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# *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*

Haochen Sun\*

## **Abstract**

*Designed to respond to concerns about the negative impact of the TRIPS Agreement on access to medicines, the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), adopted at the Doha Ministerial Conference, explicitly clarified for the first time what flexibilities inherent in the TRIPS Agreement can be used by WTO Members to combat a public health crisis. Nevertheless, the Doha Declaration did not fully dismantle the obstacles created by the TRIPS Agreement. Even after the most recent agreement on access to generic medicines in poor countries, serious differences of interpretation and implementation difficulties under the TRIPS Agreement are likely to persist. This article explores the global debate on the TRIPS Agreement and public health, as it has evolved over the years. Specifically, it focuses on the implications, and limitations, of the Doha Declaration. It is argued that the TRIPS Agreement should be implemented and interpreted so as to allow WTO Members the maximum flexibility in increasing access to essential medicines for all.*

## **Introduction**

As evidenced first by the failure of its third Ministerial Meeting in Seattle in December 1999 and, more recently, by a similar failure at Cancun in September 2003, the World Trade Organization (WTO) faces a severe legitimacy crisis.<sup>1</sup> At stake is the ability of the organization to meet the needs of all of its 148 members, in spite of wildly disparate levels of development. Critics charge that trade rules are rigged in favour of rich countries and point to huge human costs in poor countries as a result of unfair trade rules. High on the critics' list is the Agreement on Trade-Related Aspects of

\* LLM Candidate, Faculty of Law, National University of Singapore.

<sup>1</sup> See, e.g., Esty, 'The World Trade Organization's Legitimacy Crisis', 1 *World Trade Review* (2002) 7; Howse, 'The Legitimacy of the World Trade Organization', in J. Coicaud and V. Heiskanen (eds), *The Legitimacy of International Organizations* (2001) 355.

Intellectual Property Rights (TRIPS Agreement),<sup>2</sup> which has come to be viewed as perhaps *the* most controversial WTO agreement of all. On a general level, it is widely blamed for its failure to fully take into account the complex links between intellectual property protection and development. An increasing number of experts question its one-size-fits-all approach and take the view that different levels of development call for different levels of intellectual property protection.<sup>3</sup> In addition, the Agreement has come under attack for severely curtailing the availability of inexpensive copies of patented medicines, raising the price of new medicines in developing countries as a result of patent monopolies, and diminishing public access to essential medicines as a consequence. Most dramatically, the cost of patented drugs has been a significant obstacle to increasing the availability of AIDS treatment in the developing world. In Africa, in particular, millions of people have died due to lack of access to affordable treatment.<sup>4</sup> This has led to an unprecedented public outcry against the WTO, and has done much to de-legitimize the organization in the eyes of the general public.<sup>5</sup>

While agricultural subsidies may recently have displaced drug patent rules as the most talked-about issue in the WTO today, it is submitted that the debate on the TRIPS

<sup>2</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, 33 *ILM* (1994) 81. The TRIPS Agreement is part of the Uruguay Round of trade agreements establishing the World Trade Organization (WTO), the successor to the General Agreement on Tariffs and Trade (GATT). It was signed in Marrakech on 15 April 1994 and entered into force on 1 January 1995. Its stated objective is to reduce distortions and impediments to international trade by outlining a framework for minimum intellectual property standards, including remedies for enforcement, which binds all WTO Members. The Agreement covers all aspects of intellectual property, including literary and artistic property (copyrights), and industrial property (trademarks, patents, geographical indications, industrial designs and trade secrets), and incorporates by reference some of the basic provisions of international agreements already in force, such as the Paris Convention for the Protection of Intellectual Property, the Berne Convention for the Protection of Literary and Artistic Works, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, and the Treaty on Intellectual Property in Respect of Integrated Circuits. All four agreements continue to coexist with the TRIPS Agreement and are administered by the World Intellectual Property Organization (WIPO), founded in 1967. One of the main features of the TRIPS Agreement is that it binds all WTO Members to grant minimum periods of protection for the various IP rights it covers (20 years for patents; seven years, renewable, for trademarks; life of the author plus 50 years for copyrights). In particular, it requires Member states to provide 20-year patent protection in all fields of technology, which implicitly includes pharmaceuticals. Prior to the launching of the negotiations for the TRIPS Agreement, countries had various approaches to drug patents, suited to their domestic public health policies and needs. Over 40 countries, including middle-income countries such as Brazil and Argentina, and seven developed countries, provided no product patent protections for medicines, and some 20 WTO members still did not do so by the time of the conclusion of the negotiations.

<sup>3</sup> See e.g. Report of the UK Commission on Intellectual Property Rights (dated September 2002), available at [www.iprcommission.org](http://www.iprcommission.org).

<sup>4</sup> See Table in Section 1.

<sup>5</sup> See Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil', 6 *Yale Human Rights & Development Law Journal* (2003) 103; Sun, 'A Wider Access to Patented Drugs Under the TRIPS Agreement', 21 *Boston University of International Law Journal* (2003) 101; Abbott, 'The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference', 5 *Journal of World Intellectual Property* (2002) 15.

Agreement and public health is far from closed. Even after the most recent agreement<sup>6</sup> on access to generic medicines in poor countries, serious differences of interpretation and implementation difficulties under the TRIPS Agreement are likely to persist.<sup>7</sup> In this author's opinion, implementing and interpreting the TRIPS Agreement in a manner conducive to public health remains key to re-establishing WTO's legitimacy.

This article explores the global debate on the TRIPS Agreement and public health, as it has evolved over the years. Specifically, it focuses on the implications, and limitations, of the Doha Declaration. Designed to respond to concerns about the negative impact of the TRIPS Agreement on access to medicines, the Declaration on the TRIPS Agreement and Public Health (Doha Declaration),<sup>8</sup> adopted at the Doha Ministerial Conference, explicitly clarified for the first time what flexibilities inherent in the TRIPS Agreement can be used by Members to combat a public health crisis. It was rightly viewed as a step in the right direction for the WTO. Nevertheless, the Doha Declaration did not fully dismantle the obstacles created by the TRIPS Agreement. Instead, there are still significant legal and economic barriers to the implementation of policies that will actually result in the availability of reasonably priced medicines. This paper argues that the TRIPS Agreement should be implemented and interpreted so as to allow WTO members the maximum flexibility in increasing access to essential medicines for all. The first section analyses the context of the Doha Declaration and outlines the important events leading to the Declaration. Section 2 offers a detailed analysis of the main provisions of the Doha Declaration. Section 3 reviews the post-Doha negotiations on the TRIPS Agreement and public health.

## 1 The Road to Doha

### A Global Epidemic Crises

In many regions, the health situation has sharply deteriorated in recent years, primarily because of the devastating impact of the HIV/AIDS pandemic. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) statistics, the HIV/AIDS pandemic, in only 20 years, has caused untold suffering and death worldwide, destroying entire communities, reversing development gains, and posing a serious threat to whole continents.<sup>9</sup> Dozens of countries are already in the grip of serious HIV/AIDS epidemics, and many more are on the brink.<sup>10</sup> Worldwide, more than 65

<sup>6</sup> Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, WT/L/540 (see discussion *infra* Section 3).

<sup>7</sup> See Abbott, 'Trade Diplomacy, the Rule of Law and the Problem of Asymmetric Risks in TRIPS', *Quaker UN Office Occasional Paper no. 13* (September 2003), available at [www.quano.org](http://www.quano.org).

<sup>8</sup> Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Fourth Session, Doha, Adopted on 14 November 2001, WT/MIN(01)/DEC/2.

<sup>9</sup> See generally, UNAIDS, *Twenty Years of HIV/AIDS*, [www.unaids.org/UNGASS/index.html](http://www.unaids.org/UNGASS/index.html). A new report concludes that, in 2002 alone, the AIDS epidemic claimed more than 3 million lives, and an estimated 5 million people acquired HIV, bringing to 42 million the number of people globally living with the virus. See UNAIDS, *ADIS Epidemic Updates: December 2002*, at 2–3.

<sup>10</sup> See UNAIDS, *Report on Global HIV/AIDS Epidemic 2002*, at 22–41.

million persons have been infected with the immunodeficiency virus (HIV) since the epidemic began. In all, AIDS has claimed more than 25 million lives and orphaned more than 14 million children throughout the world. In addition, two other major infectious diseases, tuberculosis and malaria, are on the rise. According to the World Health Organization (WHO), two million people die from tuberculosis every year, while malaria causes 3,000 deaths a day, primarily among children.<sup>11</sup> Taken together, these three epidemics account for 500 million or more illnesses, and a staggering 6 million deaths each year.<sup>12</sup> By way of illustration, the following table provides statistical evidence of the stunning burden, in terms of deaths and disability-adjusted life years (DALYs)<sup>13</sup>, from these three diseases, from 1999 to 2001.

**Table 1**

**Deaths and DALYs caused by three major diseases, estimates for 1999–2001  
(000s)**

Disease	World		Africa		The Americas		South-East Asia	
	Deaths	DALYs	Deaths	DALYs	Deaths	DALYs	Deaths	DALYs
HIV/AIDS	8482	268240	6743	214560	241	7942	1176	33951
TB	4973	132569	1074	27450	162	2079	2260	45016
Malaria	3290	127491	2882	94845	5	295	215	8625

Sources:

WHO, *The World Health Report 2000 Health Systems: Improving Performance*, Annex 2 and 3.

WHO, *The World Health Report 2001 Mental Health: New Understanding, New Hope*, Annex 2 and 3.

WHO, *The World Health Report 2002 Reducing Risks, Promoting Health Life*, Annex 2 and 3.

As the table shows, these three diseases affect different continents and different countries unevenly, with the heaviest burden falling on poor regions. This is particularly true of malaria, which was eliminated from Europe, North America and much of the Middle East by 1970. It is also true of HIV/AIDS and TB. Although HIV/AIDS represents a global health crisis, sub-Saharan Africa is by far the most severely afflicted region.<sup>14</sup> In parts of southern Africa, two in five adults are now infected. Average life expectancy in the region is now 47 years, while it would have

<sup>11</sup> See WHO, *Fact Sheets: Tuberculosis*, No. 104, available at <http://www.who.int/mediacentre/factsheets/who104/en/>; *Fact Sheets: Malaria*, [www.who.int/inf-fs/en/fact094.html](http://www.who.int/inf-fs/en/fact094.html).

<sup>12</sup> WHO, *Coordinates 2002. Charting Progress against AIDS, TB and Malaria (2002)*, at 1.

<sup>13</sup> Disability-adjusted life years (DALY) along with healthy life expectancy (HALE) are summary measures of population health. It is a measure that considers the burden of a disease to a population in terms of years of lost life, adjusted for the effect on health to those living with the disease. One DALY can be thought of as one lost year of 'healthy' life and the burden of disease as a measurement of the gap between the current health of a population and an ideal situation where everyone in the population lives to old age in full health. See WHO, *The World Health Report 2002 Reducing Risks, Promoting Healthy Life* (2003) Annex Notes.

<sup>14</sup> Nearly three-quarters of persons living with HIV/AIDS are in sub-Saharan Africa. Of 3 million people who died of AIDS in 2000, 2.4 million were in sub-Saharan Africa. See WHO Commission on Macroeconomics and Health, *Macroeconomics Health: Investing in Health for Economic Development* (2001), at 48–49.

been 62 years without AIDS.<sup>15</sup> After sub-Saharan Africa, the Caribbean is the next hardest-hit region as measured by HIV/AIDS prevalence.<sup>16</sup> The Eastern European region continues to experience the fastest-growing HIV/AIDS epidemic in the world, with a 1,300 per cent increase in prevalence over the last five years.<sup>17</sup> In Asia and the Pacific, despite well-documented and successful HIV prevention programmes, the HIV/AIDS epidemic continues to spread quickly.<sup>18</sup> In contrast, in most of the industrialized world, and in some countries in Latin America, the number of AIDS deaths is now declining, thanks to access to anti-retroviral treatment.<sup>19</sup>

## **B Access to Essential Medicines**

Although much has been achieved during the last five decades and the number of people with access to essential drugs<sup>20</sup> has doubled in the last 20 years, many millions of people still cannot get affordable access to essential medicines and vaccines. The World Health Organization estimates that one-third of the world's population still lacks such access, with this figure surpassing 50 per cent in parts of Asia and Africa.<sup>21</sup> With regard to the highly expensive treatments, such as anti-retroviral therapy for HIV/AIDS, the statistics are much worse. It is estimated that fewer than 5 per cent of people in the developing world in need of anti-retroviral treatment receive it. In sub-Saharan Africa, the figure is only 1 per cent.<sup>22</sup>

## **C The Role of International Organizations and Non-governmental Organizations**

### *1 WIPO and OHCHR Panel Discussion on Intellectual Property and Human Rights*

On 9 November 1998, the World Intellectual Property Organization (WIPO), in collaboration with the Office of the United Nations High Commissioner for Human Rights (OHCHR), held a Panel Discussion on 'Intellectual Property and Human Rights' to mark the fiftieth anniversary of the Universal Declaration of Human Rights (UDHR). The objective of the panel was to highlight the universality of intellectual

<sup>15</sup> UNAIDS, *supra* note 10 at 44.

<sup>16</sup> See UNAIDS, *HIV/AIDS: Key Facts*, [www.globalfundatm.org/journalists/fsheets/hiv&aids.htm](http://www.globalfundatm.org/journalists/fsheets/hiv&aids.htm).

<sup>17</sup> In 2001, there were an estimated 250,000 new infections, bringing to 1 million the number of people living with HIV/AIDS in Eastern Europe. See UNAIDS, *supra* note 10, at 32–33.

<sup>18</sup> See *ibid.*, at 28–30. See also, UNAIDS, *AIDS Epidemic Updates: December 2002*, at 7–9. See also Eberstadt, 'The Future of AIDS', *Foreign Affairs* (Nov./Dec. 2002) 22.

<sup>19</sup> See WHO, *supra* note 12, at 4.

<sup>20</sup> Essential medicines, as defined by WHO, are drugs that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparable cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicine is intended to be flexible and adaptable to many different situations: exactly which medicines are regarded as essential remains a national responsibility.

<sup>21</sup> See WHO, *WHO Medicines Strategy: 2000–2003* (December 2000).

<sup>22</sup> See WHO, *supra* note 12, at 1.

property and its role in social, economic and cultural development.<sup>23</sup> During the discussion, the participants expressed their respective views on the role of intellectual property in development and related policy areas. Sharing the view that it is possible to afford universal access to intellectual property rights, the specialists analysed ways of building up the linkages between the protection of intellectual property and the promotion of human rights.<sup>24</sup> The panel paid special attention to the complex and controversial relations between intellectual property and the right to health, including the pros and cons of drug patenting.<sup>25</sup>

## 2 *UN Sub-Commission on Human Rights*

In August 2000, the UN Sub-Commission on Human Rights adopted Resolution 2000/7 on 'Intellectual Property Rights and Human Rights'.<sup>26</sup> The Sub-Commission concluded that the implementation of the TRIPS Agreement could affect the enjoyment of human rights, including the right of all to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right of self-determination. As a follow-up to the resolution, two reports focusing on approaches to the Agreement that ensure the promotion and protection of human rights, in particular the right to health, were submitted to the Sub-Commission.<sup>27</sup> In August 2001, the Sub-Commission adopted another resolution on 'Intellectual Property Rights and Human Rights', urging all governments to take fully into account existing state obligations under international human rights instruments in the formulation of proposals for the ongoing review of the TRIPS Agreement.<sup>28</sup>

## 3 *WHO and WHO Workshop on Affordable Drugs*

On 8–11 April 2001, WHO and WTO jointly held a workshop in Norway on affordable drugs, bringing together for the first time all major interest groups concerned with the

<sup>23</sup> See WIPO, 'Intellectual Property and Human Rights: WIPO and the UN High Commissioner for Human Rights Hold a Panel Discussion to Highlight Common Ground', Press Release PR/98/143, Geneva, 20 October 1998.

<sup>24</sup> The main Panel contributions include: Drahos, 'The Universality of Intellectual Property: Origins and Development'; Steiner, 'Intellectual Property and the Right to Culture'; Salazar, 'Intellectual Property and the Right to Health'; Mugabe, 'Intellectual Property Protection and Traditional Knowledge'; Chapman, 'A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science'; von Lewinski, 'Intellectual Property, Nationality and Non-Discrimination'. All these papers may be found at <http://www.wipo.org/globalissues/activities/1998/humanrights/program/index.html>.

<sup>25</sup> See one of the discussion papers, Salazar, *supra* note 24.

<sup>26</sup> UN Commission on Human Rights, Sub-Commission for the Promotion and Protection of Human Rights, *Intellectual Property and Human Rights*, 2000, E/CN.4/Sub.2/2000/7.

<sup>27</sup> UN Commission on Human Rights, Sub-Commission for the Promotion and Protection of Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Report of the High Commissioner, 27 June 2001, E/CN.4/Sub.2/2001/13. UN Commission on Human Rights, *Globalization and Its Impact on the Full Enjoyment of Human Rights*, Progress report submitted by J. Oloka-Onyango and Deepika Udagama, in accordance with Sub-Commission Resolution 1999/8 and Commission on Human Rights Decision 2000/102, 2 August 2001, E/CN.4/Sub.2/2001/10.

<sup>28</sup> UN Commission on Human Rights, Sub-Commission for the Promotion and Protection of Human Rights, *Intellectual Property and Human Rights*, 2000, E/CN.4/Sub.2/2001/21.

financing and pricing of essential drugs.<sup>29</sup> The experts explored the complex questions involved in ensuring access to essential drugs at affordable prices, securing adequate financing for this purpose, and also providing incentives for research and development (R&D) into new drugs. Specifically, the workshop focused on two important topics: the practice of differential pricing (whereby prices are adapted by the seller to the different purchasing powers in different countries) and the role of financing (through increased domestic resource mobilization as well as increased aid flows) in ensuring access to essential drugs.<sup>30</sup>

#### 4 The 54th World Health Assembly

On 14–22 May 2001, the World Health Assembly (WHA), which is the annual meeting of the 191 Member states of the WHO, took place in Geneva. The Assembly sought various ways to strengthen global health systems and strategies to combat HIV/AIDS, including access to essential drugs. Recognizing the unprecedented scale of the HIV/AIDS crisis, the Assembly adopted Resolution WHA 10, *Scaling Up the Response to HIV/AIDS*, urging Member states to make every effort to provide the highest standard of treatment for HIV/AIDS progressively and in a sustainable manner.<sup>31</sup> Additionally, in the following Resolution, *WHO Medicines Strategy*, states were urged to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries, consistent with applicable international law.<sup>32</sup>

#### 5 United Nations Special Session on HIV/AIDS

On 25–27 June 2001, Heads of State and Representatives of Governments met at the United Nations General Assembly Special Session (UNGASS)<sup>33</sup> dedicated to HIV/AIDS and issued a Declaration of Commitment on HIV/AIDS.<sup>34</sup> The Declaration is not a legally binding document. However, it is a clear statement by governments on what they have agreed should be done to fight against the HIV/AIDS epidemic and the commitments they have given, often with specific deadlines. Therefore, the Declaration is a powerful instrument with which to guide and secure action, commitment, support and resources for all those fighting the epidemic, both on the national and global levels. The UNGASS provided people with ‘an occasion as never before to face up to our responsibility to future generations, and take decisive action now to turn

<sup>29</sup> For various aspects of this workshop, all the presentations, background papers and final reports are available at [http://www.wtp.org/english/tratop\\_e/trips\\_e/tn\\_hosbjor\\_e.htm](http://www.wtp.org/english/tratop_e/trips_e/tn_hosbjor_e.htm).

<sup>30</sup> See in general, *Report of the Workshop on Differential Pricing and Financing of Essential Drugs*, prepared by the WHO and WTO Secretariats.

<sup>31</sup> See The 54th World Health Assembly, Agenda item 13.6, *Scaling Up the Response to HIV/AIDS*, WHA54.10, 21 May 2001.

<sup>32</sup> See The 54th World Health Assembly, Agenda item 13.8, *WHO Medicines Strategies*, WHA54.11, 21 May 2001.

<sup>33</sup> Relevant information about this session is available at <http://www.un.org/ga/aids/coverage/index.html>.

<sup>34</sup> United Nations General Assembly, *Declaration of Commitment on HIV/AIDS*, A/RES/S-26/2, 27 June 2001.

back the progress of this terrible disease',<sup>35</sup> while indicating that the HIV/AIDS epidemic is a “global crisis” requiring global action'. In addition, a Global Fund was launched by UN Secretary-General Kofi Annan to raise \$7–10 billion a year to fight against the ravages of HIV/AIDS.

## 6 Civil Society

Starting as early as 1998, a number of influential non-governmental organizations (NGO), such as *Médecins Sans Frontières* (MSF), Oxfam, CpTech, Health Action International and Third World Network (TWN), expressed concern that the implementation of the TRIPS Agreement could be detrimental to the protection of public health in poor countries. They soon joined forces and launched ambitious and effective campaigns in which they voiced their objections to the TRIPS Agreement.<sup>36</sup> Their principal arguments may be summarized as follows. First, strengthened drug patent protection in developing countries will likely result in higher drug prices, especially for new medicines.<sup>37</sup> Even if one accepts the assumption that strengthened patent protection under the TRIPS Agreement should induce greater scientific and technological development, and lead to an increase in the number of new, innovative drugs, the cost of these new, patented drugs will likely be too high for poor people in developing countries. Secondly, pharmaceutical patent protection under the TRIPS Agreement will not necessarily make a significant contribution to increasing R&D expenditure by the private sector for the treatment of diseases, such as malaria, which plague developing countries but have little incidence in rich countries.<sup>38</sup> Given the low purchasing power and uncertain profit prospects prevalent in poor countries, a strong patent protection system, in and of itself, is unlikely to provide sufficient incentives for the pharmaceutical industry to invest in R&D for drugs which have no lucrative markets. Additional measures of support (such as increased international financing) for such R&D would be needed.<sup>39</sup>

Finally, a major problem, well recognized and emphasized in NGO campaigns is that developing countries are under pressure from both developed countries and the pharmaceutical industry to implement patent protection that is stricter than the obligations of the TRIPS Agreement<sup>40</sup> under bilateral and regional agreements commonly referred to as “TRIPS plus” agreements. Examples of “TRIPS plus”

<sup>35</sup> Remark by UN Secretary-General Kofi Annan, available at [www.un.org/ga/aids/background.htm](http://www.un.org/ga/aids/background.htm).

<sup>36</sup> For a comprehensive description of the role of civil society in the debate on TRIPS and public health, see S. K. Sell, *Private Power, Public Law: The Globalization Of Intellectual Property Rights* (2003).

<sup>37</sup> See Oxfam Briefing Paper, ‘Patent Injustice: How World Trade Rules Threaten the Health of Poor People’ (February 2001); Oxfam GB Policy Paper, ‘Fatal Side Effects: Medicine Patents under the Microscope’ (February 2001).

<sup>38</sup> See *Médecins Sans Frontières* (MSF), *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (2001).

<sup>39</sup> See *ibid.*

<sup>40</sup> See Drahos, ‘Bits and Bips — Bilateralism in Intellectual Property’, 4 *Journal of World Intellectual Property* (2001) 791. This paper was commissioned by Oxfam GB as part of its Cut the Cost of Medicines Campaign.

obligations include extending patent life beyond the 20-year TRIPS minimum, limiting compulsory licensing in ways not required by TRIPS, or limiting exceptions which facilitate the prompt import of generics in developing countries.

## **D Two Cases Regarding TRIPS and Public Health**

### *1 The South African Medicines Act Litigation*

In the midst of a catastrophic HIV/AIDS epidemic, in November 1997, the South African Government introduced the Medicines and Related Substances Control Amendment Act in order to promote the availability of affordable HIV/AIDS-related drugs via parallel imports and compulsory licensing under the TRIPS Agreement.<sup>41</sup> The goal of this amendment was to implement key elements of the South African national drug policies, including generic substitution, greater competition in public drug procurement, improved drug quality, and more rational use of medicines. Shortly thereafter, a number of pharmaceutical companies lodged protests against the Amendment Act. In February 1998, 39 drug companies submitted a formal complaint to the Pretoria High Court in South Africa, challenging the constitutionality of the Act, including its compatibility with the TRIPS Agreement. In addition, at the request of the US pharmaceutical industry, the US Trade Representative placed South Africa on its 'Section 301 Watch List'<sup>42</sup> and the US administration tentatively withheld preferential treatment for several South African exports. It is only thanks to the activism of NGOs that the situation was reversed. Public outrage, particularly at the Seattle WTO Ministerial, was such that the US had to change its policies. In May 2000, President Clinton issued an executive order to promote access to HIV/AIDS medicines,<sup>43</sup> and the five largest pharmaceutical companies signed an agreement with the United Nations to cut the price of HIV/AIDS drugs by up to 80 per cent for poor countries (the 'Accelerating Access' Initiative)<sup>44</sup>. Thanks to a well-organized grassroots campaign, the legal action turned into a public relations disaster for the drug companies, and the suit was finally withdrawn in April 2001.<sup>45</sup>

The successful resolution of this case had a number of far-reaching implications.

<sup>41</sup> The amendment provided for the: (1) generic substitution of off-patent medicines and medicines imported and produced under compulsory licences, (2) parallel importation of patented medicines, and (3) a transparent medicine pricing system through the establishment of a pricing committee.

<sup>42</sup> Section 301 of the Trade Act of 1974 enables the Office of the US Trade Representative to impose trade sanctions on other countries, including those countries that 'deny fair and equitable market protection to US persons that rely upon intellectual property protection'.

<sup>43</sup> Exec. Order No. 13155, 3 C.F.R. 268–70 (2000). 'This order prohibits the US Government from taking action pursuant to Section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary Sub-Saharan countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.'

<sup>44</sup> For a description of the Accelerating Access to HIV Care, Support and Treatment Initiative, see [www.unaids.org/acc\\_access/](http://www.unaids.org/acc_access/) (last visited June 23, 2003); for a critique of the Initiative, see Act Up Paris, "'Accelerating Access" Serves Pharmaceutical Companies While Corrupting Health Organizations', available at [http://www.actupparis.org/pdf/nord\\_sud/02\\_05\\_15\\_Accelerating\\_Access\\_ENG.pdf](http://www.actupparis.org/pdf/nord_sud/02_05_15_Accelerating_Access_ENG.pdf).

<sup>45</sup> For the details of the lawsuit, see Kongolo, 'Public Interest versus Pharmaceutical Industry's Monopoly in South Africa', 4 *Journal of World Intellectual Property* (2001), 609–627.

First, the adjournment of the court case will allow South Africa to concentrate on the concrete implementation of its existing legislation and policies and will help make essential HIV/AIDS-related medicines more widely available.<sup>46</sup> It will give South Africa the ability to combat the HIV/AIDS epidemic more effectively with expanded access to low-priced drugs. Another positive factor is that the case, thanks to a well-organized grassroots campaign, brought international attention to the plight of AIDS sufferers in the region. As a result, increased resources for prevention and care are now forthcoming both domestically and internationally, and broad commitments have finally been made to improve the health infrastructure throughout Africa.<sup>47</sup> Thirdly, even though no decision was made, the case has given rise to a wealth of expert opinions on the TRIPS Agreement. Encouragingly, the bulk of expert opinion is that the Amendment Act is consistent with the TRIPS Agreement.<sup>48</sup> The case has thus strengthened the view that the TRIPS Agreement contains the necessary flexibility to meet the health needs of developing countries and can be used as a basis for resolving difficult issues concerning access to essential drugs.<sup>49</sup> In particular, it has encouraged the view that developing countries afflicted with grave public health crises should be entitled to avail themselves of TRIPS-compatible policy options, such as parallel importation and compulsory licensing, to implement the Agreement in a manner conducive to public health. However, in early 2001, these conclusions and opinions still needed authoritative interpretation to confirm their validity under the TRIPS Agreement.

## 2 *US v. Brazil*

At around the same time (February 2001), the United States filed a complaint before the WTO dispute settlement body challenging the compatibility of Article 68 of Brazil's Industrial Property Law with the TRIPS Agreement.<sup>50</sup> The United States argued that this provision for the granting of compulsory licences in the event that a patented invention was not in manufacture in Brazil within three years of the issuance of the patent ('local working' requirement), was a protective industrial policy

<sup>46</sup> This is the view of UNAIDS, see 'UNAIDS Welcomes Outcome of the South Africa Court Case', [www.unaids.org/whatsnew/press/eng/pressarc01/SAfrica\\_190401.htm](http://www.unaids.org/whatsnew/press/eng/pressarc01/SAfrica_190401.htm).

<sup>47</sup> See e.g. G8 Africa Action Plan adopted at the Kananaskis Summit in 2002 and G8 Action Plan on Health adopted at the Evian Summit, both available at [www.g8.fr](http://www.g8.fr). See also 'United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act of 2003', P.L. No. 108–25.

<sup>48</sup> See e.g. B. Hoekman, A. Mattoo, and P. English (eds), *Development, Trade and the WTO* (2002), at 374, and Abbott, *supra* note 7.

<sup>49</sup> This view is expressed by the former WTO Director-General, Mike Moore. See WTO News, 'Moore Welcomes News of Settlement of South Africa Drug Lawsuit', available at [http://www.wto.org/english/news\\_e/spmm\\_e/spmm58\\_e.htm](http://www.wto.org/english/news_e/spmm_e/spmm58_e.htm). However, it does not necessarily mean that the TRIPS Agreement does not exert any negative influences on more affordable access to some essential drugs.

<sup>50</sup> See *Brazil — Measures Affecting Patent Protection — Request for Consultation by the United States*, WT/DS199/1, *Brazil — Measures Affecting Patent Protection — Request for the Establishment of a Panel by the United States*, WT/DS199/3, available at [www.wto.org](http://www.wto.org).

measure and inconsistent with the provisions of the TRIPS Agreement.<sup>51</sup> In the 2001 'Special 301' Report, the United States Trade Representative (USTR), Robert Zoellick, defined Article 68 as a protectionist measure intended to create jobs for Brazilian nationals.<sup>52</sup> The Brazilians took the view that this measure was a necessary part of their programme to combat the HIV/AIDS epidemic and was entirely consistent with the TRIPS Agreement. Following bilateral consultations, in June 2001, rather than pursuing the dispute under the WTO Dispute Settlement Understanding procedures, Brazil and the United States announced that they had reached a mutually agreed solution.<sup>53</sup>

Although the dispute between the US and Brazil was successfully settled, the question remained: To what extent could developing country Members avail themselves of the flexibility afforded by the TRIPS Agreement to combat public health crises? In this dispute, the US and Brazil had completely different views on the compatibility of Brazil's local working requirement with Article 27.1 of the TRIPS Agreement. The settlement of the dispute left both the broad question of the flexibility of the TRIPS Agreement and the narrower question of the legality of 'local working' requirements open.<sup>54</sup>

### ***E September 11 Terrorist Attack and Subsequent Biological Attack***

The terrorist attack of September 11, involving four hijacked planes, demolished the World Trade Center and struck the Pentagon, killing more than 5,000 US citizens and other nationals.<sup>55</sup> Shortly after the September 11 attack, there followed a series of anthrax attacks in the US, with several grave illnesses and deaths. To prepare for the possibility of a massive bio-terrorist attack, the US and Canadian Governments both decided to stockpile an adequate supply of Cipro, an antibiotic to treat anthrax. Canada promptly overrode the German pharmaceutical company Bayer's patent for

<sup>51</sup> The US considered that such a requirement is inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement, and Article III of the GATT 1994. Essentially, the US asserted Brazil's breach of Article 27.1 of the TRIPS Agreement. Article 27.1 of the TRIPS Agreement provides: 'Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable *without discrimination* as to the place of invention, the field of technology and whether products are *imported or locally produced*' (emphasis added).

<sup>52</sup> See USTR, 2001 'Special 301' Report, at 10, available at [www.ustr.gov/enforcement/index.shtml](http://www.ustr.gov/enforcement/index.shtml).

<sup>53</sup> See Brazil — Measures Affecting Patent Protection — Notification of Mutually Agreed Solution, WT/DS199/4, available at [www.wto.org](http://www.wto.org).

<sup>54</sup> The US and Brazil reached a mutually-agreed solution on the basis of the establishment of a US–Brazil bilateral Consultative Mechanism. Under this Mechanism, Brazil will provide advance notice to the US Government before utilizing this provision. Therefore, if Brazil seeks to activate this provision there will be an adequate opportunity for consultations in the bilateral Consultative Mechanism. This will provide an early warning system to protect US interests. The United States reserves all its rights in the WTO with respect to this matter.

<sup>55</sup> U.S. Department of State, Office of the Historian, *Significant Terrorist Incidents, 1961–2001: A Brief Chronology*, [www.state.gov/r/pa/ho/pubs/ls/5902.htm](http://www.state.gov/r/pa/ho/pubs/ls/5902.htm).

Cipro, and ordered a million tablets of a generic version from a Canadian company.<sup>56</sup> For its part, the US Government won a major price concession from Bayer A.G. for its antibiotic Cipro, after the Bush administration threatened to override the drug's patent and allow generic production.<sup>57</sup> The anthrax scare drew a new focus on the relationship between patent protection and access to essential drugs. Some legal experts pointed out that the Canadian Government had not completed the procedures required under its own intellectual property legislation for overriding Bayer's patent, and further remarked that it would be difficult for the Government to justify its decision by claiming a national emergency, given that there had been no cases of anthrax in Canada at that time.<sup>58</sup> The international community was particularly critical of the US Government, which was accused of following double standards.<sup>59</sup> Developing countries were quick to ask how developed countries could insist on poor countries respecting patent rights, even in the face of genuine public health crises, while the US Government itself threatened to override patents on the antibiotic Cipro during the outbreak in October 2001 of anthrax infections.

The anthrax scare revealed that every nation in the world, even the most powerful, could be faced with a national public health emergency. The subsequent debate focused on a number of questions. First, what constitutes a national public health emergency? If confronted with a public health emergency, can a government grant compulsory licences on the ground of protecting national public health? If so, is this action legitimate under the TRIPS Agreement? Apart from the granting of such compulsory licences, what other TRIPS-compatible flexibilities can Member governments use to combat national public health crises? In addition, will the use of such flexibilities discourage new research and development into new drugs? All these questions required prompt answers at the Doha Ministerial Conference, which took place just weeks after the anthrax scare.

## 2 The Doha Declaration

On 20 June 2001, the TRIPS Council held a special discussion on intellectual property and access to medicines at the request of the African Group. The goal was to initiate discussions on the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying the flexibilities that Members are entitled to and, in particular, to establish the relationship between intellectual property rights and access to medicines. During the session, a wide range of relevant issues were

<sup>56</sup> See Harmon and Pear, 'Canada Overrides Patent for Cipro to Treat Anthrax', *New York Times*, 19 October 2001. The Canadian Government subsequently withdrew its decision after agreeing on the Monday to buy the tablets from Bayer.

<sup>57</sup> See Bradsher and Andrews, 'U.S. Says Bayer Will Cut Cost of Its Anthrax Drug', *New York Times*, 24 October 2001.

<sup>58</sup> See Dyer and Michaels, 'Anthrax Scare Raises Awkward Patent Questions', *Financial Times*, 22 October 2001.

<sup>59</sup> See *ibid.*

discussed, some for the first time ever in the TRIPS Council.<sup>60</sup> The former WTO Director-General Mike Moore described the discussion as an opportunity for Member governments to feel secure that they can use the flexibility that is written into the TRIPS Agreement.<sup>61</sup>

On 19 and 21 September, the TRIPS Council held its second special discussion on TRIPS and public health, which primarily focused on objectives and principles (TRIPS Articles 7 and 8), parallel imports (Article 6) and compulsory licensing (Article 31). The discussion broadened to cover other related issues because of three draft texts that members submitted for a ministerial declaration at the Doha Conference. The developing country draft emphasized the importance of TRIPS's role in the protection and promotion of fundamental human rights. The core of this 14-point draft lies in the proposition that 'nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health'.<sup>62</sup> Therefore, various flexibilities available in the TRIPS Agreement, including parallel imports and compulsory licensing, should be made more user-friendly to the developing country Members. The alliance of developing country Members, and their insistence on the need for a strong ministerial declaration on the protection of public health, sent a clear signal that they were determined to reverse the unbalanced outcome of the Uruguay Round in the future new round of multilateral trade negotiations.<sup>63</sup> In contrast, the draft proposed by a group of developed country Members (including Australia, Canada, Japan, Switzerland and the US, but not the European Union) held the opposite position by stressing the merits of strong patent protection. The developed countries' draft proposed that ministers recognize that 'strong, effective and balanced protection for intellectual property is a necessary incentive for research and development of life-saving drugs' and, therefore, 'recognize that intellectual property contributes to public health objectives globally'. Additionally, the developed country draft omitted

<sup>60</sup> There are two papers respectively submitted to the TRIPS Council from the African Group and EU. See Communication From the European Communities and Their Member States, 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines', 12 June 2001, IP/C/W/280; 'TRIPS Public Health', Submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, 29 June 2001, IP/C/W/296.

<sup>61</sup> See WTO NEWS, 'Moore: Countries Must Feel Secure That They Can Use TRIPS' Flexibility', 20 June 2001.

<sup>62</sup> This is the developing countries' negotiating target in the Doha Conference. See C. M. Correa, *Implication of the Doha Declaration on the TRIPS Agreement and Public Health* (2002).

<sup>63</sup> See Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, 'Ministerial Declaration on the TRIPS Agreement and Public Health', 4 October 2001, IP/C/W/312.

any mention of the role of compulsory licensing in expanding access to affordable medicines.<sup>64</sup>

In the course of negotiating the prospective ministerial declaration at the Doha Conference, the developed country Members came to understand that no broad negotiating mandates such as investment and competition would emerge from the conference in the absence of a meaningful result on medicines. In the end, the United States accepted the essentials of the developing country group's recommendations, which were strongly supportive of public health.<sup>65</sup> On 14 November 2001, the Ministers at the Doha Conference adopted the final Declaration by consensus.

## ***A Content of the Doha Declaration***

### *1 The Relationship between the TRIPS Agreement and Public Health*

First, the Declaration explicitly recognizes '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'.<sup>66</sup> Next, in paragraph 2, the Declaration stresses that the TRIPS Agreement should be viewed as part of the wider national and international action to address public health problems.<sup>67</sup> In paragraph 3, the ministers recognize the complexities of drug patent protection, by stating that 'intellectual property protection is important for the development of new medicines', but also recognizes 'concerns about its effect on prices'. In paragraph 4, the core of the Declaration, ministers 'agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health'. Therefore, they 'affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.<sup>68</sup> In this connection, they 'reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose'.<sup>69</sup>

### *2 Principles Applied to Interpreting the TRIPS Agreement*

The Doha Declaration requires 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

<sup>64</sup> See Contribution from Australia, Canada, Japan, Switzerland and the United States, 'Preambular Language for Ministerial Declaration', 4 October 2001, IP/C/W/313. The third draft was submitted by Hong Kong China. Hong Kong China took the view that TRIPS does not allow a government to compulsorily license foreign companies and that therefore governments of the two countries might have to cooperate. See WTO NEWS, 'Members Discuss Drafts for Ministerial Declaration', 19 and 21 September 2001. For its part, the EU tried to present itself as an 'honest broker' in the negotiations.

<sup>65</sup> See Abbott, 'The Doha Declaration on The TRIPS Agreement and Public Health: Lighting a Dark Corner in WTO', 5 *JIEL* (2002) 486.

<sup>66</sup> *Supra* note 8, at para. 1.

<sup>67</sup> *Ibid.*, at para. 2.

<sup>68</sup> *Ibid.*, at para. 4. See also, Doha WTO Ministerial Declaration, 20 November 2001, WT/MIN(01)/DEC/1, para. 17.

<sup>69</sup> *Ibid.*, at para. 4.

objectives and principles'.<sup>70</sup> The fundamental rule of treaty interpretation as set out in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (Vienna Convention),<sup>71</sup> which are firmly grounded in the antecedent state practice and international cases,<sup>72</sup> had attained the status of a rule of customary or general international law.<sup>73</sup> These two articles not only prescribe basic rules for the interpretation of treaties, but also enumerate several sources of law by defining the scope of the treaty and its context.<sup>74</sup> Guided by the key elements of treaty interpretation defined in these two rules, the would-be interpreters<sup>75</sup> should examine the provisions in the context of objectives and principles highlighted by the TRIPS Agreement, rather than merely confine themselves to a restrictive textual approach.

### 3 Flexibilities Available in the TRIPS Agreement

#### a. Compulsory Licensing

The Doha Declaration clarifies Article 31 of the TRIPS Agreement by restating propositions that big pharmaceutical companies, in particular, had put in doubt.<sup>76</sup> Paragraph 5(b) clearly states that 'each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.<sup>77</sup> The Declaration makes it clear that Article 31, while including a number of procedural conditions for granting compulsory licences, does not limit the *grounds* on which compulsory licences can be granted, leaving Members the right to stipulate such grounds in their domestic legislations. Therefore, Members can grant such licences on the grounds of protecting public health beyond the three illustrations explicitly included in Article 31, which are national emergency,<sup>78</sup> public non-commercial use<sup>79</sup> and anti-competitive practices.<sup>80</sup>

#### b. Determination of National Emergency

The Doha Declaration explicitly gives each Member 'the right to determine what constitutes a national emergency or other circumstances of extreme urgency'. It

<sup>70</sup> *Ibid.*, at para. 5(a).

<sup>71</sup> Vienna Convention on the Law of Treaties, done at Vienna, 23 May 1969, entered into force on 27 January 1980. For the detailed explanations of these two articles, see at 114–158.

<sup>72</sup> See *ibid.*, at 153.

<sup>73</sup> See J. H. Jackson, *The WTO Constitution and Jurisprudence* (1998), at 95; Cameron and Gray, 'Principles of International Law in the WTO Dispute Settlement Body', 50 *ICLQ* (2001) 248, at 254–256; see also Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements', 5 *JIEL* (2002) 17.

<sup>74</sup> See Palmetier and Mavroidis, 'The WTO Legal System: Source of Law', 92 *AJIL* (1998) 400. See also Cattaneo, 'The Interpretation of the TRIPS Agreement — Considerations for the WTO Panels and Appellate Body', 3 *Journal of World Intellectual Property* (2000) 670.

<sup>75</sup> The Ministerial Conference/General Council has the exclusive authority to adopt interpretations of the WTO Agreement and of the Multilateral Trade Agreements, including the TRIPS Agreement. See Article IV:2 of the WTO Agreement. Although the legal effect of the interpretations rendered by the Panels and Appellate Body still remain controversial, it should be noted that these interpretations are only binding on the disputed parties concerned.

<sup>76</sup> See Abbott, *supra* note 65, at 493.

<sup>77</sup> *Supra* note 8, at para. 5(b).

<sup>78</sup> See Article 31(b) of the TRIPS Agreement.

<sup>79</sup> *Ibid.*

<sup>80</sup> See Article 31(k) of the TRIPS Agreement.

specifies that ‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency’.<sup>81</sup> Hence, ministers reiterate the freedom to grant compulsory licences in order to combat public health crises. The combination of paragraphs 5(b) and 5(c) of the Declaration should enable developing country and least-developed country Members to use TRIPS-compatible compulsory licensing as a tool to protect public health without fear of challenge from the pharmaceutical industry.

### c. Parallel Imports

Subject to the most favoured nation (MFN) and national treatment provisions of Articles 3 and 4, Members are free to adopt their own policies concerning the exhaustion of intellectual property rights, and to establish their own parallel importation system within the chosen policy.<sup>82</sup> This had been a disputed point of interpretation under the TRIPS Agreement. By making it clear that Member states may adopt legislation to allow parallel imports without the consent of the patent holder, the Declaration greatly advances the interests of developing Members in obtaining low-cost access to pharmaceutical supplies.<sup>83</sup>

### d. Pharmaceutical Patent Protection in Least-developed Countries

The Doha Declaration exempts least-developed country Members from providing patent protection to pharmaceutical products and enforcing such rights until 1 January 2016.<sup>84</sup> Prior to this deadline, the least-developed country Members will be free to increase their own capacity to manufacture generic drugs or obtain low-priced drugs imported from other Members.

## 4 *Technology Transfer*

Though some developed country Members provide different forms of technical assistance on IPR-related issues, least-developed country Members have repeatedly noted that no or little action has been taken by developed countries to specifically implement their obligations under Article 66.2.<sup>85</sup> Importantly, the Doha Declaration reaffirms the commitment of technology transfer made by developed country Members,<sup>86</sup> and urges such Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members.<sup>87</sup> In addition, the ministers agreed to establish a Working Group under the auspices of the General Council to examine the relationship between trade and transfer of technology, and to make possible recommendations on steps that might be

<sup>81</sup> *Supra* note 8, at para. 5(c).

<sup>82</sup> *Ibid.*, at para. 5(d).

<sup>83</sup> See Abbott, *supra* note 65, at 497.

<sup>84</sup> *Supra* note 8, at para. 7.

<sup>85</sup> Correa, ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’, *WHO Health and Economics Policy Paper*, EDM Series No. 12 (2002), at 36.

<sup>86</sup> See Article 66.2 of the TRIPS Agreement.

<sup>87</sup> *Ibid.*, at para. 7.

taken within the mandate of the WTO to increase technology flows to developing countries.<sup>88</sup>

## B Issues Remaining Unresolved

### 1 Effectiveness of Extension Accorded to Least-Developed Countries

Although the Doha Declaration extends the deadline for the least-developed country Members to provide patent protection to pharmaceutical products, it does not explicitly address the restrictions placed by Articles 70.8<sup>89</sup> and 70.9<sup>90</sup> of the TRIPS Agreement. In the Indian patent protection case, both the Panel and the Appellate Body made it clear that all WTO Members were required to implement the so-called mailbox rule and the exclusive marketing rights (EMR) provision embodied in the above two articles starting as of the date of entry into force of the TRIPS Agreement (1 January 1995).<sup>91</sup> This means establishing systems for receiving and filing pharmaceutical and agricultural chemical product patent applications for later review (mail-box rule) as well as providing exclusive marketing rights for those products that are the subject of the mailbox rule. EMRs appear to be very similar to patent rights under the obligation of the TRIPS Agreement<sup>92</sup> and are possibly even stronger than patent rights.<sup>93</sup> Combined with the mailbox rule, the obligation to grant EMRs severely curtails the discretion of the national patent office to grant or reject patent rights and has been found by countries such as India to diminish significantly the benefits from the transitional arrangements provided for in Articles 65.4 and 66.1.<sup>94</sup> Similarly, were it applicable to LDCs, the obligation to grant EMRs could jeopardize the benefits of the additional extension accorded by the Doha Declaration to the

<sup>88</sup> See Doha WTO Ministerial Declaration, 20 November 2001, WT/MIN(01)/DEC/1, para. 37.

<sup>89</sup> Article 70.8 of the TRIPS Agreement deals with the requirement that each WTO Member shall establish 'a means' that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional periods provided for in Article 65 of the TRIPS Agreement.

<sup>90</sup> Article 70.8 of the TRIPS Agreement provides that each WTO Member shall establish, from 1 January 1995, a mechanism to provide for the grant of exclusive marketing rights to parties who file mailbox applications.

<sup>91</sup> See *India — Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R, adopted on 5 May 1997, at paras 7.24–7.66.

<sup>92</sup> The Panel in the *India Patent Protection* case described the economic function of the grant of EMRs as follows: 'Depending on the situation of a particular market, an exclusive marketing right for a period of five years followed by a gap of a few years until full patent protection is granted some time subsequent to 1 January 2005 might be essential for manufacturers of pharmaceutical and agricultural chemical products in order to set up their position in the market. Competitors, knowing that the grant of subsequent patent protection is imminent, are likely to be discouraged from entering into the market during this brief window of opportunity.' *Ibid.*, at para. 7.59.

<sup>93</sup> See J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (2001), at 118–119.

<sup>94</sup> Article 65.4 provides that some developing country Members may delay providing patent protection on pharmaceutical products from 1 January 1995 until 1 January 2005. Article 66.1 gives the least-developed country Members a period of 11 years (from 1 January 1995 until 1 January 2006) to delay application of the Agreement, other than Articles 3, 4 and 5.

least-developed country Members with respect to drug patent protection. Paragraph 7 of the Declaration, instead of resolving this issue, merely instructs the TRIPS Council to take the necessary action to give effect to this extension.

### *2 Members with Limited Manufacturing Capacities in the Pharmaceutical Sector*

Paragraph 6 of the Declaration recognizes that developing Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. This is because Article 31(f) of the TRIPS Agreement provides that the manufacture of on-patent pharmaceuticals under a compulsory licence must be predominantly for the supply of the domestic market of the Member authorizing such compulsory licence.<sup>95</sup> The term ‘predominantly’ is not defined in the TRIPS Agreement but ‘it would generally suggest that more than 50% of the production by a compulsory licensee should be intended for supply of the domestic market’.<sup>96</sup> Difficulties could arise, therefore, when a country with insufficient domestic manufacturing capacity and experiencing grave health problems seeks to import a needed pharmaceutical from a manufacturer in a WTO Member country where a patent exists on that pharmaceutical. The Doha Declaration did not resolve the issue but instead instructed the TRIPS Council to find an expeditious way to facilitate the effective use of compulsory licensing by countries with insufficient manufacturing capacity and to report to the General Council before the end of 2002.<sup>97</sup>

## 3 Beyond Doha

### *A Results of the Post-Doha Negotiations*

#### *1 Exclusive Marketing Rights*

As the Doha Declaration instructed, the TRIPS Council promptly undertook the necessary action to give effect to the extension accorded to LDCs. Considering that obligations of granting exclusive marketing rights, where applicable, should not prevent attainment of the objectives of extension accorded by the Declaration, the General Council, on the basis of the report submitted by the TRIPS Council, formally adopted a waiver decision in July 2002. Pursuant to this decision, the obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement are waived with respect to pharmaceutical products until

<sup>95</sup> Article 31(f) of the TRIPS Agreement provides: ‘(f) any such use shall be authorized *predominantly* for the supply of the domestic market of the Member authorizing such use’ (emphasis added).

<sup>96</sup> Abbott, *supra* note 65, at 499.

<sup>97</sup> See *supra* note 8, at para. 6.

1 January 2016.<sup>98</sup> In the meantime, this waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates.<sup>99</sup> The decision is part of the WTO Members' ongoing efforts to ensure that intellectual property protection supports, rather than hampers, poorer countries' efforts to tackle serious public health problems. By granting this waiver, Members saw fit to go beyond the strict reading of the Declaration.<sup>100</sup>

## 2 *Technology Transfer*

Recently, particular attention has been paid to the effects of the TRIPS Agreement on the transfer of technology to developing countries. The North–South technological gap has continued to grow since the adoption of the Agreement.<sup>101</sup> Against this background, the Doha Decision of 14 November 2001 on Implementation-related Issues and Concerns both reaffirmed that developed country Members' obligations to provide incentives to their enterprises and institutions to transfer technology to the least-developed Members under Article 66.2 of the TRIPS Agreement are mandatory, and instructed the TRIPS Council to put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question.<sup>102</sup> In February 2003, the TRIPS Council adopted a decision pursuant to this mandate. Developed country Members are required to submit annual reports on actions taken or planned in pursuance of their commitments under Article 66.2 of the TRIPS Agreement. The decision also provides that such submissions shall be reviewed annually by the TRIPS Council.<sup>103</sup>

## 3 *Article 31(f) of the TRIPS Agreement*

Under paragraph 6 of the Doha Declaration, the TRIPS Council was instructed to find an expeditious solution to the problem confronting WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector when they attempt to effectively use compulsory licensing. Pursuant to this mandate, the TRIPS Council held several meetings in the year 2002 to discuss what came to be known as the 'paragraph 6 problem' or the 'export problem'. A number of possible solutions were

<sup>98</sup> See the General Council Decision, 'Least-developed Country Members — Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products,' 12 July 2002, WT/L/478.

<sup>99</sup> *Ibid.*

<sup>100</sup> See Press Release, WTO, 'Council Approves LDC Decision with Additional Waiver', Press/301 at 1 (28 June 2002), available at [www.wto.org/english/news\\_e/pres02\\_e/pr301\\_e.htm](http://www.wto.org/english/news_e/pres02_e/pr301_e.htm).

<sup>101</sup> Correa, 'Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries', Third World Network (TWN), Trade and Development Series No. 13.

<sup>102</sup> See 'Implementation-Related Issues and Concerns', Decision of 14 November 2001, WT/MIN(01)/17, para. 11.2. In addition, the Doha Ministerial Declaration instructs the General Council to examine the relationship between trade and transfer of technology. See Doha WTO Ministerial Declaration, 20 November 2001, WT/MIN(01)/DEC/1, para. 37.

<sup>103</sup> See 'Implementation of Article 66.2 of the TRIPS Agreement', Decision of the Council for TRIPS of 19 February 2003, 20 February 2003, IP/C/28.

explored in the TRIPS Council: (i) an amendment to Article 31(f);<sup>104</sup> (ii) a waiver with regard to Article 31(f);<sup>105</sup> (iii) a moratorium on dispute settlement;<sup>106</sup> and (iv) an authoritative interpretation of Article 30.<sup>107</sup> A compromise deal was nearly reached in late December 2002, but failed because of US objections on the scope of diseases.<sup>108</sup> In the end, a belated compromise, analysed in Section 3 below, was finally reached on 30 August 2003, just days before the opening of the fifth WTO Ministerial in Cancun.<sup>109</sup>

#### 4 *Non-violation Complaints*

Ordinarily, disputes in the WTO involve claims that a country has violated the provisions of a WTO agreement. Non-violation complaints refer to a government's ability to bring a dispute to the dispute settlement body, based on loss of an expected benefit under a WTO agreement (or impairment of an objective of such agreement) caused by another Member's measures — even if such measures do not actually conflict with the provisions of the Agreement in question.<sup>110</sup> The TRIPS Agreement (Article 64.2) set a temporary moratorium on non-violation complaints until 1 January 2000. In the meantime, the TRIPS Council started looking at the extent and way (scope and modalities) in which non-violation complaints could be applied.<sup>111</sup> 'At least two countries (the US and Switzerland) take the position that non-violation complaints should be allowed in intellectual property protection in order to discourage Members from engaging in "creative legislative activity" that would

<sup>104</sup> Some developing country Members advocate the deletion or revision of Article 31(f). See Joint Communication from the African Group in the WTO, 'Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', IP/C/W/351, at para. 3(e) (24 June 2002); the EU favours the specific amendment to Article 31(f). See communication from the European Communities and their member states, 'Concept Paper Relating to Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health', IP/C/W/339, Sec. III.1 at 4 (4 March 2002); Communication from the European Communities and Their Member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/352 (20 June 2002).

<sup>105</sup> See Second Communication from the United States, Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health, IP/C/W/358 (9 July 2002).

<sup>106</sup> See Communication from the United States, 'Moratorium to Address Needs of Developing and Least Developed Members with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector', IP/C/W/396 (14 January 2003).

<sup>107</sup> See Communication from the United Arab Emirates, 'Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health', IP/C/W/354 (24 June 2002); Communication from Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, 'Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health', IP/C/W/355 (24 June 2002).

<sup>108</sup> See WTO News 2002, 'Supachai Disappointed over Governments' Failure to Agree on Health and Development Issues', Press/329 (20 December 2002) available at [www.wto.org/english/news\\_e/pres02\\_e/pr329\\_e.htm](http://www.wto.org/english/news_e/pres02_e/pr329_e.htm).

<sup>109</sup> General Council Decision of 30 August 2003, IP/C/W/405.

<sup>110</sup> See Article XXIII: 1(b) of the GATT 1994. For more information about non-violation complaints, see TRIPS Council, 'Non-violation Complaints; Background and the Current Situation', available at [www.wto.org/english/tratop\\_e/trips\\_e/nonviolation\\_background\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm).

<sup>111</sup> See *ibid.*

enable them to get around their TRIPS commitments.<sup>112</sup> The non-violation complaint mechanism, however, could potentially function as a tool to circumscribe the developing countries from effectively using flexibilities concerning public health in the TRIPS Agreement. Non-violation complaints could force Members to raise intellectual property protection beyond minimum requirements in the TRIPS Agreement. They could also be used to constrain the adoption of national measures consistent with Article 8 of the TRIPS Agreement to protect public health and nutrition. This issue is largely neglected in the discussion of the TRIPS Agreement and public health. Although the developing group, in its draft ministerial declaration, contended that non-violation complaints should, at least, not apply to measures adopted by them for the protection of public health,<sup>113</sup> the final text of the Doha Declaration was still silent on this issue. Instead, the Implementation Decision adopted at the Doha Conference directed the TRIPS Council to continue to discuss this and to make recommendations to the 2003 Fifth Ministerial Conference. Until then, Members have agreed not to file non-violation complaints under TRIPS.<sup>114</sup> Most developing countries would like to see the ban continued or made permanent.<sup>115</sup> As of the date of conclusion of this article, the TRIPS Council had been unable to reach an agreement on this subject.

<sup>112</sup> WTO, 'TRIPS: "Non-violation" Complaints (Article 64.2), Background and the Current Situation', at [http://www.wto.org/english/tratop\\_e/trips\\_e/nonviolation\\_background\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm). Other Members, like the EU and Canada, oppose the instant application of the non-violation remedy to the TRIPS-related disputes without careful deliberations on its potential impact on the international protection of intellectual property rights. See Communication from Canada, 'Non-violation Nullification or Impairment under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)', IP/C/W/127(10 February 1999); Proposal from Cuba, the Dominican Republic, Egypt, Indonesia, Malaysia and Pakistan, 'Non-violation Nullification or Impairment under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)', IP/C/W/141 (29 April 1999); Communication from Canada, the Czech Republic, the European Communities and their member States, Hungary and Turkey, 'Non-violation Complaints under the TRIPS Agreement — Suggested Issues for Examination of Scope and Modalities under Article 64.3 of the TRIPS Agreement', IP/C/W/191(22 June 2000); Communication from Australia, 'Non-violation Complaints under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)', IP/C/W/212 (27 September 2000); Communication from Canada, 'Further Consideration of Non-violation Nullification or Impairment under the Agreement on Trade-Related Aspects of Intellectual Property Rights', IP/C/W/249 (29 March 2001); Communication from Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela, 'Non-Violation and Situation Nullification or Impairment under the Trips Agreement', IP/C/W/385 (30 October 2002).

<sup>113</sup> Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/312 (4 October 2001).

<sup>114</sup> See 'Implementation-Related Issues and Concerns', Decision of 14 November 2001, WT/MIN(01)/17, para. 11.1.

<sup>115</sup> See Cancun WTO Ministerial Briefing Notes, TRIPS, Negotiations, implementation and TRIPS Council Work, available at [www.wto.org/english/thewto\\_e/minist\\_e/min03\\_e/brief\\_e/brief06\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min03_e/brief_e/brief06_e.htm).

## B *Some Reflections on the Post-Doha Negotiations*

The terrorist attack of 11 September has been called a crime against humanity.<sup>116</sup> Terrorism is a global threat with global effects.<sup>117</sup> The attack against the US threatens more than the tragic loss of individual lives and the collapse of the World Trade Center. It has had profound effects not only at the psychological, economic and political level, but also at the international legal level. With respect to the multilateral trading system, many developed country Members became more aware that the launching of a new round of multilateral trade negotiations could not be separated from the overall need to alleviate poverty, promote equity and foster economic growth in most of the developing and least developed country Members. In a globalized world, countries are interlocked both economically and politically. Most of the developed country Members realized that there exists a truly global interest in effectively combating regionally or globally transmitted diseases. As some commentators have noted, the events in the months preceding the Doha Ministerial Conference were likely more influential than international public pressure.<sup>118</sup> The terrorist attack and the subsequent anthrax scare taught the US a good lesson that, in the process of deeper globalization, it should play a more positive rather than self-centred role in the new round of multilateral trade negotiations. The positive attitude of the US was a key factor in the success of the Doha Conference. As one economist observed:

The 11 September 2001 attacks on the World Trade Center left the United States more determined than ever to launch the new round. The United States wanted to send a clear message that such attacks could not undermine its resolve to achieve progressively open markets. The US determination translated into a greater willingness to grant concessions than at Seattle. Other WTO members shared the US goal and reciprocated by being more flexible than they were at Seattle.<sup>119</sup>

Compared with the frustrating failure of the Seattle Conference in 1999, the Doha Conference was regarded by many commentators as a turning-point in the history of the WTO and in relations between developed and developing countries.<sup>120</sup> The success applauded at the Doha Conference was based on the joint efforts and shared interest between developed and developing countries. Unfortunately, it would now appear that the ‘spirit of Doha’ was short-lived. No sooner had the Declaration on TRIPS and

<sup>116</sup> See Cassese, ‘Terrorism is Also Disrupting Some Crucial Legal Categories of International Law’ 12 *EJIL* (2001) 1003.

<sup>117</sup> UN Press Release, ‘Addressing Security Council, Secretary-General Endorses Three-pronged Counterterrorism Strategy’, SG/SM/8417, SC/7523.

<sup>118</sup> See, e.g., Gold and Lam, ‘Balancing Trade in Patents — Public Non-Commercial Use and Compulsory Licensing’, 6 *Journal of World Intellectual Property* (2003) 6.

<sup>119</sup> Panagariya, ‘Developing Countries at Doha: A Political Economy Analysis’, 25 *World Economy* (2002) 1205.

<sup>120</sup> See WTO, *The Road to Doha and Beyond — A Road Map for Successfully Concluding the Doha Development Agenda* (2002), at 8.

public health been adopted than it was clear that differences of opinion on TRIPS and public health had not been truly bridged.

As we saw above, the drafting process of the Doha Declaration revealed huge gaps in opinions on the relationship between TRIPS and public health. While the developing country group emphasized that patent protection should not impede public access to affordable drugs,<sup>121</sup> the US and other developed countries insisted that patent protection contributes to public health objectives and took the position that globally the TRIPS Agreement contributes to the availability of medicines.<sup>122</sup> After the adoption of the Doha Declaration, there were still substantially different viewpoints on the relationship between the TRIPS Agreement and public health, as if no compromise had ever been reached, or promises made. In particular, the pharmaceutical industry, which had traditionally lobbied hard for high levels of intellectual property protection in developing countries, took the position that the main theme of the Declaration was to reaffirm the value of intellectual property protection and to recognize that the TRIPS Agreement is part of the solution to better public health rather than a barrier to access.<sup>123</sup> On the contrary, most academics and NGOs point out that the final text more closely resembles the developing countries' draft than the developed countries' positions. Outside the pharmaceutical industry, most commentators emphasize that the Declaration gives broad discretion to Member states in deciding how to counter the negative effects of the TRIPS Agreement, especially its impact on prices. They stress that, for the first time, the Doha Declaration explicitly underscores that public health concerns outweigh full protection of intellectual property.<sup>124</sup>

The difficulty of the post-Doha negotiations was not a total surprise. There had long been signals that the pharmaceutical industry did not universally share 'the spirit of Doha', and would lobby hard for tight restrictions on the interpretation of the Declaration. Nonetheless, many observers were surprised by the intensity of the fight that the US pharmaceutical industry put up. For instance, many observers were taken aback when, as early as February 2002, the US pharmaceutical industry lobbied to urge the Office of the United States Trade Representative (USTR) to make four new countries listed as 'Priority Foreign Countries' for monitoring and potential trade sanctions under the 'Special 301' provisions of the US trade law, for 'their failure to protect patented pharmaceutical products'.<sup>125</sup>

Under pressure from powerful pharmaceutical industry lobbies, the US voiced firmly the significance of safeguarding the minimum patent protection standards

<sup>121</sup> See Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, 'Ministerial Declaration on the TRIPS Agreement and Public Health', 4 October 2001, IP/C/W/312.

<sup>122</sup> See Contribution from Australia, Canada, Japan, Switzerland and the United States, 'Preambular Language for Ministerial Declaration', 4 October 2001, IP/C/W/313.

<sup>123</sup> PhMRA, WTO Doha Declaration Reaffirms Value of Intellectual Property Protection, 14 November 2001, available at [www.phrma.org/mediaroom/press/releases/14.11.2001.310.cfm](http://www.phrma.org/mediaroom/press/releases/14.11.2001.310.cfm).

<sup>124</sup> Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha', 3 *Chicago Journal of International Law* (2002) 27, at 47–48.

<sup>125</sup> See Oxfam Brief Paper, *TRIPS and Public Health: The Next Battle* (2002), at 2.

provided for in the TRIPS Agreement, and stuck to its position that the obligation under the TRIPS Agreement should be strictly interpreted and implemented, as if the Doha Declaration had never been adopted. During the post-Doha negotiations, the US, which has the strongest bargaining power in the WTO, played the most negative role. Throughout 2002 and most of 2003, as the negotiations dragged on, the limitations of the Doha Declaration were apparent. While the Declaration corrects, to some degree, the unbalanced nature of the TRIPS Agreement, it was not followed by a sufficient shift in the relative bargaining powers of developing and developed Members, nor by any softening of the negotiating stance on the part of the US.<sup>126</sup> For instance, The USTR 2002 ‘Special 301’ report reaffirmed the US pharmaceutical patent policy in the following terms:

The U.S. Government also remains committed to a policy of promoting intellectual property protection, including for pharmaceutical patents, because of intellectual property rights’ critical role in the rapid innovation, development, and commercialization of effective and safe drug therapies. Financial incentives are needed to develop new medications. No one benefits if research on such products is discouraged.<sup>127</sup>

In December 2002, the US rejected a near deal on paragraph 6 because of ‘concerns that it would undermine the WTO rules on patents that provide incentives for development of new pharmaceutical products, including those of a non-epidemic nature’.<sup>128</sup> By the time it finally lifted its veto in late August 2003, two million more Africans had died from AIDS, for want of treatment.<sup>129</sup> As of the time of writing this paper, the US is still aggressively pursuing TRIPS-plus agreements. The recently signed US-Singapore Free Trade Agreement (FTA)<sup>130</sup> and the US-Chile FTA<sup>131</sup> set out the highest standards of protection and enforcement for intellectual property yet achieved in the bilateral and multilateral instruments. TRIPS-plus measures are still being inserted into future FTAs<sup>132</sup> and in the proposed Free Trade Agreement of the Americas (FTAA).<sup>133</sup> Last but not least, the US still wants to end the temporary ban on non-violation complaints. This issue should not be overlooked, as it could significantly constrain Members’ abilities to introduce new and perhaps vital social, economic,

<sup>126</sup> See Panagariya, *supra* note 119, at 1218–1232.

<sup>127</sup> USTR, 2002 ‘Special 301’ Report, at 5, available at [www.ustr.gov/reports/2002/special301.htm](http://www.ustr.gov/reports/2002/special301.htm).

<sup>128</sup> See USTR Press Release of 20 December 2002, available at [www.ustr.gov](http://www.ustr.gov).

<sup>129</sup> According to Morocco’s Ambassador to the WTO, 2.1 million Africans have died from diseases such as AIDS since 16 December 2002 when the near-deal collapsed. See <http://www.gulf-times.com/2003/08/31/finance.htm>.

<sup>130</sup> US-Singapore Free Trade Agreement, available at <http://www.ustr.gov/new/fta/singapore.htm>. For discussions about the US-Singapore FTA, see Kang and Stone, ‘IP, Trade, and U.S./Singapore Relations — Significant Intellectual Property Provisions of the 2003 U.S.–Singapore Free Trade Agreement’, 6 *Journal of World Intellectual Property* (2003) 721.

<sup>131</sup> US-Chile Free Trade Agreement, available at <http://www.ustr.gov/new/fta/chile.htm>.

<sup>132</sup> These future FTAs include: US-Australia FTA, US-CA FTA, US-Morocco FTA, US-SACU FTA. See <http://www.ustr.gov/new/fta/index.htm>.

<sup>133</sup> See Médecins sans Frontières, ‘Don’t Trade Away Health in the FTAA’, available at [www.accessmed-msf.org](http://www.accessmed-msf.org). See also, Vivas-Eugui, ‘Regional and Bilateral Agreements in a TRIPS-plus World: The Free Trade Area of the Americas (FTAA)’, *TRIPS Issues Paper* No. 1, Quaker United Nations Office, available at [www.quno.org](http://www.quno.org). For FTAA, see [www.ustr.gov/regions/whemisphere/ftaa.shtml](http://www.ustr.gov/regions/whemisphere/ftaa.shtml).

development, health, environmental and cultural measures that might be construed as denying ill-defined benefits under the TRIPS Agreement.<sup>134</sup>

## C *The Decision on Implementation of Paragraph 6*

### 1 *A Complex, Controversial Decision*

The Decision on Implementation of Paragraph 6<sup>135</sup> is meant to enable developing countries to import generic medicines made under compulsory licensing if those countries are unable to produce the medicines themselves. Commentators sharply disagree on its assessment. For Director-General Supachai Panitchpakdi, it was 'a historic agreement for the WTO', which 'proves once and for all that the organization can handle humanitarian as well as trade concerns.'<sup>136</sup> Others call the deal 'largely symbolic.'<sup>137</sup> Prominent NGOs such as Oxfam and *Médecins sans Frontières*, which had campaigned hard for a broad agreement, have charged that it is so complex, riddled with restrictions, safeguards and red tape as to be 'unworkable'.<sup>138</sup> For their part, African countries seem to welcome the deal. South Africa's Ambassador to the WTO, for instance, immediately announced that he believed 'the mechanism will work, it can work and we intend to use it'.<sup>139</sup> Professor Abbott, a leading TRIPS expert who was involved in advising a group of developing countries, has an interesting viewpoint. First of all, he confirms that the negotiating process was 'ugly', and that he is concerned about the implementation of the Decision.<sup>140</sup> He makes it very clear, however, that the rules are not the problem. Unlike Oxfam or *Médecins sans Frontières*, he does not see the paragraph 6 procedures as particularly burdensome. The problem, in his view, is the risk that poor countries may be pressured into not making use of the mechanism. As a possible solution, he calls for leadership from the stronger of the developing countries, as well as active support from multilateral institutions such as WHO, the World Bank, UNCTAD and the UN human rights bodies in order to encourage developing countries to use the paragraph 6 mechanism.

### D *Promoting Public Health in the Post-Doha Era*

The TRIPS Agreement establishes universal minimum standards of legal protection and enforcement for a number of different forms of intellectual property rights.<sup>141</sup> Due

<sup>134</sup> See Abbott, 'Non-Violation Nullification or Impairment Causes of Action under the TRIPS Agreement and the Fifth Ministerial Conference', *Occasional Paper* No. 11, July 2003, Quaker United Nations Office, available at <http://www.quono.org>.

<sup>135</sup> See *supra* note 6.

<sup>136</sup> See Press Release 350, 30 August 2003, available at [www.wto.org](http://www.wto.org).

<sup>137</sup> Comment, 'Drug Resistance', F.T., 29 August 2003.

<sup>138</sup> See Joint Oxfam-MSF Press Release, 30 August 2003, available at [www.oxfam.org](http://www.oxfam.org) and CPTech Statement, available at [www.cptech.org](http://www.cptech.org).

<sup>139</sup> See 'WTO Clinches Deal on Cheap Medicines', 31 August 2003, at [www.gulf-times.com](http://www.gulf-times.com).

<sup>140</sup> See Abbott, *supra* note 5.

<sup>141</sup> See e.g., Reichman, 'Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement', in C. M. Correa and A. A. Yusuf (eds), *Intellectual Property and International Trade: The Trips Agreement* (1998) 21; M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the Trips Agreement* (1996); J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (2001).

to different social and economic structures and scientific and technological capacities in various Members, this one-size-fits-all approach to intellectual property protection simply does not work. The optimal intellectual property regime is bound to vary widely from one country to another, taking full account of each Member's own development levels. Patent law itself owes its very birth not to harmony but to diversity of national law.<sup>142</sup> Recognizing the Doha Declaration as a guideline for the protection of public health, developing and least-developed country Members should make every effort to incorporate their respective sustainable development policies into their patent laws on the basis of effective use of the flexibility inherent in the TRIPS Agreement.

### *1 Use of the Flexibility in the TRIPS Agreement*

Using safeguards in intellectual property law to protect public health necessitates the following national legislative provisions and policies:

- compulsory licensing is essential to many developing country Members so that sources of generic or low-cost drugs can be made available.<sup>143</sup> Developing countries can limit the costs of the patent system for their population by facilitating generic entry and generic competition by using compulsory licensing. Therefore, developing countries should establish workable laws and related procedures to give effect to compulsory licensing and then make cautious use of this tool.
- limited exceptions provided for in Article 30 of the TRIPS Agreement are crucial to developing country Members. Although the wording of Article 30 is ambiguous and what 'limited exceptions' could be used is therefore not yet clear, it is widely accepted that the 'early working exception'<sup>144</sup> falls under the category of 'limited exceptions'. Generally, developing countries should include this exception in their patent laws to facilitate early entry of generic competition in the pharmaceutical sector on patent expiry. Meanwhile, developing countries should also seek Article 30-compatible exceptions to patent rights.
- under the TRIPS Agreement, Members are free to shape the legal system regarding the exhaustion of intellectual property rights and the control of anti-competitive practice.<sup>145</sup> Therefore, developing country Members may establish the parallel importation and control of anti-competitive practices systems conducive to the protection and promotion of public health.

<sup>142</sup> See Duffy, 'Harmony and Diversity in Global Patent Law', 17 *Berkeley Technology Law Journal* (2002) 685.

<sup>143</sup> See Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health', *Occasional Paper* No. 9 (2002), at 17. See also, Scherer and Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Nations', 5 *JIEL* (2002) 914.

<sup>144</sup> The early working exception makes it legal for a generic producer to import, manufacture and test a patented product prior to the expiry of the patent in order that it may fulfil the regulatory requirements imposed by particular countries as necessary for marketing as a generic.

<sup>145</sup> See Articles 6 and 40.2 of the TRIPS Agreement.

## 2 Beyond TRIPS

According to the WHO, a number of socio-economic factors other than the patent system have contributed to the diminishing availability of affordable drugs in poor nations. WHO recognizes four key factors that influence access to drugs: rational selection and use, affordable prices, sustainable financing, and reliable health and supply systems.<sup>146</sup> Many different actors have roles to play in making these factors into enabling forces, rather than obstacles. These actors include governments of developing countries, governments in industrialized countries, manufacturers, consumer groups and non-governmental organizations, and international agencies and private foundations. Therefore, TRIPS-related reforms will not suffice. The following five recommendations should be given top priority.

First, given the lack of commercial interest in researching infectious diseases prevalent in developing countries,<sup>147</sup> public funding for research on health problems in developing countries should be increased. This additional funding should seek to exploit and develop existing capacities in developing countries for this kind of research, and promote new capacity, both in the public and private sectors. The increased funds should aim at assisting developing countries to gradually build a sound technological base to address the public health and public policy concerns, and to provide a sufficient economic incentive to spur the development of low-cost generic drugs by companies located in developing countries.

Second, governments in both developing and developed countries should play a stronger role in formulating risk prevention policies, including more support for scientific research, improved surveillance systems and better access to global information. Meanwhile, they should give top priority to developing effective, committed policies for the prevention of globally increasing high risks to health.<sup>148</sup>

Third, global efforts to find a workable, cost-effective and transparent way to expand access to affordable drugs should be continued. Recently, a number of ways have been sought to improve public access to essential drugs for people in poor countries, for instance, differential pricing and financing,<sup>149</sup> the initiative of a global fund to fight against diseases of poverty<sup>150</sup> and the establishment of a public-private partnership model.<sup>151</sup> Think tanks, independent researchers and policy makers should

<sup>146</sup> See WHO, 'More Equitable Pricing for Essential Drugs: What Do We Mean and What Are the Issues?', Background paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, 8–11 April 2001.

<sup>147</sup> See Médecins Sans Frontières (MSF), *supra* note 38.

<sup>148</sup> See WHO, *supra* note 13.

<sup>149</sup> See WHO, *supra* note 146; WTO, Background Note Prepared by Jayashree Watal for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, 8–11 April 2001. See also, Hammer, 'Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health', 5 *JIEL* (2002) 883.

<sup>150</sup> 'The Global Fund to Fight AIDS, Tuberculosis & Malaria' is one of most influential programmes. It may be visited at [www.globalfundatm.org/](http://www.globalfundatm.org/).

<sup>151</sup> See Kettler, 'Using Intellectual Property Regimes to Meet Global Health R&D Needs', 5 *Journal of World Intellectual Property* (2002) 655, at 674–677; see also, Reichman and Lange, 'Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions', 9 *Duke Journal of Comparative International Law* (1998) 11.

continue to research the issues concerned and provide intellectual input to governmental negotiating agencies. There needs to be a concerted and united fight against global public health crises.

Fourth, international collaboration should be strengthened to combat disease crises. Based on the principle of transparency, WTO should cooperate with other relevant international organizations and non-governmental organizations. The cooperation should encourage states to make constructive dialogues on how to have successfully married implementations of the TRIPS Agreement with their obligations under international human rights law. Additionally, it should inspire the engagement and participation of civil society for the sake of fostering public scrutiny of governmental policies on intellectual property protection.

Fifth, the pharmaceutical industry should perform its corporate social responsibility and respond to the growing public concern about the accountability and the social, and economic, impact of its comparatively high-priced drugs and corporate policies. The pharmaceutical industry can and should play an important role in addressing the deeply unequal or asymmetrical access to essential drugs between rich and poor countries. Therefore, pharmaceutical companies should scrutinize how they can undertake their core business in a way that ensures that benefits are shared more evenly between rich and poor countries, and re-evaluate the impact of their business policies on the universal enjoyment of fundamental human rights.

## Conclusions

We live in a dangerous world, a world which is becoming increasingly vulnerable to potential public health crises. The recent alarming outbreak of Severe Acute Respiratory Syndrome (SARS) in South-east Asia makes it clear once again that international cooperation is essential in combating global public health crises. Only through global action can we solve global health problems. We are in the midst of a global expansion in the extent to which pharmaceutical innovations are protected by the intellectual property system. Finding a balanced intellectual property system that can provide appropriate incentives to motivate private participation in R&D solutions and which also ensures that patients and governments can have access to the results of scientific and technological progress is a global challenge confronting international health policy-makers and WTO negotiators.

The Doha Declaration clarifies the right of WTO Members to incorporate flexibilities built into the TRIPS Agreement into their domestic intellectual property laws to protect and promote public health. With the Declaration, Members are now more confident of their right to shape their intellectual property laws in a manner conducive to public health. It is crucial, however, that the 'spirit of Doha' be preserved, and that both the Declaration and the implementation decisions thereunder be applied in good faith. Not only is the legitimacy of the WTO at stake but, even more importantly, so are the lives and health of millions of poor people throughout the world.