under licence issued in the Member exporting the product. Others believed that the TRIPS Council should establish guidelines for remuneration. It was also noted that suppliers should be encouraged to make medicines available on as-close-to-cost-recovery-basis as possible.

On **safeguards** the 16 December 2002 compromise proposal contains obligations for the exporting Member, the importing Member and other Members. As regards the obligations already listed in Article 31 of the TRIPS agreement Article 2 of the proposal starts from the presumption that the only obligation that is waived for the exporting Member is the obligation not to export production under a compulsory license, but to use the quantities produced predominantly for the supply of its domestic market (Article 31 f). Therefore the exporting Member may produce and export the pharmaceutical product concerned to the extent required by the importing Member, but all other Article 31 obligations remain fully applicable. The same presumption applies to the importing Members in which the product concerned is patented but several of its obligations are waived including the obligation under Article 31 h TRIPS to pay remuneration to the right holder if remuneration is paid in the exporting country and, for certain importers, the obligation under article 31 f and Article 4 of the draft decision not to re-export the products concerned (see below).

In addition the proposal lists a number of other requirements concerning the exporting and importing Member. First, the eligible importing Member must make a prior notification to the TRIPS Council (Article 2 a) specifying the names and expected quantities of the products needed, confirming insufficient or no manufacturing capacity for those products (not applicable to least developed countries), and confirming that where the products are patented in its territory it also intends to issue a compulsory license in accordance with Article 31 TRIPS. Second the compulsory license issued by the exporting Member (Article 2b) must contain a number of conditions. These limit the amount of production to the amount necessary to meet the notified needs of the importing Member and oblige exportation of the entire amount produced to that importing Member. These also provide for clear identification of those products (e.g. through packaging or colouring and

[61] The African group suggested that imports could be permitted either on the basis of the doctrine of regional or international exhaustion of intellectual property rights adopted in the country, or on the basis of compulsory licences issued by other Members that export some of the products produced under the licence, or importation under compulsory licences that issue from legitimate sources abroad.

[62] In this regard the African countries resisted the obligation that the products imported under a compulsory license should be sold predominantly on the domestic market and not be re-exported abroad. The African group insisted to define the term "domestic market" as the market of any regional integration movement and not the market of an individual country/WTO member.

shaping) and for full web-site disclosure prior to shipment of information concerning those quantities and distinguishing features. In addition these oblige the exporting Member to notify the license and conditions to the TRIPS Council[63]. Third, the proposed text (Article 3) explicitly confirms the existing TRIPS obligation that adequate remuneration must be paid to the right holder in the exporting Member, but it prevents double remuneration by specifying that if the product is patented also in the importing Member (which also issues a compulsory license in accordance with Article 31 TRIPS) double remuneration is avoided by waiving the obligation on the importing Member to pay remuneration for that same product. Fourth, to ensure domestic consumption of the products concerned and to prevent re-exportation the importing Members must take "reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion" (with a large exception for Africa)[64]. If a developing country importer experiences difficulty to prevent re-exportation, developed Members shall provide, on request and mutually agreed terms, technical and financial co-operation in order to facilitate implementation of this provision (Article 4). Parallel to this obligation on the importer to prevent re-exportation is the obligation of all Members to ensure the availability of effective legal means to prevent the importation of the products concerned into their territory (Article 5) and any Member that considers such measures insufficient may bring the matter for review to the TRIPS Council.

A fifth question on which views diverged in Geneva concerned **the legal form** which the proposed mechanism should take[65]. Several industrialised countries who favoured a minimal use of the proposed mechanism, suggested that an expeditious, workable, transparent, sustainable and legally certain solution could be achieved through either a moratorium for dispute settlement[66] or a waiver (under Article IX of the Marrakech Agreement)[67] of the TRIPS obligation to use a compulsory

---

[63] This notification must disclose the name and address of the licensee, the products concerned, the quantities, the countries of destination and the duration of the license.

[64] In response to the African request to define "domestic market" in terms of regional integration movements, however, Article 6 of the Draft Decision allows re-exportation of the products concerned from an eligible importing Member to other Members with which it forms a regional trade agreement (in the sense of the GATT or the enabling clause) at least half of the current membership of which is made up of countries presently on the UN list of least developed countries.

[65] Bourgeois J.H.J. and Burns T.J. (2002): "Implementing para 6 of the Doha Declaration on TRIPS and Public Health: the waiver solution", Journal of World Intellectual Property of 2002.

[66] The WTO Agreement does not have any specific provisions concerning decisions on moratoria, but under Article IV:1 WTO the MC/GC has the authority to take decisions on all matters and there is precedent including the moratorium concerning non violation and situation complaints under Article 64.2 of the TRIPS Agreement (extended by the DOHA implementation decision Article 11), the peace clause of Article 13 of the WTO Agreement on Agriculture, and the moratorium on dispute settlement concerning telecommunication accounting rates (Document S/L/19 reports the Understanding on this of the Group on Basic Telecommunications). Ministers' declarations relating to electronic commerce have also been characterised as moratoria on imposing customs duties on electronic transmissions (Declaration on Global Electronic Commerce, adopted by the Second Session of the Ministerial Conference in Geneva in 1998, document WT/MIN(98)/DEC/2 and Ministerial Declaration, adopted at the Fourth Session held in Doha in November 2001, para. 34 of document WT/MIN(01)/DEC/1).

[67] The Secretariat clarified that under Article IX:3 WTO (plus the Understanding in Respect of Waivers of Obligations under the GATT 1994) the MC/GC may waive an obligation imposed on a Member in exceptional circumstances. A waiver request, which is usually by individual Members but can be of a collective nature (see Preferential Tariff Treatment for Least-Developed Countries adopted on 15 June 1999, document WT/L/304, Harmonised System 2002 Changes adopted on 13 May 2002, document WT/L/469 and Least-Developed Country Members Obligations with respect to Pharmaceutical Products adopted on 8 July 2002, document WT/L/478), must be submitted to the relevant Council which has 90 days to examine it and to forward it to the MC/GC for decision-making (by consensus or by three-fourths of the Members, according to Decision-Making Procedures under Articles IX and XII of the WTO Agreement agreed by the General Council in November 1995, document WT/L/93). Under Article IX:4 a waiver states the justifying exceptional circumstances, the terms, conditions and duration of the waiver. Any waiver granted for more than a year must be reviewed annually by the MC/GC to examine whether the exceptional circumstances still

license essentially only for the domestic market (Article 31f), to be granted on a country by country basis. To meet developing countries calls for legal certainty some added that the waiver could be formulated on a long-term basis with the annual renewal requirement being essentially a pro forma assessment of any associated conditions such as transparency, efforts to prevent diversion and applications of the provisions of Article 31.

Most developing countries on the other hand favoured an authoritative interpretation[68] of Article 30 so as to recognise the right of WTO Members to authorise third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country. In this regard Africa submitted that exports could be permitted as a limited and reasonable exception to patent rights under Article 30, or as a ground for a compulsory licence determined by a Member in its own discretion (the ground being to protect public health in another country), or as a measure taken in compliance with UN responsibilities regarding the international health crisis as recognised by the United Nations and the World Health Organisation.

The EU sought a legally secure and long term solution and, after initially favouring an Article 30 solution, ultimately suggested amending Article 31[69] to add a para which would carve out a clearly

---

exist, whether the terms and conditions have been met, and whether to extend, modify or terminate the waiver. These reviews are usually brief and not contentious. To date, some 140 waivers have been granted under Article IX of the WTO Agreement, mostly concerning the Harmonised System and regional trade agreements. The scope of waivers is rarely subject to dispute (but see *EC – Bananas III* in which the EC argued, the panel accepted but the AB rejected, that a GATT Article I waiver also justified a deviation from GATT Article XIII. See also GATT Panel Report on *US – Sugar Waiver* adopted 7 November 1990, BISD 37S/228).

[68] Article IX:2 gives the MC/GC the exclusive authority (*See Japan – Alcoholic Beverages* (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R) at p.12; *US – Wool Shirts and Blouses* (WT/DS33/AB/R) at p.19; and *US – Certain EC Products* (WT/DS165/AB/R) para. 92.) to adopt interpretations, on the basis of a recommendation by the relevant Council, by consensus, or by a three-fourths majority of the Members (but interpretation decisions can not go so far as to amend WTO provisions). No authoritative interpretations have been adopted to date explicitly under Article IX:2 of the WTO Agreement. One request for such an interpretation has been made, but it did not lead to action by the General Council (The 21 January 1999 EC request for an authoritative interpretation of certain provisions of the DSU (document WT/GC/W/133 and document WT/GC/W/143) was opposed by the US *inter alia*, on the basis that the requested interpretation would have amounted to an amendment of the substantive provisions of the DSU and that addressing the request as an interpretation would have contradicted the last sentence of Article IX:2 (document WT/GC/W/144). The General Council did not hold a special meeting to consider the request.

[69] The TRIPS Council may submit a proposal to amend the Agreement in accordance with Article X:1 WTO to the MC/GC which decides (for a period of 90 days by consensus and thereafter by a two-thirds majority), whether to submit the proposed amendment to the Members for acceptance. Article X:7 provides that a Member may accept an amendment by depositing an instrument of acceptance with the WTO Director-General within the time limit specified by the MC/GC. Paragraphs 2-4 of Article X deal with the entry into force of amendments. Paragraph 4 provides that amendments of a nature that *would not alter the rights and obligations* of the Members shall take effect for all Members upon acceptance by two-thirds of the Members. Paragraph 3 provides that amendments of a nature that would alter the rights and obligations of the Members (other than those concerning most-favoured-nation treatment), shall take effect for the Members that have accepted them upon acceptance by two-thirds of the Members and thereafter for each other Member upon acceptance by it. The Ministerial Conference/General Council may decide by a three-fourths majority of the Members that any amendment made effective under this paragraph is of such a nature that any Member which has not accepted it within a period specified by the Ministerial Conference/General Council in each case shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference/General Council. To date, the MC/GC has not submitted any amendments to the Members for acceptance in accordance with Article X of the WTO Agreement. Two proposals to amend the DSU were submitted to the Third Session of the Ministerial Conference held in Seattle in 1999, one by Canada, Costa Rica, Czech Republic, Ecuador, the European Communities and its member States, Hungary, Japan, Korea, New Zealand, Norway, Peru, Slovenia, Switzerland, Thailand and Venezuela in respect of footnotes 6 and 7

circumscribed exception to the "domestic market" restriction imposed by Article 31(f) to allow production and export, under a compulsory licence, of a pharmaceutical product needed to address public health problems in another Member. Pending agreement and entry into force of the amendment, Members should agree on a temporary arrangement such as a dispute settlement moratorium, or possibly a waiver, although the latter was believed to require more time for adoption. Many developing countries could also accept an amendment of Article 31 of the TRIPS Agreement resulting in an elimination or amendment of paragraph f, it being understood that all procedures for an amendment would be completed by June 2003 and that the amendment would be binding on all Members. Moratoria or waivers were not acceptable to some as these would not amount to sustainable or legally predictable solutions.

The proposed compromise text combines the waiver and amendment approaches. It takes the form of a decision under Article IX of the WTO agreement and provides waivers from the obligations set out in Article 31 f (production under compulsory license predominantly for the domestic market) and 31 h (adequate remuneration to the right holder to avoid double remuneration) of the TRIPS agreement. It also provides in its final Article 11 that the Decision and the waivers granted therein shall terminate on the date on which an amendment to the TRIPS agreement replacing its provisions takes effect. The TRIPS Council is instructed to initiate work on such an amendment before the end of 2003 with a view to its adoption within 6 months.

4. The scope of diseases as deal-breaker and repair efforts beyond the Doha deadline

On the question for **which diseases** imports of pharmaceutical products should be made possible the DOHA Declaration contained the same ambiguity as for the product scope since it could be interpreted as referring to the pharmaceutical products needed to address more specifically "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (para 1) or to the wider concepts of "medicines" (para 4) or products of the "pharmaceutical sector" (para 6). In addition, the very wording of para 1 of the Declaration is ambiguous because it does refer to major diseases (which suggests a limitation), but that reference is non-exhaustive in itself (referring also to other epidemics) and also part of the much wider concept of "public health problems afflicting many developing and least-developed countries".

Initially many developed countries submitted that the scope of the diseases should be limited to the ones mentioned in para 1 of the Declaration and that a fact-finding survey should be conducted with regard to which countries faced public health difficulties as a result of which diseases and at what level of seriousness. However, a broad majority of the WTO Membership believed that the mechanism should not be limited to the diseases mentioned in para 1 of the DOHA Declaration, but that it should be up to each Member to decide when it faces a public health problem. They relied on the non-exhaustive nature of the DOHA declaration to claim a large discretion to decide when to use the proposed mechanism.

The discussions went backwards and forwards between these two extreme positions and in the end

---

of the DSU (Document WT/MIN(99)/8) and the other by Turkey that proposed adding a new paragraph to Article 10 of the DSU (Document WT/MIN(99)/15.). Examples of amendments to GATT 1947 include the 1955 Protocol Amending the Preamble and Parts II and III of GATT 1947 (requiring acceptance by two-thirds) which entered into force on 7 October 1957 and the 1965 Protocol to Introduce a Part IV on Trade and Development which entered into force on 27 June 1966. For more information on the GATT practice under Article XXX of GATT 1947, see the Analytical Index, Guide to GATT Law and Practice (WTO, 1995), pp. 1002-1009.

most countries, underlining the humanitarian nature of the issue, accepted the position that it would be very difficult to choose any formulation that would limit the ambiguous wording of para 1 of the DOHA Declaration. The USA, however, where the large majority of pharmaceutical patents are registered and where the bulk of global pharmaceutical research is located, had a more legalistic approach. It felt that the DOHA wording, though ambiguous and agreed, should not be allowed to be construed as covering all medicines for all diseases. It sought reassurance with other WTO Members that this was also their understanding, but did not get a confirmation on that point. It then suggested that the proposed mechanism should cover a list of 22 of the most devastating diseases that frequently occur in Sub Saharan Africa[70] as well as "other epidemics of comparable gravity and scale including those that might arise in the future whether due to natural occurrence, accidental release or deliberate use". But certain other WTO Members felt that this would be a step back from DOHA and the Chair was reluctant to amend his compromise proposal. In a last minute attempt to broker a compromise it was suggested to combine a USA statement, indicating its interpretation of the limited number of diseases covered by the mechanism, with a statement by the Chair of the TRIPS Council that, without prejudice to the DOHA Declaration, the implementation of the proposed Decision would be likely to remain within the limits indicated in the USA Declaration. Though elegant, the compromise fell short of the legal certainty sought by the USA, which consequently reserved its position on the draft decision as proposed by the Chair, leaving the TRIPS Council, in the night of 20 to 21 December, no other choice than to note its failure to resolve the issue[71] and to refer it back to the General Council[72].

The period since 20 December 2002 was characterised by unilateral action as well as some suggestions to try to get the multilateral process out of its deadlock. As regards unilateral action it was USTR Zoellick who end December 2002 explained to all his WTO colleagues that the USA had been unable to join the consensus because "some WTO Members and advocacy organisations" had sought to expand the scope of disease beyond that intended at DOHA to include "a wide range of public health concerns, including obesity, asthma, cancer, diabetes, among others even including the use of viagra". He further indicated that the USA had unilaterally decided that it would not challenge any WTO Member exporting certain medicines produced under compulsory license to a country in need. This unilateral dispute settlement moratorium would apply to certain exporting members (those who notified the TRIPS Council of their issuing a TRIPS-compliant compulsory license), exporting certain products (patented pharmaceutical products or HIV/Aids test kits), to certain beneficiary importing countries (least developed countries, plus developing countries with insufficient production capacities in the pharmaceutical sector, excluding those classified by the World Bank as high income countries), in particular situations (facing a public health crisis

[70] The USA refereed to public health problems arising from yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, HIV/AIDS, leishmaniasis, TB, malaria, hepatitis, leptospirosis, pertussis, polimyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers and arboviruses.

[71] Several developing countries indicated that they would also suggest changes (in particular as regards the proposed safeguards and the legal mechanism) if the 16 December text were to be re-opened on the scope of diseases covered.

[72] In between Ministerial Conferences the General Council has the power to decide issues, in principle, by consensus, but if no consensus can be found, Articles IX and X WTO allow for voting and qualified majority decisions. In practice, however, failing consensus on a matter, further consultations are held with a view to seeking consensus. The only time that the voting procedure has been used was when the General Council, at its meeting of 31 July 1995, agreed to submit the draft decisions on the accession of Ecuador and on certain draft waivers to a vote by postal ballot (pp. 2-5 of document WT/GC/M/6). However, this was done after consensus had been reached on the contents of these decisions. At its meeting of 15 November 1995, the General Council agreed on a statement on the procedures regarding decision-making by the General Council under Articles IX and XII of the WTO Agreement (WT/GC/M/8, pp. 5 and 6, subsequently circulated in document WT/L/93). This document makes it clear that the General Council will seek a decision on a matter related to a request for a waiver or an accession by consensus and that, except as otherwise provided, a vote will be taken only where the matter cannot be decided by consensus.

associated with HIV/AIDS, malaria or tuberculosis or other infectious epidemics of comparable scale and gravity, including those that might arise in the future), and under certain safeguards (both importing and exporting country notify the TRIPS Council of their issuing an otherwise TRIPS compliant compulsory license; exporting country ensures that entire production is exported and that products can be identified through packaging, labelling and product characteristics; exporting Member notifies and publicises information on the licensee, type of products, quantities, destinations, and duration of the license; importing member first gives right holder an opportunity to supply; all economies must take reasonable measures to prevent diversion).

In January 2003 the USA followed up on its dispute settlement moratorium with the announcement by President Bush in his State of the Union address of an Emergency Plan for Aids Relief. The US President invited the US Congress to commit 15 billion USD over 5 years to help turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean.[73]

In January 2003 European Commissioner Lamy announced that pending a multilateral solution the EU would "as a purely stop gap temporary measure" also "refrain from challenging any Member which would want to export medicines according to the terms and modalities set out in the draft decision of 16 December 2002". While containing similar safeguards, the EU moratorium was more generous than the USA moratorium because it referred to the 16 December 2002 Chair's compromise text, thus neither limiting the scope of diseases (reference to open ended para 1 of DOHA Declaration), nor the scope of importing countries (all that consider they have insufficient production capacity except for the 23 countries that excluded themselves), nor the scope of exporting countries (all countries). In addition to the USA and the EU, Switzerland and Canada also indicated that they would apply similar unilateral moratoria.

In order to get the multilateral process back on the rails, Commissioner Lamy proposed, in January 2003[74], as a confidence building measure that should allow full consensus on the 16 December compromise text of the Chair, to assume that all WTO Members agreed that the mechanism would automatically cover the USA list of 22 diseases. For other potential public health problems the Commissioner suggested that WTO members be encouraged to seek advice from the World Health Organisation. In a similar but more restrictive version Japan suggested at the 10 February General Council that any other than the 22 diseases the "TRIPS Council will be mandated to be ready to confirm, if necessary, the coverage of other diseases" and "to make available for itself, as appropriate, views of any outside experts in the course of the deliberations".

However, none of these attempts to reach consensus on a multilateral solution have been successful and in this light it is the more regrettable that no agreement could be reached on the 16 December compromise text of the TRIPS Council Chair. The issue under negotiation is of such political and societal concern, that in itself the negative signal that Geneva was unable to carry out the DOHA Ministerial Mandate to find a solution before the end of 2002, is damaging to the credibility of the WTO as an organisation. It also reinforces the false impression that the WTO is not capable to deal with non-commercial interests and ill equipped to make the necessary trade off between commercial concerns and wider public interests such as the need to protect public health. In addition to this negative political effect on the organisation, the failure to resolve this key development issue, puts a potential roadblock on the way of the Doha Development Round.[75] This is the more so because the February 2003 WTO General Council was also unable to reach positive conclusions on how to facilitate implementation by developing countries of the different WTO agreements and how to operationalise special and differential treatment for them (issues that have been discussed since the

[73] See USA, Office of Public Affairs: "Daily Bulletin" of 31 January 2003, published by the US Mission to the UN in Geneva (subscriptions available at DailyBulletin@usmission.ch).
[74] See for instance Pascal Lamy in Le Monde of 23 January 2003.
[75] See 27 and 28 January 2003 international press reporting on indications made by WTO Director General Supachai at the Davos World Economic Forum.

1998 Geneva Ministerial Conference). These non-results on important development related issues have fuelled developing countries' concerns that the DOHA Round of multilateral trade negotiations is not about development. Though this is not necessarily correct it is a perception that may easily contribute to a further erosion of political support for the New Round in major developing countries. The addition of the delay in the establishment of the market access modalities by the spring of 2003 (March for agriculture, May for non agricultural market access), has resulted in a slow down in the overall preparatory process for the September 2003 Cancun Ministerial Conference, which requires an intensification of preparatory work over the remaining weeks in July and August to avoid an overload of the Ministerial agenda with all the risk involved. An agreed solution to the TRIPS and Public Health issue would certainly help the Cancun preparatory process.

Against this background it is important to further reflect on the reasons why no agreement could be reached on the 16 December 2002 text of the Chair of the TRIPS Council. The primary reason of-course was that the USA refused to join the consensus because it wanted to be ensured that the Doha wording would not be interpreted as not at all limiting the scope of diseases for which eligible Members should be allowed to use the mechanism. Though understandable one might, upon further reflection, wonder whether the US fears of trade diversion and erosion of patent protection for pharmaceuticals were well founded and enough a threat to refuse to join the consensus in the light of the elaborate safeguards provided by the compromise and taking account of the fact that more than 90% of the essential medicines listed by the WHO are produced and marketed without patent protection anyway. On the other hand there were other factors contributing to the failure of the negotiations and some of these are worth mentioning. For instance, it is always dangerous to try to negotiate a key societal issue in the margins of a round of multilateral trade negotiations that must result in a single undertaking of multiple commitments and rules. Not only is that issue bound to become part of the overall negotiating dynamics in which tactical as well as substantive considerations may play a role. It may also be considered on its commercial merits rather than on its humanitarian nature. In other words, what was initially intended to be a mechanism to allow sub-Saharan Africa to have access to generic medicines to address its Aids crisis, became a negotiating subject in which purely commercial considerations had an important impact. Certainly a clash of commercial interests occurred between traditional base countries of pharmaceutical industry, which realised that the proposed mechanism would give extra bargaining power to developing countries when negotiating lower prices with the pharmaceutical industry, and large producers of generic medicines in search of export markets and a way to legally dispose of their products. The latter, though developing countries, had their own reasons not to accept any limit on the scope of importing and exporting countries, or on the scope of the medicines covered by the mechanism (their mantra was that "no step backwards could be made from the DOHA text"), and they opposed the US limited diseases list even though those proposals could have offered a basis for arriving at a real solution for the most devastating and acute public health crisis occurring in sub-Saharan Africa. Furthermore, the highly politicised nature of the debate took the issue out of its proper context and into an unnecessary and unproductive simplification and rigidity of positions and opinions on opposite sides of the debate, whether among representatives of different civil society groupings or among the multilateral negotiators.

Stepping back from the noises of the negotiating table, it seems useful to recall the situation of the poorest countries in Africa and Asia and the need for concrete solutions, in particular in Sub-Saharan Africa where in some countries up to one third of the population is HIV positive. One should also continue to realise that access to medicines depends on a large number of factors including productive capacity, distribution systems, prices and the availability of financial resources in the hands of the patients concerned or their insurance institutions. One can only conclude that in 2002 the negotiators in the WTO missed a unique opportunity to solve one part of this complicated puzzle and to allow countries in need access to cheaper generic medicines under a compromise solution which in combination with a donor financed distribution system (whether through bilateral or multilateral channels) could have made a difference. This failure seems particularly astonishing

in view of the fact that the issue was recognised by Ministers as being of an urgent humanitarian nature, which was the very reason why a Ministerial consensus on a separate DOHA Declaration was achieved in a record time period.

In principle, however, the 16 December 2002 compromise proposal is still on the table and it must be said that it provides for a balanced mechanism that would create the additional flexibility needed by allowing all developing countries to import from all potential sources all pharmaceutical products needed to address serious public health problems, while at the same time comprising elaborate safeguards against trade diversion. In other words developing countries would have a very large discretion to trigger the use of the mechanism, but only on condition of full transparency and full compliance with adequate safeguards against diversion. It is very well imaginable that with a minimum of political will on all sides a solution based on the 16 December 2002 compromise can be reached whenever political attention can be re-focused on the need to address the grave public health concerns in the poorest developing countries. An identification of those grave health problems must be possible on an objectified basis which takes account of real needs on the ground while ensuring, for the benefit of further pharmaceutical research, the maximum possible respect for existing intellectual property rights.

July 2003
Geneva, Switzerland
Servaas van Thiel
