

THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO

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'I hope as we move forward, Europe and the United States can work together to stress the notion we have removed this issue from the area of public debate. This is really off the table.' Alan Larson, US Undersecretary of State for Economic Affairs, 28 November 2001¹

INTRODUCTION

The adoption by Ministers on 14 November 2001, in Doha, of the Ministerial Declaration on the TRIPS Agreement and Public Health marked a turning point in political and legal relations at the WTO. Developing country Members sent a clear signal that they would take steps to protect and advance their essential interests. These Members demonstrated that by establishing a coalition, and maintaining it throughout a negotiating process, they could prevent themselves from being outmaneuvered by the EU–US block.

The essence of the Declaration is captured in paragraph 4:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement

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¹ On 28 November 2001, at the European Institute Forum, US Undersecretary of State for Economic Affairs Alan Larson, in addition to the statement quoted above, said 'There's going to be a discussion in the WTO about compulsory licensing for export but my reading of the room at Doha is that no one is seriously interested in this, not the Africans, not the middle income countries with generic drug producing capabilities' (*Inside US Trade* (30 November 2001)). The report on these statements noted that developing country, industry, and EU representatives did not share the assessment that the TRIPS and public health agenda was exhausted.

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.²

The TRIPS Agreement is a flexible legal instrument, and the decision of Ministers will prove significant in supporting interpretations that promote the protection of public health. While the Declaration does not resolve developing country concerns regarding access to medicines and TRIPS, it is a significant milestone.

I. THE CONTEXT OF THE DOHA DECLARATION

A. Historic perspective

1. *The Uruguay Round*

The Declaration on TRIPS and Health traces its more immediate roots to discussions leading up to the GATT Uruguay Round negotiations launched in 1986,³ and to the controversial mandate of that launch.⁴ From the outset of the process, developing Members of the GATT strongly objected to moving IPRs into the trading regime. More particularly, Members such as Brazil and India continually expressed misgivings on social interest grounds about subjecting inventions related to public health and nutrition to strict patenting rules.⁵ Those concerns, shared by other developing Members, were overcome by a US-led effort to secure the interests of the developed country pharmaceutical sector.⁶

² Ministerial Conference, Fourth Session, Doha, 9–14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001.

³ Controversy regarding the appropriate scope of patent protection, including its application to medicines, is present throughout the historical evolution of the international intellectual property system. See, e.g. Roffe, P., 'The political economy of intellectual property rights – An Historical Perspective', in J. Faundez *et al.* (eds) *Governance, Development and Globalization* 397 (Warwick, UK: University Warwick 2000).

⁴ For US negotiating objectives, see United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, 3 November 1987, at Patents (text reprinted in 'US Framework Proposal to GATT Concerning Intellectual Property Rights', 4 BNA Int'l Tr Repr 1371 (4 November 1987)). For EU negotiating objectives, see, e.g. Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/26, July 1988.

⁵ See, e.g. statements by delegate of India, Note by the Secretariat, Meeting of Negotiating Group of 12–14 July 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/14, 12 September 1989, at, e.g. para. 79.1.

⁶ See contributions on TRIPS in Daniel Kennedy and James Southwick (eds), *The Political Economy of International Trade Law: Essays in Honor of Robert Hudec [Political Economy]*, (Cambridge University Press 2002).

2. South Africa

The concerns of developing Members intensified as the US, EU, and their research-based pharmaceutical enterprise constituency (hereinafter referred to as 'Pharma')⁷ initiated aggressive campaigns against countries that threatened to take advantage of the IPRs related policy options left open by the TRIPS Agreement. The most visible case involved a multi-pronged attack against the government of the Republic of South Africa that combined government threats to impose trade and economic sanctions with private Pharma litigation to delay the implementation of health reform legislation.⁸ Despite the obvious harshness of USTR and the European Commission threats of trade sanctions against a country whose population suffered from an alarming HIV/AIDS infection rate, it was not until NGO protesters threatened to disrupt the political campaign of Vice President Gore that the US backed away from its threats.⁹ Pharma persisted in its litigation effort until NGOs had inflicted tremendous public relations damage. Pharma then withdrew, taking away from Pretoria an array of weak legal claims.

3. Brazil

USTR followed-up the South Africa experience by initiating a WTO dispute settlement proceeding against Brazil regarding its compulsory licensing legislation.¹⁰ Brazil had initiated a highly successful HIV/AIDS treatment program using generic antiretrovirals (ARVs)¹¹ and, despite USTR protests to the contrary, the move was widely perceived as directed toward Brazil's treatment program. USTR withdrew its complaint against Brazil at only the beginning of another international relations disaster.¹²

Although the specific objectives of USTR and Pharma were not achieved in these cases, in large measure the Uruguay Round concerns of the developing countries were being realized. The TRIPS Agreement would in fact be

⁷ The term 'Pharma' is commonly used, and is so used in this article, to refer to the major research-based pharmaceutical enterprises on a worldwide basis. That term is distinct from the related acronym 'PhRMA' that is the identifier of a US-based pharmaceutical industry NGO. See discussion at notes 42 and 43 on pages 478–479.

⁸ The legal issues at stake in the case brought by 39 pharmaceutical companies against Nelson Mandela and the South African Department of Health are discussed in Study Paper 2a, above n *.

⁹ See Frederick M. Abbott, 'The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO', in *Political Economy*, above, n 5.

¹⁰ See Request for Consultations by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/1, G/L/385, IP/D/23, 8 June 2000, and Request for the Establishment of a Panel by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/39, January 2001.

¹¹ See Tina Rosenberg, 'Look at Brazil', *NY Times*, Sunday Magazine (28 January 2001).

¹² See Joint Communication Brazil-United States, 25 June 2001. The US had by this time effectively been condemned by the UN Commission on Human Rights (Resolution 2001/33, Access to Medication in the Context of Pandemics such as HIV/AIDS, 57th Sess. April 2001).

invoked to prevent them from addressing their public health needs. The battles, even if won, were costly and time consuming. Moreover, the highly visible cases were only the tip of an iceberg with a much broader impact. There were many cases in which developing Members changed their policies as a consequence of political and economic pressure asserted on the basis of TRIPS rules.¹³

B. The role of generic medicines

1. *Affordability and access*

There is substantial evidence that the availability of generic (off-patent) drugs, especially from multiple sources, substantially reduces prices. A report from the WHO indicates:

Very different degrees of competition characterise different sub-components of the pharmaceuticals market. Some drugs which are available over the counter, such as cough syrup, and many generics (such as aspirin) are produced in conditions which resemble those of a perfectly competitive market – multiple producers and purchasers, minimally differentiated products, information asymmetries unimportant, low barriers to entry. Each firm in such a market tends to be a price taker, and price will be close to marginal cost.

At the other end of the pharmaceuticals market, a relatively small number of firms have limited monopolies (limited in time and subject to therapeutic competition) for complex drugs (such as anti-retrovirals), available only on prescription. This sub-market is characterised by information problems, and legal barriers to entry posed by patent protection. Here price is commonly several times the marginal cost of production, particularly in the early years of patent life. Profits generated under patent protection are a reward for risk-taking and innovation – in the form of research and development expenditures – by the patent-holding company.

Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug's price when there is just one generic competitor, and to 29% with 10 competitors . . . [footnotes omitted]¹⁴

The debate on patenting of public health related inventions involves a complex set of economic and social issues.¹⁵ On one side, Pharma claims that strong patent protection establishes expected income streams that provide the necessary incentive to conduct expensive research and development (R &

¹³ Countries that were subject to intensive and well-documented USTR pressures include, e.g. Argentina, the Dominican Republic, Kenya, and Thailand.

¹⁴ Working paper by Andrew Creese and Jonathan Quick, 'Differential Pricing Arrangements and Feasibility: Context Setting Paper', World Health Organization, 21 January 2001.

¹⁵ This policy debate is described in some detail in CIPR Study 2a, above n *, and was discussed by this author in general terms in an earlier article in this journal, Frederick M. Abbott, 'The Enduring Enigma of TRIPS: A Challenge for the World Economic System', 1 JIEL 497 (1998).

D).¹⁶ Low standards of patent protection reduce expected income streams, and with it the incentive to invest. Consumers pay high prices for on-patent drugs, but this must be understood in the context that high prices are the mechanism for funding long-term R & D, thus yielding an offsetting social good.

From the developing country side come a number of responses. With regard to immediate disease crises like HIV/AIDS, long-term R & D is not useful if the patients have already died. In the non-crisis context, some individuals in developing countries can afford to pay for expensive drugs whose price incorporates Pharma R & D. The vast majority cannot. For the latter, recognition of patent rights is an unbearable burden. For diseases principally of relevance to developing countries (such as malaria and sleeping sickness), Pharma does not meaningfully invest in the development of new drugs because patients cannot pay for them. From a developing country standpoint, the market fails in a variety of ways.¹⁷ It adjusts to the public health situation in developing countries by allocating scarce resources to areas of higher return, and in doing so leaves the poor to suffer.

As an expression of OECD industrial policy, the TRIPS Agreement is producing a paradoxical result. While intended to extract greater technology rents from developing countries, it has succeeded in focusing media attention on the role of pharmaceutical patents in OECD public health systems. Pharma is increasingly anxious about the back draft.

2. Generics as self-help

The response of the international community to disease crises, and more generally to the public health situation in developing countries, has been poor. The scale of the HIV/AIDS pandemic has been evident for some years. Recent reports regarding rapid increases in infection rates in Eastern Europe, Central Asia, and China only heighten the attention the crisis demands. Credit is due to Kofi Annan at the UN for attempting to put HIV/AIDS at the top of the international agenda. The response was the creation of a Global Fund mechanism that has so far attracted only modest (and inadequate) financial support. Due to the internal political preferences of certain donor countries, the attention of the Fund has so far been directed to preventive measures that are doubtless desirable, but leave those in need of treatment in no better condition. The Bush Administration downgraded attention to the pandemic as it upgraded attention to addressing the threat of bio-terrorism.¹⁸

This author has suggested that the World Bank and IMF become much

¹⁶ A wide-ranging selection of policy papers reflecting the views of the research-based pharmaceutical sector are found or referenced at the PhRMA website, www.phrma.org.

¹⁷ Economic studies in support of these points are set out in CIPR Study 2a, above n *.

¹⁸ Sheryl Gay Stolberg, 'Buckets for Bioterrorism, But Less for Catalog of Ills', *NY Times* (5 February 2002), at A20.

more directly involved in funding the build-up of the response to HIV/AIDS and more generally supporting attention to public health needs.¹⁹ The funding must take the form of grants, not loans, since any prospect of repayment would only undermine economic development. Unfortunately, there is no reason at the moment to be optimistic about a large scale World Bank/IMF response.

The HIV/AIDS pandemic is only the most urgent disease threat facing the developing world. Malaria and tuberculosis continue to kill millions each year. Even these disease threats remain only part of the general equation. The fact is that public health care throughout most of the developing world is a continuing catastrophe.²⁰

The 'net' is that developing countries cannot rely on an organized response to their problems by the international community. These countries must be prepared to address their public health needs by themselves. Patents cannot and should not stand in the way of these efforts. From the developing country standpoint, the manufacture and sale of generic versions of drugs that are patented by Pharma is the principal self-help remedy available to confront disease threats and burdens.

C. The role of international institutions

1. *The World Health Organization*

The World Health Organization (WHO) was largely absent from the TRIPS negotiations, although it was obvious that placing newly-developed pharmaceuticals under universal patent protection would have an impact on public health systems throughout the world.²¹ Yet as the implications of the new TRIPS regime began to take hold, state members of the WHO made increasing demands that the organization begin to address the TRIPS Agreement and, at the least, provide guidance regarding how to cope with its requirements. A small technical group within the WHO began to prepare and distribute concrete recommendations for coping with TRIPS by using the built-in flexibility to ameliorate the effects of introducing its requirements.²² These

¹⁹ See CIPR Study Paper 2a, above n *.

²⁰ The state of public health in the developing countries is reported on regularly in WHO publications, see, e.g. *WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000–2003*, WHO/EDM/2000.1 (2000). Médecins sans Frontières (MSF)/Doctors Without Borders also extensively reports on public health in developing countries. See Campaign for Access to Essential Medicines, <http://www.accessmed-msf.org>.

²¹ Eric Stein has recently described and analyzed the governance structure of the WHO in Eric Stein, 'International Integration and Democracy: No Love at First Sight', 95 AJIL 489 (2001).

²² See, e.g. *Globalization and Access to Drugs, Perspectives on the WTO/TRIPS Agreement* (revised), Health Economics and Drugs, DAP Series No. 7, Action Programme on Essential Drugs (1998) (Velásquez, Germán and Boulet, Pascale).

recommendations included, for example, authorizing parallel importation and granting compulsory licenses where appropriate.²³

As developing Members increasingly demanded that WHO aid them in responding to the impact of TRIPS, the institution gradually extended its capacities and willingness to address specific requests for assistance. A number of training seminars regarding TRIPS implementation have been conducted with public health, patent office, and trade officials.²⁴ These activities of WHO remain relatively unpublicized because increased attention would risk drawing a stronger reaction from Pharma. However, it is becoming substantially more difficult to find developing country officials who are unaware of compulsory licensing, parallel importation, and the importance of patent application reviews.

WHO is a complex international institution. Much of its funding comes from the OECD, and this gives Pharma a substantial voice in WHO policy. The United States and EU Member states have resisted the role played by WHO in advising and assisting developing Members.²⁵ The WTO Secretariat has been less than entirely cooperative with the WHO in TRIPS matters.²⁶ A portion of the WTO Secretariat resistance might be attributable to normal inter-institutional competition for jurisdictional primacy.

2. United Nations Conference on Trade and Development

The United Nations Conference on Trade and Development (UNCTAD) provides and supports economic development programs. UNCTAD has long been involved in the North–South dialogue on the problem of disparity in technology capacity, and has played an active role in developing instruments such as the Restrictive Business Practices Code.²⁷ More recently, UNCTAD (along with the International Centre for Trade and Sustainable Development) has turned its attention to the impact of the implementation of the TRIPS Agreement, and on providing advice to developing UN Members in its

²³ See, e.g. *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines, No 3, March 2001, WHO Geneva.

²⁴ See, e.g. *WHO Medicines Strategy: Perspectives on TRIPS and Access to Drugs*, Warsaw, September 2001 (meeting materials). Similar meetings were held in Harare, Zimbabwe, in August 2001, and in Ouagadougou, Burkina Faso, in December 2001.

²⁵ See, e.g. P. Benkimoun, *Agressions et menaces contre un responsable de l'OMS défenseur de l'accès du tiers-mond aux médicaments*, *Le Monde* (23 Aug 2001) (cited in 't Hoen, below n 31).

²⁶ The WTO Secretariat has directly and indirectly criticized the involvement of WHO in providing advice regarding interpretation and implementation of the TRIPS Agreement. See, e.g. correspondence of Adrian Otten reprinted on IP-Health list server, 'Adrian Otten missive on WTO/WHO cooperation', posting of 21 September 2001. This correspondence was inadvertently attached to a submission to the TRIPS Council.

²⁷ The Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices', adopted by the UN General Assembly.

implementation.²⁸ This extends to advice concerning implementation in a manner supportive of public health interests.

3. *UN High Commissioner for Human Rights*

The UN High Commissioner for Human Rights, at the request of the Commission on Human Rights Sub-Commission for the Promotion and Protection of Human Rights, has taken a strong interest in the effect the TRIPS Agreement and intellectual property protection are having on human rights interests, specifically in the light of the various human rights instruments that establish rights to health.²⁹ The human rights side of the TRIPS dialogue received substantial attention in the lead-up to the Doha Ministerial and may in the longer term have a significant effect.

4. *World Intellectual Property Organization*

So far the World Intellectual Property Organization (WIPO) has paid limited attention to the public health interests of its developing country member constituency. The organization has been criticized by the NGO community for appearing to promote high protection interests when recommending legislation to countries seeking assistance from it.³⁰ WIPO played no visible role in the run-up to Doha.³¹ There is increasing concern among developing member states and the NGO community regarding renewed negotiations at WIPO on substantive patent law harmonization.³² There is a fairly widely held perception that the US and EU industry interest groups will attempt to achieve in WIPO what cannot be achieved at the WTO.³³ Since WIPO does not operate on the same consensus principles as the WTO, there indeed is a risk that rules will be adopted without the active support of many developing members. These rules may be used as benchmarks by OECD patent offices, and effectively filter into developing country patent systems.

²⁸ See, e.g. Project on Handbook for TRIPS Negotiators that, while not directed specifically at medicines, necessarily takes into substantial account the need for guidance in this area.

²⁹ See UN High Commissioner for Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, UN Economic and Social Council, E/CN.4/Sub.2/2001/13, June 2001.

³⁰ See, e.g. Conference Report, 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to Get It Right', prepared by MSF Campaign for Access to Essential Medicines, Consumer Project on Technology, Oxfam International and Health Action International, regarding meeting of 28 March 2002, International Conference Centre of Geneva (CICG), available at <http://www.accessmed-msf.org>.

³¹ See, e.g. Ellen 't Hoen, 'WTO TRIPS Agreement, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha', draft of 18 December 2001, forthcoming in *University of Chicago Journal of International Law*.

³² See reports on activities of Standing Committee on the Law of Patents (<http://wipo.int>).

³³ Author's discussions with WTO and WIPO delegates and NGO representatives.

5. The World Bank and IMF

Improvements in the capacity of developing (including least developed) countries in the field of public health, including in the capacity to manufacture generic medicines, requires public funding through and from international institutions. Assistance in improving capacity to address public health is within the World Bank mandate, though this objective may not at the moment be given priority.³⁴ The IMF plays an unavoidable role in determining the direction of developing country health policy because it aids in the development and implementation of national budgets.³⁵ Expanding the roles of the World Bank and IMF may be necessary to effectively confront the major disease threats facing developing countries.

6. World Trade Organization

The WTO Secretariat operates on behalf of the Members, and has long been understood not to formulate policy. Nonetheless, it is well to recall that the Secretariat has indeed formulated policy, perhaps most notably illustrated by the distribution in late 1991 of the so-called 'Dunkel Draft' text of the Uruguay Round Agreements that provided an almost completed blueprint for the final texts adopted at Marrakesh.³⁶ While the Dunkel Draft text of the TRIPS Agreement reflected the work of the TRIPS Negotiating Group, it differed in many important respects from the text distributed by the Chair of that Group in mid-1990.³⁷ The GATT Secretariat played a key role in determining that negotiations would not move to conclusion unless the bold step of issuing an essentially completed text was taken. This decision may well have shaped the outcome of the Uruguay Round.

The Secretariat, and particularly the Intellectual Property and Investment Division, has played a substantial and visible role in the TRIPS and medicines dialogue.³⁸

³⁴ See World Development Report 2002.

³⁵ See description of IMF activities at <http://www.imf.org>.

³⁶ Trade Negotiations Committee, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNG/W/FA, 20 December 1991 (generally referred to as the 'Dunkel Draft', with reference to the then GATT Director General, Arthur Dunkel). The policy significance of the Secretariat's role in preparation and distribution of the Dunkel Draft text was first called to this author's attention by Prof. Robert Hudec.

³⁷ In his 23 July 1990 report on the status of work in the TRIPS Negotiating Group, the Chairman (Lars E. R. Anell) presented a draft composite text. The July 1990 draft included alternative 'A' (developed country supported) and 'B' (developing country supported) proposals.

³⁸ This role will be evident from description of the formulation of texts in preparation for Doha. However, the role is evidenced in many other ways, including, for example, review and comment by the Secretariat on WHO interpretations of TRIPS provisions, and the organization of meetings and workshops on TRIPS that inherently place the Secretariat in a position to select actors and define agendas.

D. Non-governmental organizations (NGOs)

The public relations efforts of NGOs such as Médecins sans Frontières (MSF), Consumer Project on Technology (CPT), Oxfam, Third World Network (TWN), and Treatment Action Campaign (TAC) have been a decisive factor in moving forward the interests of the developing countries in fora such as the WTO and WHO. MSF has been particularly successful in persuading at least a part of the European Commission to rethink close identification with the perspective of Glaxo-SmithKline.³⁹ In consequence, the US has not always been able to count on its Uruguay Round partner for unwavering support in WTO and WHO negotiations.

Pharma is aware that efforts to block access to essential medicines in virtually any part of the world will be brought to the attention of the international media, and will in significant cases receive widespread publicity. In January 2002, MSF and TAC began importing antiretroviral medicines from Brazil into South Africa, reportedly infringing patents held by Pharma enterprises in South Africa.⁴⁰ The response of one Pharma spokesperson was 'You don't tilt against windmills'.⁴¹ This is something of a turnaround in light of the earlier challenge to the South African government.

The NGOs have not limited their efforts to media campaigns. They are also involved in formulating policy positions and in offering guidance in regard to national legislative matters.⁴² This extends to an active participation with developing country governments in pursuing their interests at the WTO.

The International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), the Pharmaceutical Research and Manufacturers of America (PhRMA) and European industry groups, such as InterPharma, are of course NGOs representing the interests of particular sectors. The world pharmaceutical industry sector is comprised of a small number of major R & D companies, such as Glaxo-SmithKline, Merck, and Bristol-Myers Squib (BMS), and

³⁹ The extensive efforts made by MSF and other NGOs to provide a public health oriented perspective to European Commission TRIPS policies are chronicled from the Commission's perspective at DG Trade, Towards Sustainable Trade, Assessment by the Chairman of the Health Issue Group/Access to Medicines, 16 January 2001, at <http://europa.eu.int/comm/trade>.

⁴⁰ See, e.g. Mark Schoofs, *Physicians' Group Defies Patent Law to Bring AIDS Drugs to South Africa*, online.wsj.com, updated 30 January 2002. Also reported on by MSF at <http://www.accessmed-msf.org>.

⁴¹ As reported by the Wall Street Journal:

The two companies that hold patents on the medicines MSF imported from Brazil – Glaxo-SmithKline PLC and Boehringer Ingelheim GmbH – said they are observing the situation but didn't have immediate plans to take legal action, which would almost certainly bring down a hail of bad publicity. 'You don't tilt against windmills,' said Kevin McKenna, a spokesman for Boehringer Ingelheim South Africa.' (Mark Schoofs, *id.*)

⁴² Consumer Project on Technology, one of the most active advocates of changes to relevant legislation, reports on its activities at <http://cptech.org>. These activities include proposals in detail to amend US legislation on compulsory licensing and exceptions to patent rights.

a large number of smaller manufacturers typically producing generic drugs.⁴³ The interests of these various industry sectors are in many cases quite different. At the international level, the generics sector is much less well organized, and plays a limited role in policy formulation and execution. By way of contrast, the large generics industry in India plays a major role in the political dialogue there.

E. Organization of the developing country group

Perhaps the most notable development in the Doha process was the emergence of a cohesive group of developing countries articulating and advocating an essentially common position. The explanation for the cohesion among the developing countries may be attributable to a number of factors:

1. The issue of access to medicines involves highly shared common interests among developing countries. Although some, such as Brazil and India, are more equal than others in the extent of their internal pharmaceutical manufacturing capacity, all are affected by TRIPS rules that will mandate higher health care costs. Developing a common approach on the basis of a shared and urgent interest, other things being equal, is less difficult than developing a common approach when differential interests exert centrifugal pressure.
2. The comparative lack of resources among developing country delegations in Geneva is a systemic and persistent problem. The United States and European Union each maintain local operations with capacity to develop and track policy positions in multiple fora, and with sufficient staff to attend meetings in these fora. For many developing country delegations in Geneva, a few individuals (if that) may be called upon to attend not only to all WTO matters, but to matters at various other international institutions.

Although the Geneva-capacity problem is widely recognized, only a few developed Members have thought it important to address. Members such as the Netherlands and Norway have provided funding to assist in the formulation of developing country policy papers, and for the organization of fora where developing countries may exchange views.⁴⁴ The assistance provided toward the systematic development

⁴³ The structure of this industry is described in some detail in CIPR Study 2a, above n *, referring, *inter alia*, to Gambardella *et al.*, *Global Competitiveness in Pharmaceuticals, A European Perspective*, Report prepared for the Directorate General Enterprise of the European Commission, November 2000, and Organization for Economic Cooperation and Development (OECD), Directorate for Financial, Fiscal and Enterprise Affairs, Committee on Competition Law and Policy, *Competition and Regulation Issues in the Pharmaceutical Industry*, DAFFE/CLP (2000) 29, 6 February 2001.

⁴⁴ In this regard, the Quaker United Nations Office (QUNO) has actively provided logistic support for developing country delegations.

of coordinated WTO policy among developing countries began to bear fruit in the lead-up to the Doha Ministerial.

3. While developing WTO Members did not uniformly support a particular candidate, the lengthy and highly contentious process that brought about the sequentially split WTO Director Generalship of Michael Moore and Supatchai Panitchpakdi sent a strong message to all WTO Members that achieving institutional objectives requires determined effort and maintaining a common front. Developing countries went into the Doha TRIPS and public health negotiations well aware that concerted efforts would be made to fragment their coalition, and with a commitment to resist those efforts.

At least during the GATT era, the United States, Europe, and Japan consistently approached negotiations by first developing a shared position, a process that may require each to sublimate particularized interests.⁴⁵ In the period leading up to Doha, USTR Zoellick said, ‘I am extremely disappointed by the lack of Japanese – I would not expect leadership – but respectable followership’.⁴⁶ This is what the United States has come to expect, and the USTR presumably would not have risked a rupture in US–Japan relations if he did not think the point important.⁴⁷ The end of the cold war era may have reduced to some extent the perceived need among the US, EU, and Japan delegations to approach negotiations in a coordinated way, but it is difficult to avoid the perception that these major OECD actors share, and therefore pursue (at least at the ‘macro’ policy level), common interests at the WTO.

II. THE PRE-DOHA SETTING

A. Meetings of the TRIPS Council

1. Meeting of 20 June 2001

Developing country concerns with the impact of the TRIPS Agreement on access to medicines evolved over a period of years, and these concerns were expressed in many fora. In response to pressure from NGOs such as MSF,

⁴⁵ This was evident, for example, in preparations for the TRIPS negotiations that involved extensive coordination among EU, Japanese, and US industry groups, as well as the evolution of common negotiating positions over the course of the round. As Thomas Cottier has noted, there were variable geometries on particular issues, but on the question of pharmaceutical patent protection, for example, the common position was ‘firmly considered nonnegotiable’. Thomas Cottier, ‘The Prospects for Intellectual Property in GATT’, 28 CMLR 383 (1991), reprinted in F. M. Abbott, T. Cottier, and F. Gurry, *The International Intellectual Property System: Commentary and Materials*, at 686, 687, 695 (Kluwer Law International 1999).

⁴⁶ ‘Zoellick Attacks Japan for Failure to Push Ahead WTO Agenda’, *Inside US Trade* (2 November 2002), <http://www.insidetrade.com>.

⁴⁷ As a matter of record (see discussion of US-led group below), Japan did follow the US line on TRIPS and medicines, and this was not a foregone conclusion in light of internal (domestic) Japanese concerns (a) about providing the developing countries with support in addressing the HIV/AIDS pandemic and (b) continuing regulatory conflicts with Pharma members concerning price controls.

the European Commission held several meetings prior to which position papers were prepared and circulated by the Commission and interested groups. However, the request of Zimbabwe on behalf of the Africa Group at a TRIPS Council meeting in April 2001, and the decision of the TRIPS Council to convene a special session on access to medicines in June 2001, was a concrete starting point of the process that ultimately yielded the Doha Declaration.

Many WTO Member delegations submitted papers for consideration at the TRIPS Council meeting held on 20 June 2001. The 'lead' paper was a submission on 'TRIPS and Public Health' from the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.⁴⁸ A number of the Members joining the lead paper also submitted separate or co-sponsoring papers setting out statements made at the meeting.⁴⁹ In addition to those co-sponsors, other developing Members (including regional groups) submitted detailed papers.⁵⁰ The Vatican/Holy See submitted a note that strongly supported the position of the developing country group.⁵¹

The European Communities circulated a paper in advance of the special session.⁵² The United States submitted 'pre-decisional draft' talking points and a final US Statement to the meeting.⁵³ Switzerland submitted a Statement to the session.⁵⁴

The developing group papers presented in a detailed and concrete way the difficulties that were created for Members by various provisions of the TRIPS

⁴⁸ Advance Copy (Unrestricted-IP/C/W/296), Council for TRIPS, 19 June 2001 (final text available at <http://www.wto.org>).

⁴⁹ See, e.g. Bolivia, Intervención de la Delegación de Bolivia N. Propiedad intelectual y el acceso a los medicamentos, 21 de junio del año 2001; Brazil, Council for TRIPS, TRIPs and Access to Medications, 20 June 2001; India, Statement of India at the TRIPS Council Meeting on 20 June 2001 on Public Health and Access to Medicines; Kenya, Statement by Kenya on the Impact of TRIPS Agreement on Public Health; Indonesia, Statement by the Indonesian Delegation, WTO-Council Meeting, Geneva 18–22 June 2001; Philippines, Statement of the Philippines; South Africa, Special Discussion on TRIPs and Public Health, South Africa's Statement, 20 June 2001; Sri Lanka, Statement of Sri Lanka Delegation at the TRIPS Council meeting on 20 June 2001 on Public Health & Access to Medicines. The author's files may not presently contain all of the relevant submissions.

⁵⁰ See, e.g. Statement by ASEAN – TRIPS and Health, 20 June 2001.

⁵¹ Note of the Holy See to the Council for TRIPS, Intellectual Property and Access to Basic Medicines, made available 20 June 2001.

⁵² Communication from the European Communities and their Member States, 'The Relationship Between the Provisions of the TRIPS Agreement and Access to Medicines', 11 June 2001, Council for TRIPS, IP/C/W/280, 12 June 2001.

⁵³ United States, Intellectual Property and Access to Pharmaceutical Products, and US Statement (undated). See also Canada, Canadian Intervention on Intellectual Property and Access to Medicines – 20 June 2001.

⁵⁴ Statement by Switzerland, Special discussion on 'Intellectual Property and Access to Medicines', 20 June 2001, Council for TRIPS, JOB(01)/97/Add.10, 5 July 2001.

Agreement, and also voiced concern about the contexts of its invocation by developed Members and their industry groups. The lead paper recalled the evolution of concerns that had been expressed in a variety of fora, such as in the UN Commission on Human Rights, the World Health Assembly, the UN General Assembly, and the Group of Fifteen. Particular attention was directed to the objectives and principles of the TRIPS Agreement framed in Articles 7 and 8, rules regarding parallel importation and compulsory licensing, flexible implementation, differential pricing, data protection, transitional arrangements, and non-violation nullification or impairment claims.⁵⁵

The European Communities paper reflected papers and discussions that had been undertaken earlier, and noted with some sympathy the bases for concerns that developing Members had expressed regarding interpretation of provisions on compulsory licensing. However, in areas such as Article 30 exceptions and data protection, the EC took a fairly hard line industry-oriented perspective.

The US statement essentially took the US PhRMA position that patents were not an obstacle to access to medicines since price is only one factor in the public health equation,⁵⁶ that compulsory licensing should be used restrictively, that exceptions to patent rights must be limited, that protection of test data is mandated, and again suggested that the TRIPS Agreement does not allow each Member to determine its own policy on parallel trade. The US Final Statement indicated a need for explanation from least developed Members as to why they might be concerned about the impact of patent protection since they were not yet required to implement protection.⁵⁷

The TRIPS Council Meeting of 20 June was largely confined to the presentation of prepared statements. However, that should not belie its historic importance. The US and like-minded group,⁵⁸ as well as the WTO Secretariat, appeared to have underestimated the intense concern among developing Members on this set of issues.

The developing country group articulated concerns that were specific, and sought remedial measures. This was not a request for the initiation of a vaguely chartered 'work program'. The United States and Switzerland had responded to developing country concerns with policy positions that sought

⁵⁵ See Africa Group *et al.*, above n 48.

⁵⁶ 'Health experts inform us that the cost of drugs is only one of many important issues that must be addressed in any health crisis.' (Final US Statement, at 2.)

⁵⁷ 'We would like to understand better what impact the TRIPS Agreement could be having on the health care regimes of least developed country Members given that these Members are not currently obligated to implement the Agreement, including its patent provisions. We are particularly interested because certain Members have suggested that these transition periods be extended, even before these Members have had any experience implementing the Agreement.' (*id.*, at 7)

⁵⁸ The members of the group (Australia, Canada, Japan, Switzerland, and the United States) were formally linked in the submission of a draft Declaration for Doha discussed below.

to discount the fact that problems existed, drawing battle lines rather than establishing bases for further discussion. At least to this author, it was surprising to see the US strongly suggest that the price of drugs is not particularly important to developing Members since they have a number of other problems to address.

The immediate results of the 20 June meeting included a request to the WTO Secretariat for the preparation of a checklist of articles referred to and concerns expressed by Members at the special session, and the scheduling of an informal session of the Council on 25 July 2001 to further consider the issues.⁵⁹ The principal result of the 25 July meeting was the scheduling of another formal session of the TRIPS Council to consider access to medicines and public health for 19 and 21 September 2001.⁶⁰

2. Interim preparations

Following the 20 June TRIPS Council meeting, there was intensive additional work within the developing country group toward the objective of presenting a draft instrument for consideration at the following formal meeting. This work was carried out before 11 September 2001 and its aftermath, with an essentially completed preliminary text in circulation among the developing country group by 12 September, and a final text with a few minor adjustments presented as a non-paper to the TRIPS Council Meeting on 19 September.⁶¹

The most serious concerns of the developing country group might be best understood by reference to their non-paper, 'Ministerial Declaration on the TRIPS Agreement and Public Health'. The heart of the developing country text was the proposed declaration that:

Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.

Although initially treated by the US/like-minded group as a radical statement, this formulation appears intended to establish a fairly unremarkable proposition: that is, sovereign governments have the right to establish and maintain public health systems without restriction by an agreement regulating international trade and intellectual property rights. In fact, at the end of the Doha Ministerial process this proposition was accepted in a closely approximate form.

The basic points made by the developing group included that:

⁵⁹ See Note by the Secretariat, Checklist of Articles of the TRIPS Agreement and matters raised in relation to them at the Council's special discussion on intellectual property and access to medicines of 20 June 2001, JOB(01)/113, 16 July 2001.

⁶⁰ A brief summary of the latter meetings can be found at <http://www.wto.org>, along with the texts of proposals by the developing and US/like-minded group.

⁶¹ That non-paper is posted at <http://www.wto.org>.

1. Public health concerns must be considered in a broad context. While HIV/AIDS and other crises are of the most grave concern, they do not represent the limit of developing country interests in public health and medicines;
2. Patents raise the price of medicines and are therefore of serious concern, whether or not other factors affect access to medicines;
3. Developing Members must be free to use measures such as compulsory licensing and parallel importation to enhance access to medicines, without being subject to threat from developed Members;
4. Developing Members face increasing problems as TRIPS transition periods expire, and as the supply of off-patent medicines will diminish. There must (a) be an extension of the transition periods for least developed Members, and (b) the provisions of the TRIPS Agreement regulating compulsory licensing and exceptions must be understood not to inhibit their use for the export of generic medicines to Members that need them.
5. The flexibility that might otherwise be available to developing Members in addressing patents may be limited by increasingly broad developed Member assertions of rights in data submitted for regulatory purposes. Data protection should not be used as a back door route to patent protection.

Although most of the key concerns raised by the developing group in the non-paper are addressed in the adopted Declaration, several were not directly addressed. These include (a) the problems confronted by developing Members when threatened with trade sanctions and the deprivation of other benefits outside the framework of the WTO; (b) the fact that the TRIPS Agreement does not encourage R & D on diseases of particular relevance to developing countries, and; (c) the increasing level of conflict over assertion of rights in data (although addressed for LDCs in the context of a transition period extension). As will be discussed further on, developing country concerns regarding compulsory licensing for export and exceptions were put over for further deliberations.

Viewed in its totality, the Ministerial Declaration on the TRIPS Agreement and Public Health is a closer approximation to the developing group draft text than might have been expected based on prior history between the developed and developing country groups.

3. Late September impasse

The Talking Points put forward by the US delegation, and the draft text from the US/like-minded group (composed of Australia, Canada, Japan, and Switzerland) revealed a chasm between the two main sides of the public

health debate. The US Talking Points echoed US PhRMA press releases regarding the value of strong intellectual property protection, and suggested TRIPS-plus additions to further restrict the express text of the TRIPS Agreement.

By way of illustration, the US Talking Points referred to an unpublished 'study by Harvard University' that 'demonstrates that very few patents exist in sub-Saharan Africa for medicines for HIV/AIDS, including anti-retrovirals'.⁶² USTR's opening position that patents were not an issue evidenced two fundamental disconnects with its negotiating context. First, USTR was addressing a number of the very same WTO delegates who were besieged by threats of sanctions from the USTR (as well as involved in fighting lawsuits by Pharma member companies). Second, and almost equally perplexing, presenting the case that patents are not important in developing country public health regimes would seem to justify the result opposite to that which USTR was pursuing. If patents in developing countries are not important to Pharma, why so much concern about obtaining and enforcing them?

On the subject of parallel imports, USTR promoted the line argued by PhRMA that Article 28, TRIPS Agreement, effectively overrides Article 6 in each Member's internal law since it imposes an obligation to protect against infringing imports.⁶³ This would be considered a 'TRIPS-plus' interpretation. USTR reiterated by cross-reference the positions on compulsory licensing taken in its submission to the June TRIPS Council session.

The US/like-minded group submitted a draft preamble to a declaration titled 'Access to Medicines for HIV/AIDS and other Pandemics',⁶⁴ and the United States also submitted a text of intended operative provisions. As indicated from the title, the intention of these drafts (including the US text of proposed operative provisions), was to largely limit discussion to the situation

⁶² When questions arose after the TRIPS Council meeting about the reference to an unpublished study and the conclusions supposed to be drawn from it, the USTR delegate to the meeting denied having referred to it. The colloquy between various parties involved was a feature of the IP-Health list-server for some weeks, and was finally more or less put to an end when the Brazilian delegate to the meeting quoted the reference from the US paper. The study in fact reflects the results of a paper first commissioned by PhRMA with its Washington think-tank headed by the former Commissioner of Patents, Bruce Lehman, and sent to this author by a Merck lawyer prior to a debate with Merck's public relations director in connection with the South Africa case. The think-tank work was later revised by an adjunct at Harvard. The study reveals nothing more than any competent patent lawyer would anticipate. That is, Pharma members extensively patented their drugs in countries such as South Africa where there was significant capacity for production (and disposable income) and Zimbabwe where (at least until recently) there was sufficient income to establish demand. In least developed sub-Saharan African countries where there was negligible disposable income or prospect for generic competition, patents were not routinely obtained.

⁶³ The US/PhRMA argument is explained and responded to in detail in Abbott, QUNO 7, above n *. Although the Swiss delegation supported USTR's line, the Swiss Federal Supreme Court has expressly and directly rejected the USTR/PhRMA/Swiss delegation position.

⁶⁴ This preambular draft is available on the WTO website. The US draft operative provisions are not.

regarding HIV/AIDS, and to add restrictive interpretations to the TRIPS text.⁶⁵

The EU's position at the 19–21 September meeting was unusual. The Commission delegation presented a non-paper draft declaration, but noted that it had not been approved by the Member states.⁶⁶ The text was subsequently withdrawn. The draft submitted by the delegation was closer to the US-like-minded line than might have been anticipated based on earlier EU position papers on TRIPS and medicines, and the departure from those earlier attempts to occupy a middle ground may explain the withdrawal. At the least, the EU draft text did not incorporate some of the concepts more favorable to developing countries that had been floated in previous position papers.

The September meetings did not appear to bring the developing group and US/like-minded group closer to common ground. However, it was apparent to the US group that public pressure dictated that there be some reference to TRIPS and medicines at Doha. The drafting task was turned over to the Chair of the General Council, Amb. Stuart Harbison, with the understanding that he would work in consultation with the Chair of the TRIPS Council, Amb. Boniface Chidyausiku of Zimbabwe.

From a practical standpoint, this put the task of developing a compromise text in the first instance in the hands of the WTO Secretariat, and initial results of those efforts emerged in a 'combined text' of 10 October 2001.⁶⁷ This was followed by a more fully articulated (but bracketed) text 'prepared by the Chairman of the General Council, in cooperation with the Director-General', distributed to the General Council under cover of 27 October 2001.⁶⁸ The latter text begins to approximate the Doha result.

B. Anthrax and cipro intervene

The tragic events of 11 September 2001 played a significant (though of course unanticipated) role in the unfolding story in Geneva and on the outcome

⁶⁵ For example, the US operative provisions draft said:

3. An affected Member government can declare pandemics of life-threatening communicable diseases such as HIV/AIDS, malaria and tuberculosis, as situations of 'national emergency' or as a circumstance of 'extreme urgency' within the meaning of Article 31(b) of the TRIPS Agreement.

This formulation is substantially more restrictive than Article 31(b), TRIPS Agreement, with reference only to pandemics. Compare paragraph 5(c), Doha Declaration, affirming Member discretion.

⁶⁶ EC, Non-Paper, Draft Declaration on TRIPs and access to affordable medicines, 20 September 2001. Since the text was withdrawn, it is not published on the WTO website.

⁶⁷ MIN-QATAR\Combined text for distribution (10.10.01).doc.

⁶⁸ General Council, Preparations for the Fourth Session of the Ministerial Conference, Draft Declaration on Intellectual Property and [Access to Medicines][Public Health], JOB(01)/155, 27 October 2001.

at Doha. The events are fresh, and do not require extensive recapitulation here.⁶⁹

Following the terrorist attacks on the World Trade Center (WTC) and Pentagon, the United States experienced a bio-terror threat apparently via mailings of highly refined powder containing the anthrax virus. A number of serious illnesses and deaths occurred. Several government buildings in the Washington, DC area were contaminated with anthrax-laden powder, including US congressional office buildings. Because of the temporal proximity with the WTC and Pentagon attacks, one distinct possibility was that the United States was under bioterrorist attack by foreign-based forces, and it appeared that a large scale public health emergency response might be needed.

On or about 18 October 2001, the government of Canada announced that it had overridden Bayer's patent on ciprofloxacin, the antibiotic thought to be most effective against anthrax, and granted a compulsory license to a Canadian generics producer so that the government might obtain low-cost and prompt access to supplies. As the *New York Times* reported:

'These are extraordinary and unusual times,' said Paige Raymond Kovach, a spokeswoman for Health Canada. 'Canadians expect and demand that their government will take all steps necessary to protect their health and safety.'⁷⁰

Shortly thereafter (on or about 23 October), the Secretary of the US Department of Health and Human Services, Tommy Thompson, a senior member of the Bush Cabinet, announced that he had threatened Bayer executives with the grant of a compulsory license on the Bayer ciprofloxacin patent if the company did not meet his demands for price reductions.⁷¹ Bayer subsequently reduced by half the price at which it had initially offered to supply the drug.⁷²

The news that the US government had within weeks of the onset of a disease outbreak threatened to grant compulsory licenses was startling. Although the anthrax situation was indeed serious, the disease threats and burdens facing the developing countries are taking place on a far more massive scale. The US government had persistently threatened to impose trade sanctions and withdraw economic benefits from countries that granted compulsory licenses. Even if narrow distinctions on technical legal grounds

⁶⁹ Because journal articles are sometimes referred to in distant years, the author recounts a few relevant facts, recognizing that for the contemporary reader these facts need no recounting.

⁷⁰ Amy Harmon and Robert Pear, 'Canada Overrides Patent for Cipro to Treat Anthrax', *NY Times* (19 October 2001). The Canadian government later took the position that the actions of its Health Department had been a mistake, and entered into a settlement with Bayer and the local generics producer. The later actions by the Canadian government were publicly taken in such an air of confusion that, in retrospect, Canadian officials would not be faulted for wondering if they might have been better off playing out their opening hand. See Brian Laghi and Heather Scofield, 'Ottawa Pays Twice for Cipro', *Globe and Mail* (23 October 2001).

⁷¹ Kristin Jensen, 'Thompson May Seek to Void Cipro Patent If Talks Fail', *Bloomberg News Service* (Bloomberg.com), dateline Washington, DC, 23 October 2001.

⁷² Keith Bradsher with Edmund L. Andrews, 'US Says Bayer Will Cut Cost of Its Anthrax Drug', *NY Times* (23 October 2001).

might be drawn between various situations, at the 'macro level' and for all intents and purposes the double standard was glaring. The economic and moral imperative claimed by USTR had been irreparably damaged.

In reality, the anthrax-cipro affair only illustrated the common sense underlying the heart of the developing country draft declaration. As a practical matter, no responsible government with a choice would place the public health of its citizens below the interests of a few patent holders.

C. The results at Doha

The 27 October 2001 text was the framework for discussion at the Doha Ministerial. The centerpieces of the developing and US/like-minded proposals were framed in terms of alternative bracketed paragraphs 4, labeled Option 1 and Option 2. In view of the centrality of these proposals, they are recalled here:

4. *Option 1*

[Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement shall be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to ensure access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose.]

Option 2

[We affirm a Member's ability to use, to the full, the provisions in the TRIPS Agreement which provide flexibility to address public health crises such as HIV/AIDS and other pandemics, and to that end, that a Member is able to take measures necessary to address these public health crises, in particular to secure affordable access to medicines. Further, we agree that this Declaration does not add to or diminish the rights and obligations of Members provided in the TRIPS Agreement. With a view to facilitating the use of this flexibility by providing greater certainty, we agree on the following clarifications.]

Option 2 addresses itself to crises and pandemics, and seeks to downgrade any operative legal effect of the declaration. From the developing country standpoint, it was a non-starter. The developed Members meeting in Doha had come to understand that no broad negotiating mandate in areas such as investment and competition would emerge from that meeting in the absence of a meaningful result on medicines. Option 1 became the basis of negotiations.

The working out of a compromise based on Option 1 is widely attributed to a closed negotiating session involving the Brazilian and US delegations as the central actors. In the end, the United States accepted a very strong result in support of developing country interests that closely approximates the initial developing country position, and in a sense is an improvement upon it. The final language transforms 'Nothing in the TRIPS Agreement shall prevent' to

‘the TRIPS Agreement does not and should not prevent’. Arguably, though perhaps not persuasively, the initial negative formulation is slightly ameliorated in the final positive formulation. The final formulation is, however, framed as an agreement of WTO Members, ‘We agree’, and that agreement is most properly characterized as a ‘decision’ of WTO Members (more fully discussed below), with an unarguable impact on interpretation of the TRIPS Agreement.

The 27 October draft text included a proposal from the United States to provide a moratorium on TRIPS dispute settlement actions against developing sub-Saharan African Members. That draft text raised a myriad of interpretative questions regarding who and what might be exempt from dispute settlement such that its value as a concession was open to serious question. Moreover, there appears to have been a general consensus among developing Members that no region should be singled out for preference, and this proposal was dropped from the final text. Outside that, with the exception of the title and reorganization of various provisions, the text of the Doha Declaration adopted by the Ministerial Conference on 14 November 2001 followed the 27 October draft. As will be seen below, significant issues remain on the table.

D. Closely related TRIPS developments at Doha

In addition to the Declaration on the TRIPS Agreement and Public Health, the broader Doha Ministerial Declaration, and the Decision on Implementation Issues and Concerns, also addressed TRIPS subject matter. The Ministerial Declaration provided for additional negotiations on the subject of geographical indications of origin.⁷³ It also instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), the protection of traditional knowledge and folklore, and other new developments.⁷⁴ Examining the relationship between the CBD and the TRIPS Agreement has assumed concrete importance as the patent provisions of the TRIPS Agreement were raised as a potential obstacle to certain parts of a revised International Undertaking on Plant Genetic Resources (IUPGR) while under negotiation in the Food and Agriculture Organization (FAO) forum.⁷⁵

⁷³ Ministerial Declaration, para 18.

⁷⁴ *Id.*, para 19.

⁷⁵ The proposed revised IUPGR included an obligation to pay royalties to a multilateral fund based on patented inventions arising out of use of materials obtained from a resource bank. It was suggested by some negotiating states that obligations directed solely to agricultural patents would violate the TRIPS Article 27:1 prohibition against discrimination based on field of technology. The IUPGR text as adopted avoided reference to patents, referring instead to ‘commercialisation’. See, FAO Press Release 01/08 C5, International Treaty on Plant Genetic Resources for Food and Agriculture Approved by FAO Conference, 3 Nov. 2001, and article 14.2(d)(ii) of adopted treaty available at <http://www.fao.org>.

The Decision on Implementation Issues includes direction to the TRIPS Council to continue examination of issues regarding non-violation nullification or impairment causes of action in TRIPS dispute settlement and to make recommendations to the Fifth Ministerial Conference.⁷⁶ It also includes a ‘standstill agreement’ that non-violation complaints will not be initiated prior to that conference.

III. THE LEGAL EFFECTS OF THE DOHA DECLARATION

A. Paragraph-by-paragraph commentary

The discussion and analysis of the TRIPS Agreement that preceded the Doha Ministerial was itself of legal significance. The Members of the WTO evidenced a concrete interest in addressing the complex set of issues surrounding the effects of the TRIPS Agreement on access to medicines. The expressions of interest represent action by states to direct implementation of the agreement along more particularized lines, and in this sense represent a form of state practice that may be taken into account when interpreting the agreement.

The title ‘Declaration on the TRIPS Agreement and Public Health’ incorporates the language of the initial developing Member draft, and rejects narrower formulations directed at ‘intellectual property’, ‘pandemics’ and other limiting terms. This signals that the Declaration applies to a broad scope of public health concerns, and not to a limited set of special circumstances.

1. We recognize 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.

Comment: The first three paragraphs (1–3) of the Declaration are in the nature of preambles to the operative paragraphs 4–7. Preambular language in an international agreement is used to ascertain the intention of the parties in the process of interpretation, and is part of the context of the agreement.⁷⁷ By recognizing the seriousness of the public health difficulties facing the developing and least developed countries, Ministers place decisions made in the Declaration at a high level in the hierarchy of norms should there be a conflict between rules.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

⁷⁶ Decision on Implementation Issues, para 11.1.

⁷⁷ The Vienna Convention on the Law of Treaties (VCLT) provides that treaties are to be interpreted ‘in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose’ (Article 31(1)). The context comprises, *inter alia*, ‘the text, including its preamble and annexes’ (Article 31(2)).

Comment: This paragraph can be interpreted to indicate that the TRIPS Agreement should not stand as an obstacle to addressing public health concerns, and in that sense to reinforce paragraph 4. It also suggests an effort by Ministers to disperse or shift the burden for addressing public health to other multilateral and national actors. This provision might be interpreted to recognize the primary role of the WHO in matters relating to the prevention and treatment of disease. It might provide a basis to argue against the practice of certain WTO Members of excluding representatives of organizations such as WHO from informal meetings relating to access to medicines.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

Comment: This paragraph represents a modest developing country concession to Pharma in two senses. As indicated in their draft Declaration, developing Members have serious concerns regarding whether patent protection does indeed encourage research and development on drugs for diseases especially relevant to them. The unqualified text of the first sentence does not touch on this issue. The second sentence is a relatively weak way of acknowledging that patents have negative consequences in the form of higher prices, thereby reducing access to medicines, particularly among the poor. It is a controversial juxtaposition: patents are ‘important’, high prices raise ‘concerns’.

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

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Comment: The first important point regarding this paragraph is that it is stated in the form of an agreement (i.e. ‘we agree’). Since this statement was adopted by consensus of the Ministers, and since the operative language is in the form of an agreement, this may be interpreted as a ‘decision’ of the Members under Article IX:1 of the WTO Agreement.⁷⁸ This decision of WTO Members would appear to constitute an agreement on the method of application of the agreement within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties (‘VCLT’),⁷⁹ and to be the substantive equivalent of an interpretation of the TRIPS Agreement.

⁷⁸ Article IX:1 of the WTO Agreement provides in relevant part:

1. The WTO shall continue the practice of decision-making by consensus followed under GATT 1947. Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting. At meetings of the Ministerial Conference and the General Council, each Member of the WTO shall have one vote . . . Decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast, unless otherwise provided in this Agreement or in the relevant Multilateral Trade Agreement.’

⁷⁹ Article 31 of the VCLT provides:

3. There shall be taken into account, together with the context:

Although paragraph 4 is not an ‘interpretation’ in the technical sense of Article IX:2 of the WTO Agreement since it was not based on a recommendation of the TRIPS Council,⁸⁰ a decision that states a meaning of the Agreement may be considered as a very close approximation of an interpretation and, from a functional standpoint, may be indistinguishable.

Ministers in Doha should be assumed to have acted with a purpose. The only apparent purpose for agreeing on a method of application of the TRIPS Agreement is to have an effect on the way in which the agreement is implemented by WTO Members.

There are different ways that paragraph 4 might be understood, and it is perhaps premature to venture interpretations in the absence of concrete cases. However, there is already one concrete case on the horizon, and a few words might be addressed to that.

Paragraph 6 of the Declaration, as discussed in further detail below, directs the TRIPS Council to seek a solution to the problem of use of compulsory licensing by Members with insufficient or no manufacturing capacity. This is a complex undertaking and is addressed in some detail by this author in another paper.⁸¹ To summarize analysis, establishing a productive interpretation of Article 31(f), TRIPS Agreement, may be sufficiently difficult that Members will decide that the best route for addressing imports of low priced drugs from countries where they are under patent is to formally recognize that Article 30 ‘limited exceptions’ to patent rights may be authorized for the making and export of drugs. Article 30 has been interpreted by a panel in the *Canada – Generic Pharmaceuticals* case.⁸² However, the WTO Agreements make clear that the Ministerial Conference and General Council are not bound in their formal interpretation of the TRIPS Agreement by a panel report.⁸³ The Conference and Council are instead bound to respect the terms

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- (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
 - (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (Article 31).

⁸⁰ Article IX:2 of the WTO Agreement provides:

The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1 [that includes the TRIPS Agreement], they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members. This paragraph shall not be used in a manner that would undermine the amendment provisions in Article X.

⁸¹ See Abbott, QUNO 9, above n *.

⁸² *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000.

⁸³ There are several provisions of the WTO Agreements that inform this conclusion. *First*, as noted above, Article IX:2 of the WTO Agreement grants to the Ministerial Conference and General Council ‘the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements’. *Second*, Article 3:2 of the Dispute Settlement Understanding (DSU) provides that: ‘Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations

and context in light of the object and purpose of the agreement.⁸⁴ In considering a formal interpretation of Article 30, the TRIPS Council (in its recommendation), and the General Council and Ministerial Conference, should give effect to the decision taken in the Doha Declaration that the TRIPS 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’. This may include recognition that Members may authorize the making and export of drugs in appropriate contexts.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Comment: Paragraph 5(a) states an interpretative principle that has been enunciated by the panel in the *Canada – Generic Pharmaceuticals* case, and that would already be understood by operation of Article 31 of the Vienna Convention on the Law of Treaties. By particularizing reference to objective and principles, the Declaration appears indirectly to reference Articles 7 (Objectives) and 8 (Principles) of the TRIPS Agreement. This might to a certain extent elevate those provisions above the preamble of the TRIPS Agreement for interpretative purposes.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Comment: Paragraph 5(b) states propositions that are clear from the text of Article 31 of the TRIPS Agreement, but which Pharma, among others, has

provided in the covered agreements.’ Third, pursuant to Article 3:2 of the DSU, the role of the Dispute Settlement Body (DSB) is: ‘to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law’. As a matter of customary international law, a decision of a judicial tribunal involving state parties does not bind states not party to the dispute. Fourth, Article 3:9 of the DSU provides:

9. The provisions of this Understanding are without prejudice to the rights of Members to seek authoritative interpretation of provisions of a covered agreement through decision-making under the WTO Agreement or a covered agreement which is a Plurilateral Trade Agreement.

In a DSU proceeding, a WTO Member might be able to challenge another Member on grounds that an ‘interpretation’ decided by the Ministerial Conference or General Council is WTO inconsistent. The Appellate Body might rule that the interpretation exceeded the bounds of the interpretative power under Article IX:2 of the WTO Agreement and customary international law. Whether the Appellate Body might in such circumstances ‘overrule’ an interpretative decision of the Ministerial Conference or General Council is a WTO constitutive question that might well be controversial. There is, however, no reason at this juncture to attempt to resolve this issue. For present purposes, the Ministerial Conference and General Council have the power to render formal interpretations of the WTO Agreements (including the TRIPS Agreement) without being bound by prior decisions of panels or the Appellate Body. The TRIPS Council, General Council, and Ministerial Conference are constrained in the interpretation of the TRIPS Agreement by its text, context, object and purpose.

⁸⁴ Article 31, VCLT.

attempted to put in doubt. There has been a great deal of misperception in the public press concerning the bases upon which compulsory licenses may be issued, and this inaccurate press reporting may influence national government officials who are not conversant with intellectual property law. For this reason, it is very helpful to have a direct and unequivocal statement regarding the right of Members to grant compulsory licenses.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood 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.

Comment: This is a strong statement of Member sovereignty in regard to implementation of the waiver of negotiation with patent holders prior to the grant of compulsory licenses. As such, it should act as a strong defense against any assertion in dispute settlement that a Member declared an emergency, etc., without justification. Framing the determination as one reserved to each Member ('can represent'), rather than as a joint determination, makes clear that the determination is a matter to be undertaken by each Member in its sovereign discretion.⁸⁵

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Comment: This is an unequivocal recognition of the right of each Member to permit parallel importation of medicines. This should foreclose further argument from the US, Switzerland, and the pharmaceutical sector that while Article 6 of the TRIPS Agreement precludes TRIPS dispute settlement on the issue of exhaustion, Article 28 nonetheless prevents parallel importation of patented drugs. The formulation of paragraph 5(d) does not foreclose the interpretation advanced by some commentators that parallel importation may be based on compulsory licensing.

The EU and US each proposed to incorporate in the Declaration on the TRIPS Agreement and Public Health a limit on international exhaustion to marketing with the consent of the patent holder.⁸⁶ Such limitation was not included in the Doha Declaration. Instead, paragraph 5(d) leaves each Member 'free to establish its own regime for such exhaustion without challenge'. This appears to leave each Member with the discretion to determine whether it will recognize compulsory-licensed marketing or sale of a product in a country of export as exhausting the patent holder's rights in the country of import to consent to importation and resale.

Although the Doha Declaration appears to resolve the issue of exhaustion

⁸⁵ All international agreements carry with them an implicit obligation to act in good faith.

⁸⁶ See EU and US (with like-minded) negotiating texts presented during pre-Doha negotiations.

based on marketing under compulsory license, it may be useful to consider the legal issues in more detail since they are likely to be further discussed by Members.

There are circumstances under which patented products may be first sold or put onto the market under compulsion of government authority. This is typically through the grant to the government itself, or to a third party, of a compulsory license to make and dispose of the product. Such licenses may be authorized because the government determines that public interests will be met by the grants, including as a remedy for anticompetitive practices by patent holders.⁸⁷

When patent holders are required to license third parties to produce and dispose of patented drugs, and the licensees put the drugs on the market, buyers are entitled to use or dispose of those drugs just as if the drugs had been put onto the market by the patent holders. In other words, first sales by the licensees have the same effects (in the local market) as first sales by patent holders. The right of the patent holders to control subsequent sales or transfers is extinguished or exhausted by the licensees' acts.

The question has been raised whether drugs (or other patented products) put onto the market under compulsory license in one country may be parallel imported into another country without the consent of the patent holder in that other country. Two textual bases in the TRIPS Agreement suggest a basis for authorizing parallel importation in this context. The first is Article 6, TRIPS Agreement, providing that the exhaustion issue may not be subject to dispute settlement. Since 'exhaustion' is not a specifically defined term, it would appear that each WTO Member is permitted to adopt the definition it reasonably considers appropriate. This definition might include exhaustion by first sale under compulsory license. The second textual basis is Article 31(f), providing that compulsory licenses 'shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'. If some drugs produced by compulsory licensees may be exported (i.e. the non-predominant portion), then logically they may be imported somewhere, and parallel importation is a mechanism for allowing this without the consent of the patent holder.⁸⁸

The Appellate Body has emphasized that the express language of the WTO Agreement (including the TRIPS Agreement) is its principal source for interpretative guidance, giving terms their ordinary meaning in their context, and

⁸⁷ In the competition law context, to settle government claims patent holders may authorize licensees under so-called 'consent' decrees or undertakings. In these undertakings, the patent holder agrees to remedies without a court trial, though often a consent decree will be affirmed and issued by a court in order to provide a basis for enforcement agency supervision.

⁸⁸ The leading expert commentator supporting this position is Prof. Carlos Correa. Some additional support may be found in US and EU copyright legislation that provides compulsory licenses for certain music recording, and does not prohibit local resale of recordings.

in light of the object and purpose of the agreement.⁸⁹ Only if the text is unclear does the Appellate Body resort to supplementary means of interpretation. If 'exhaustion' can reasonably be interpreted to take place upon the first sale by a compulsory licensee, then the Appellate Body might well determine that a WTO Member is not subject to WTO dispute settlement for authorizing parallel importation based on sales made by compulsory licensees.

In addition, although (as noted below) there is some case law in the developed country WTO Members holding that exhaustion of patent rights is based on the 'consent' of the patent holder to placement of goods on the market, the Appellate Body is not under an international legal obligation to interpret the TRIPS Agreement to reflect the traditional practices of developed country Members. Practice in developing Members may well evolve in an alternative direction, provided that such practice is not inconsistent with the express terms of the TRIPS Agreement.

Arguments that run counter to the suggestion that Members may authorize parallel importation based on the acts of compulsory licensees are:

- Though the exhaustion issue is not subject to dispute settlement, as reinforced by paragraph 5(d) of the Doha Declaration, the question as to what constitutes exhaustion might be determined by dispute settlement since there are limits to how the term may be interpreted.⁹⁰
- Article 28, TRIPS Agreement, expressly establishes the rights of patent holders to 'consent' to the enumerated acts, including importation. This might be argued to imply that patent holder rights are exhausted only by consent (whether nationally or internationally), though the logic of this argument is strained. That patent holders ordinarily have a right to consent to enumerated acts does not imply that exhaustion may not occur on other bases, such as governmental licensing of patent rights.
- There is a body of case law in the EU, Japan, Switzerland, and the United States holding that the notion of patent right exhaustion is based on the consent of the patent holder to first sale. There is a specific holding by the European Court of Justice that intra-Union exhaustion of pharmaceutical patent holder rights does not occur on the basis of a compulsory licensee's placement of drugs on the market. Although the US Supreme Court has not addressed international exhaustion based on the consent of the patent holder it has barred imports of goods

⁸⁹ See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Report of the Appellate Body, WT/DS50/AB/R 19 December 1997, at, e.g. para 45.

⁹⁰ Just as an example, a Member could not adopt legislation providing that 'exhaustion' is based on piracy of patented products since that would directly defeat the purpose of providing patent protection.

lawfully produced under patent abroad without the consent of the US patent holder (under a so-called prior users' right).⁹¹

- Although Article 31(f) allows export of the non-predominant portion of compulsory licensee production, there are at least two contexts in which corresponding importation does not require consent of the patent holder: (a) where the drug is not patented in the country of import,⁹² and (b) where the country of import has issued a compulsory license for importation.

From a practical standpoint, why is the question whether international exhaustion may take place under compulsory license important?

Developing countries that provide patent protection for medicines have limited potential sources for those drugs. They may be purchased locally at on-patent prices. They may be purchased following placement on the market abroad by the patent holder (or its agent) and parallel imported (assuming that the importing country recognizes international exhaustion). Although parallel importation in such circumstances may allow price savings, these savings are not likely to be on the order of magnitude seen in the relationship between on-patent versus off-patent medicines.

A drug produced under compulsory license is effectively an off-patent drug (though payment of an adequate royalty will add to the price). If parallel importation of compulsory licensed drugs is accepted, then in principle a single compulsory licensee in a major market (e.g. Brazil or India) could export a substantial (though 'non-predominant') quantity of low-price drugs, and no action would be required by importing developing countries other than to recognize a broad doctrine of exhaustion and parallel importation. Provided that one or two major market Members were willing to grant compulsory licenses, a part of the worldwide solution to the problem of low-price medicines might be found.

It is likely that developed Members such as the US, EU, and Switzerland will resist an interpretation of exhaustion doctrine that is not based on the consent of the patent holder. Paragraphs 4 and 5(d) of the Doha Declaration, however, support an interpretation that advances the interests of developing Members in obtaining low-cost access to pharmaceutical supplies.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the

⁹¹ US courts granting compulsory licenses on US patents as remedy for anticompetitive practices have recognized that they are without power to prevent invocation by patent holders of foreign patent rights, although foreign courts may as a matter of 'comity' choose to enforce a US court order. See *United States v Imperial Chemical Industries (ICI)*, (SDNY 1952), 105 F Supp 215, 227–31.

⁹² In this regard it may be noted that inventors, largely for administrative cost reasons, have rarely sought to patent their inventions in all countries where this might be possible.

Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Comment: A substantial change to the TRIPS-imposed legal conditions in developing and least developed countries will occur on 1 January 2005 and 1 January 2016. Among the important consequences of this changed situation will be that developing countries with the present capacity to export off-patent drugs will lose that capacity in regards to newly developed patented drugs (and drugs in the mailbox pipeline that come under patent). At this juncture, affordable access to on-patent medicines in developing and least developed countries will become increasingly dependent on compulsory licensing. If the prices of medicines offered by patent holders are too high, or if sustainable access is otherwise restricted or threatened, relief will be sought through the issuance of compulsory licenses.

Certain developing countries will have capacity to manufacture under compulsory license, but there will certainly be developing and least developed countries without that capacity. Moreover, developing countries will require a variety of medicines, and it may be important that production of different medicines be allocated among countries. Finally, it may well be that certain developed countries will wish to aid developing and least developed countries by producing under compulsory license to satisfy import requirements.

Article 31 of the TRIPS Agreement permits all WTO Members to grant compulsory licenses regarding, *inter alia*, pharmaceutical products and processes. The terms of Article 31 are in general permissive and flexible. As confirmed by paragraphs 5(b) and (c) of the Doha Declaration, Article 31 does not limit the grounds upon which licenses may be granted, and it permits each Member to determine in its own discretion what constitutes a national emergency or circumstances of extreme urgency (thereby establishing an exception from pre-grant negotiation). There is substantial flexibility in terms of the administrative processes that may be adopted to implement a compulsory licensing regime.

To date, developing countries have made limited use of compulsory licensing as a tool to address public health issues.⁹³ This stems from a number of causes: (1) the TRIPS Agreement has only recently begun to increase the incidence of patent protection; (2) use has been opposed by developed country WTO Members and interested industry groups within them, and a strong political commitment to act in the face of this opposition is required; (3) some developing countries have expressed concern regarding a potential backlash from foreign direct investors (4) developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons and, as noted earlier; (5) effectively imple-

⁹³ See Abbott, QUNO Occasional Paper 7, above n *.

menting compulsory licensing requires that certain preconditions relating to administrative, financial, and technical capacity be met, and these conditions are often not met in developing countries.

Addressing the limited use by developing countries of the compulsory licensing tool will require that substantial attention be paid to putting into place appropriate legal infrastructure. In this regard, developing countries will need to seek advice and assistance from sources such as UNCTAD, WHO, and non-governmental organizations (NGOs) attentive to their interests. Addressing the problem of limited use will also require access to and coordination of financial and technical resources. The solution to the limited use of compulsory licensing by developing countries requires addressing a number of important elements.

Recognizing the multi-dimensional nature of the problem, the TRIPS Agreement nevertheless establishes certain obstacles to effectively addressing access to medicines through compulsory licensing. The most widely noted of these potential obstacles is Article 31(f), which provides:

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

Article 31(f) establishes a limitation: the terms of the compulsory license should include the condition that the licensee uses the patented invention predominantly to supply the domestic market of the Member granting the license.

The word 'predominantly' would generally appear to refer to the major part or majority,⁹⁴ and would generally suggest that more than 50 percent of the production by a compulsory licensee should be intended for supply of the domestic market of the Member granting the license.⁹⁵

The limitation imposed by Article 31(f) creates two inter-linked problems:

1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;
2. By requiring compulsory licensees to supply a predominant part of

⁹⁴ 'Predominant' is defined as an adjective as: '(1) Having supremacy or ascendancy over others; predominating. (2) Constituting the main or strongest element; prevailing. (3) Rising high over.' *New Shorter Oxford Dictionary*, at 2329.

⁹⁵ It might be suggested that 'predominantly' also refers to a situation in which the domestic market of the Member granting the compulsory license takes the greatest share of supply as among those Members receiving supplies. To illustrate: the granting Member may receive forty percent (40%) of the supply, while three other Members each individually receive twenty percent (20%). In that context, supply of the domestic market of the granting Member would predominate over the supply of any other individual WTO Member. The difficulty with this interpretation is that it potentially reduces the term 'predominantly' to a nullity, for example, if there were 80 Members receiving supplies under compulsory license, perhaps only two percent (2%) might need to be supplied to the market of the Member granting the license to maintain its predominance.

their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.

Article 31(f) creates difficulties on the demand and supply side of the generic drug pipeline.

The demand side problem is self-evident. If a developing Member lacks manufacturing capacity for a particular drug, and there are no Members that are able to supply it by export under compulsory license (or exception), there may be no affordable supply of the drug. The supply side problem is identified because there are WTO Members, including developing Members, with the capacity to address the drug import needs of a wide range of developing Members under compulsory license, but that may be inhibited from undertaking this role because of the Article 31(f) limitation.

(i) *Implementation by importation.* Neither Article 31 in general, nor Article 31(f) in particular, state or imply that a compulsory licensee must produce the invention within the territory of the Member granting the license. Under Article 31, a compulsory licensee may import products in the implementation of its license.⁹⁶ The ability of a compulsory licensee to satisfy a domestic market by importation depends upon the availability of off-patent products in exporting countries, or upon some legal mechanism under which the potential rights of patent holders in exporting countries will not be infringed.

When pharmaceutical patent protection is not implemented or enforced in a WTO Member (such as an LDC subject to an extended transition period), that Member will not be required to issue a compulsory license to satisfy its import requirements in a TRIPS-consistent manner.

(ii) *Legal mechanisms for non-infringement in the country of export.* If no patent has been granted in the country of export, or if a patent in that country has expired, there will be no infringement by a party exporting in fulfillment of the compulsory license in the country of import.

The patent holder in the country of export may consent to the exportation, perhaps because that patent holder is different from the patent holder in the country of import.⁹⁷ There would be no infringement in either country if the importer also acted under compulsory license.

The producer in the country of export may itself be implementing a compulsory license, and would be entitled to export a non-predominant part of its production. In this case, there would be no infringement in either country.

⁹⁶ Imports into country A might be exported to country B. A compulsory licensee that imported to implement the license, but exported a predominant part of the imports, might be acting inconsistently with Article 31(f).

⁹⁷ The patent holder may be the same in both Members, and in theory it might consent to export to the Member that has issued the compulsory license regarding its own patent. However, it is difficult to foresee the circumstances in which this might occur.

Both the exporter and importer would act under compulsory license (or, there would be no patent protection in the importing country).

If the producer in the country of export is implementing a compulsory license issued as a remedy for anticompetitive conduct, the restriction regarding predominant part established by Article 31(f) does not apply, pursuant to Article 31(k).

(iii) *Potential infringement in the country of export.* If (a) the drug is under patent in the country of export, (b) the patent holder does not consent to the export, (c) no compulsory license has been issued, or has been issued but cannot be used for export because of a 'predominant part' problem, then the importing country that has issued the compulsory license may not be able to satisfy its requirements without a potential infringement of patent holder's rights in the country of export.

From the standpoint of TRIPS Agreement obligation, the issuance of a compulsory license in the country of import does not constitute non-compliance with TRIPS obligations, even if prospective imported products are under patent in a country of export.⁹⁸ If exports originate in another Member in a manner inconsistent with the exporting country's obligations under Article 28 of the TRIPS Agreement, it is the obligation of the exporting country to take steps in regard to its obligations.

(iv) *Future work program.* This issue of availability of low-priced medicines becomes more pressing as the transition timetables in the TRIPS Agreement draw to an end, and the available supply of generic (off-patent) pharmaceutical products is progressively reduced. If there are limited supplies made available for export, there are, by definition, limited supplies available for import. Article 31(f) appears to restrict the right of Members to grant compulsory licenses for export. Although there were several proposals made in advance of the Doha Ministerial to address this situation, including proposals in the developing Member draft Declaration, there was no political consensus to resolve it at that stage, and the matter has been set for further discussion.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We

⁹⁸ In the US paper submitted to the TRIPS Council in advance of the Doha Ministerial, there is some suggestion of liability on the part of the importing Member, though the reasons for this are not clear. Intervention of the delegation of the United States under item N (Intellectual Property and Access to Medicines) of the agenda of the Council for TRIPS meeting of 18–22 June 2001, JOB(01)/97/Add.5, Council for TRIPS, 28 June 2001.

instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

This paragraph directs the TRIPS Council to authorize the extension until 1 January 2016 of the transition period for least developed Members (hereinafter ‘LDCs’) to implement or enforce pharmaceutical patent protection. The terms of this suggest that LDCs may be required under appropriate circumstances to implement mailbox and exclusive marketing rights provisions prior to the end of the transition deadline.⁹⁹

If an LDC is required to implement mailbox protection, it must establish a procedure under which it will accept for filing pharmaceutical product patent applications filed abroad. Until the LDC establishes patent protection, the patent application remains dormant. However, during the period of dormancy, the LDC is required to grant exclusive marketing rights to the patent holder for a maximum period of five years following marketing approval of its drug.¹⁰⁰ For almost all intents and purposes, the grant of exclusive marketing rights will be at least as effective as granting a patent in preventing generic drugs from entering the LDC market. Beyond that, however, when the dormancy period of the mailbox application ends, the drug covered by the application will be patented (assuming it meets relevant criteria). An entire ‘pool’ of drugs that may be generic in an LDC during the mailbox transition period will come under patent at the end of the period. If, however, there is no

⁹⁹ The express text of paragraph 7, second sentence, exempts LDCs from the obligation to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement, and the obligation to enforce rights provided for under those sections. By its express terms, paragraph 7, second sentence, does not address obligations under Article 70:8 and 70:9 of Part VII of the Agreement. In the absence of some contrary understanding, Article 70:8 would appear to continue to apply, and require least developed Members to maintain ‘mailbox’ application mechanisms that allow for the receipt and retention of pharmaceutical patent applications until coverage is provided under local law. Pharmaceutical patent applications received before 1 January 2016 would have priority dates preserved and be reviewed under patentability criteria as of the priority dates. Patent protection would be available for the remainder of the patent term counted from the priority date.

Absent a contrary understanding, Article 70:9 also appears to apply. If so, exclusive marketing rights should be granted to the patent applicant for a maximum period of five years following marketing approval of the pharmaceutical product in the least developed country, provided that a pharmaceutical patent has been granted and marketing approval has been obtained by the patent applicant in another Member. A pharmaceutical patent applicant with exclusive marketing rights in a least developed Member has the effective equivalent of patent rights because, while it may not have exclusive rights to make or import the covered drugs, it presumptively will be able to prevent the marketing of generic equivalents, and it may thereby control the local market. Exclusive marketing rights may be even more burdensome to LDCs than patents if they are understood not to be subject to the same exceptions (e.g. Article 30, TRIPS Agreement) to which patents are subject, or to compulsory licensing (Article 31, TRIPS Agreement).

Since paragraph 7, third sentence, instructs the TRIPS Council to give effect to the mandate of paragraph 7, it is important that the Council clarify the meaning of the Declaration when it takes this action. If the Council fails to implement paragraph 7, second sentence, based on a common understanding that least developed Members are exempt from mailbox and exclusive marketing rights requirements, the legal situation regarding these requirements will be uncertain.

¹⁰⁰ Provided also that a patent has been granted and marketing approval obtained in another WTO Member.

mailbox system in place, holders of patents outside the LDC will not be able to obtain patents after the transition period has ended because the inventions covered by the patents will no longer be novel in the patenting sense. Thus, if there is no mailbox system in place, drugs that are generic (off-patent) during the transition period will remain generic after the transition period ends.

The issue whether mailbox and exclusive marketing rights requirements are applicable to LDCs during the extended transition period is of considerable importance and should be addressed by the TRIPS Council in connection with operationalizing the extension envisaged by paragraph 7.

In a limited set of circumstances, the transition period extension in favor of LDCs will allow them additional access to generic medicines. This will occur when a medicine is off-patent in a developing Member such as India (and may be exported), but prior to the extension would be on-patent in the LDC. The transition period extension relieves the LDC from the obligation to enforce local patents, so the LDC will be able to import the drug for so long as it remains off-patent in India.¹⁰¹ For drugs that go on-patent in India (and other developing Members) after 1 January 2005, either because applications filed during the mailbox period are converted to patents, or because of newly-filed applications, no relief will be provided for LDCs that otherwise wish to import drugs. Those drugs will be on-patent in the country of export and more expensive.

LDCs that are not required to implement or enforce pharmaceutical patent protection until 2016 will have a certain added measure of flexibility even as to drugs that are covered by patent in non-LDC Members. LDCs will be free to increase their own capacity to manufacture generic drugs, and export and import those drugs among themselves, without contravening the TRIPS Agreement. Since there are 14 years until patent protection will be mandated, there is a reasonable amount of time if plans are initiated soon to bring manufacturing facilities within LDCs on-line and recover investment capital prior to the end of the transition period. If the LDCs are not required to implement mailbox protection, drugs for which production is commenced during the transition period will be available indefinitely as generics. If mailbox protection is required, the end of the transition period will also mark the end of access to low priced drugs made available as a consequence of the extension, until such time as patents issued on the basis of mailbox applications expire.

The value of this added flexibility is highly dependent on the capacity of the LDCs to increase manufacturing capacity, and this will depend on factors such as the availability of World Bank grants or loans to provide working capital, and the availability of technical assistance.

¹⁰¹ There is an additional complication in that the drug in India may be subject to exclusive marketing rights, and it is not clear whether such rights would entitle the mailbox application holder to block exportation as well as local supply.

Also, paragraph 7 of the Doha Declaration is somewhat ambiguous regarding whether LDCs are relieved from implementing and enforcing pharmaceutical process patent protection during the extended transition period.¹⁰² If LDCs are not so relieved, then under TRIPS Agreement Article 66:1, pharmaceutical process patent coverage must be implemented by 1 January 2006. This may limit the capacity of LDCs to initiate production. In giving effect to paragraph 7, the TRIPS Council should clarify that it extends to pharmaceutical process patents.

IV. POST DOHA AGENDA

A. The TRIPS Council

The Doha Declaration and other Doha instruments direct the TRIPS Council to undertake actions and prepare proposals. The mandate for a solution to the compulsory licensing problem sets a deadline of 31 December 2002, and the work program on this matter may occupy a substantial part of the TRIPS Council's attention. In light of the preparations for these discussions presently underway among developing country delegations, it would be surprising – and most unfortunate – if the hope of Undersecretary of State Larson quoted at the outset of this article is realized. That hope does not capture the grave situation in developing country public health affairs.

B. Implementing the Doha Declaration

The Doha Declaration will be of enduring importance only to the extent that its letter and spirit are reflected in implementing measures adopted by WTO Members, and are recognized by the developed Members to have altered the TRIPS implementation environment. It is imperative that technical and other assistance provided to developing and least developed WTO Members in the post-Doha environment fully takes into account the new situation.

C. The WTO within a larger context

The WTO is not the primary international institution responsible for addressing the public health needs of developing countries. That task is the province of the WHO. The UN has established the Global Fund to deal with

¹⁰² The relevant part of paragraph 7 reads:

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016 . . .

This language might be construed to cover pharmaceutical process patents if those patents are considered issued with respect to pharmaceutical products. The patent 'rights provided for' in Article 28:1(b) of Section 5, Part II of the TRIPS Agreement are rights in respect to process patents, and those may be construed to be related to the subject matter of 'pharmaceutical products'.

securing and allocating resources to major disease threats, but there is urgent need for more direct action by the World Bank and IMF.

The WTO became a central focus in global public health affairs because it took on the role of developing and regulating patent policy, but neglected to exercise this mandate with attention to its broader implications. The WTO has taken steps to refine its mandate, though it remains far from accomplishing an adequate adjustment. It is not yet clear whether what needs to be done will be done, and the institution continues to walk in the shadow of a dark spectre.

In the Special Issue on TRIPS that appeared in the first volume of this journal in 1998, I observed that:

We are dangerously close to a new world order characterized by a vast schism between a prosperous and stable post-industrialized North, and a desperately poor and chaotic South. The proliferation of nuclear and bio-weapons does not portend well for the creation of a neat partition behind which the wealthy may comfortably lounge.¹⁰³

That observation was a simple statement of fact. There was an amorphous inevitability to recent events. The response so far is to envision the creation of a vast and airtight global security apparatus.

It appears to be the natural order of things that some are better off than others. Indeed, unwillingness to drive a hard bargain and let the chips fall where they may could be taken as a lack of strength. With that said, the North is perilously close to standing by while more than 30 million people die prematurely from HIV/AIDS and its complications. The danger is clear and present. The disease can be controlled with existing medicines. We will not be able to say in hindsight, 'If only we had known'.

¹⁰³ Frederick M. Abbott, 'The Enduring Enigma of TRIPS: A Challenge for the World Economic System', 1 *JIEL* 497, 521 (1998).