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TOWARD A NEW ERA OF OBJECTIVE ASSESSMENT IN THE FIELD OF TRIPS *AND* VARIABLE GEOMETRY FOR THE PRESERVATION OF MULTILATERALISM

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ABSTRACT

The TRIPS Agreement emerged from the Uruguay Round negotiations as one of the three pillars of the WTO. This article offers a preliminary assessment of the first ten years under the TRIPS Agreement. Based on that assessment, it makes suggestions for the future.

The objective of the principal developed country demandeurs of the TRIPS Agreement was to increase information and technology rent payments from developing countries. Incomplete implementation and enforcement was anticipated. Taking this into account, the Agreement has resulted in a substantial transformation of legal infrastructure in developing countries and has increased rent payment outflows to the owners of intellectual property (IP) rights. From this standpoint, the TRIPS Agreement has been successful in accomplishing its objectives.

From the standpoint of developing countries, it is more difficult to identify positive effects. China is the major developing country success story of the past decade, and it has achieved its historic accomplishments in the face of intensive criticism of its IP regime. The TRIPS Agreement has come under harsh public scrutiny for the role attributed to it by the pharmaceutical industry in South Africa, ultimately leading to the Doha Declaration on the TRIPS Agreement and Public Health. As a consequence of a somewhat more balanced approach to TRIPS now achieved at the WTO, the United States in particular has shifted to bilateral and regional fora to obtain higher standards of protection and enforcement, calling into question the relevance of TRIPS Council deliberations.

This article makes several recommendations. First, that new agreements concerning IP rights be subject to objective prior impact assessment. Second, that WTO Members give greater recognition to the fact that IP rules have significantly different public welfare implications depending on their field of

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application and the level of development of the implementing country. As the TRIPS Agreement transition periods have largely expired, the manner by which the TRIPS Council assesses its rules and makes provision for TRIPS-plus and TRIPS-minus adjustments might be restructured along industrial subject matter and developmental lines, taking better account of the impact-in-fact of IP rules on societies.

In June 2004 a group of trade specialists was brought together at the World Trade Forum in Berne in a 'preliminary stocktaking' exercise to assess the first ten years of the World Trade Organization.[1] This article was prepared for that occasion and addresses the Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement') on its ten-year anniversary.

INTRODUCTION

The two most contentious sets of negotiations in the Uruguay Round involved agricultural subsidies and TRIPS. Prior to the Cancun Ministerial in September 2003, the TRIPS Agreement remained sufficiently contentious that Members considered it imperative to reach a pre-meeting agreement on medicines.[2] Removing the subject from the agenda was necessary to allow any prospect, however remote, of success. The question of agricultural subsidies has been the key sticking point in the Doha Development Agenda.[3] It is tempting to begin and end this stocktaking with the simple observation that during the ten years of the WTO era much has happened, but nothing has changed.[4] Yet there have been changes.

First, civil society has emerged to play an active role in the TRIPS dialogue. It might have seemed inconceivable ten years ago that civil society groups around the world would take interest in the latest developments in the TRIPS Council, or that these groups might substantially influence negotiated

[1] Participants were asked to consider, among other things, whether the existing governance arrangement at the WTO adequately takes into account the differential interests of its Members, and what recommendations might be made to enhance the prospects for more effective decision-making.

[2] The negotiation and adoption of the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is analysed in Frederick M. Abbott, 'The WTO Medicines Decision: The Political Economy of World Pharmaceutical Trade and the Protection of Public Health', 99 A.J.I.L. (forthcoming 2005).

[3] Shortly before the June 2004 meeting in Berne where this article was presented, the French government had indicated its opposition to a Commission proposal for agricultural subsidies concessions, completing the symmetry with the Uruguay Round negotiations. 'Lamy, Fischler Insist Export Subsidies Offer within Commission's Mandate', *Inside U.S. Trade*, 21 May 2004.

[4] At a panel discussion on 17 May 2004, then UNCTAD Secretary General Ricupero, who on behalf of Brazil was a leader of the TRIPS-opposition in the Uruguay Round, observed that most of the debate over TRIPS today recycles arguments of the late 1980s, and called for more objective assessment of the present and prospective effects of TRIPS. Policy Dialogue on 'Intellectual Property Rights Development 10 Years after Marrakech: Where are we? Where are we heading?', UNCTAD/ICTSD, at WMO, Geneva. As noted, below text at n 66, at about the time of this discussion in Geneva an assessment of the prospective impact on the pharmaceutical sector of the US-Australia FTA was presented to the Australian Senate, and in November 2004 a report by PAHO/IFARMA on the impact on the pharmaceutical sector of a prospective US-Andean FTA was published.

outcomes.[5] Second, there has been a growing intra- and inter-institutional dialogue at the multilateral level concerning the TRIPS agenda. The subject of TRIPS is actively debated at the FAO, WHO, UN Human Rights Commission and World Bank.[6] Third, reaction to the TRIPS Agreement has helped stimulate developing countries to form increasingly close and sophisticated South–South trade and development initiatives, such as recent initiatives between Brazil, India and South Africa,[7] expanding now to China, Russia and elsewhere.[8] Fourth, growing sophistication on TRIPS at the multilateral level has led some developed countries, most notably the United States, to back away from the multilateral process and to seek solutions in bilateral and regional negotiations.[9] There are, of course, parallels to the Uruguay Round process in which the US used Special 301 and NAFTA as tools to force accommodation in Geneva.

This article offers some suggestions regarding ways in which the atmosphere surrounding TRIPS negotiations and implementation – within and outside the WTO – might be improved. Principal among them is the suggestion that new IPRs and associated regulatory provisions be subject to objective impact assessment. While governments have routinely estimated the impact of changes in tariff rates and quotas prior to concluding agreements, until recently there has been virtually no before-the-fact effort to objectively quantify and assess the impact of changes in IPRs and related regulatory regimes. In areas such as pharmaceuticals and public health, such assessments are feasible because there is a significant amount of hard data that could be assembled. The compilation and publication of assessment reports would permit government policy-makers, industry and civil society to engage in a more productive dialogue about the consequences of adopting new rules.

This article also addresses the question of variable geometry in TRIPS. Two basic principles have emerged from the first decade of TRIPS study: (1) all IPRs subject matter is not created equal, and (2) all levels of development

[5] See, e.g., Susan Sell, *Private Power, Public Law, The Globalization of Intellectual Property Rights* (Cambridge, 2003) 121–62, discussing, *inter alia*, negotiations on Doha Declaration on the TRIPS Agreement and Public Health.

[6] For example, in May 2004 the TRIPS Agreement was addressed in a resolution by the World Health Assembly at the WHO. *Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS*, Fifty-Seventh World Health Assembly, WHA 57.14, Agenda item 12.1, 22 May 2004, at para 2(6).

[7] India-Brazil-South Africa (IBSA) Dialogue Forum Trilateral Commission Meeting, New Delhi Agenda for Cooperation and Plan of Action, 4–5 March 2004 meeting report, India Embassy in Brazil, at http://www.indianembassy.org.br, and, 8 ICTSD Bridges, 10 March 2004. *India, Brazil, South Africa Strengthen South-South Cooperation.*

[8] At the XV International HIV AIDS Conference six countries (Brazil, China, Nigeria, Russia, Thailand and Ukraine) signed an agreement to increase cooperation in developing and producing generic drugs. India and South Africa are considering joining this group. See *Brazil to Coordinate Six-Country Anti-AIDS Network*, BBC Monitoring International Reports, 16 July 2004, Lexis-Nexis. See discussion of G20+ below.

[9] See discussion of bilateral and regional arrangements, below.

are not equal. A new variable geometry in TRIPS could reflect both of these principles, with a new arrangement that divided the TRIPS Agreement and its administration along subject matter lines and, within those lines, along a developmental spectrum. The impetus for negotiations on such reorganization may arise out of present unilateral demands. The establishment of a shadow negotiation in which these concepts might be elaborated in a non-ideological environment might be useful.

I. PROTECTING FIRST WORLD ASSETS REVISITED

The object and purpose of the TRIPS negotiations is not a matter of serious doubt or controversy. Commercial enterprises in the industrialized Northern Tier of countries sought to increase their information and technology rents from the Southern Tier of developing countries by demanding an enforceable set of intellectual property protection rules. In 1989 I called these efforts 'Protecting First World Assets in the Third World'.[10] No one expected conclusion of the TRIPS Agreement would lead overnight to a shift in economic policies and social attitudes toward IPRs around the world. Built-in transition mechanisms were incorporated in the TRIPS Agreement to soften structural adjustments. Moreover, it was recognized that countries without a history of IP enforcement would not suddenly be transformed into high protection regimes, and that continuing attention to enforcement would – from the Northern Tier perspective – be required to enforce new rent obligations.[11]

As a general matter, developing countries have reformed their legal systems to provide stronger IP rules and enforcement mechanisms. The results of these efforts can be seen in reports to the TRIPS Council. Although work remains to be done in calculating precise trade and investment flow effects, it appears that Northern Tier enterprises are collecting substantially higher levels of information and technology rents.[12] The World Bank has estimated a very significant rise in the outflow of patent rents from South to North based on implementation of the TRIPS Agreement.[13] The 'static' impact of the

[10] Frederick M. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', 22 Vand. J. Transnat'l L. (1989) 689. See contributions by Silvia Ostry and J. Michael Finger in Kennedy and Southwick (eds), *The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec* (Cambridge University Press, 2002), and; Sell, *Private Power, Public Law*, above, n 5.

[11] Frederick M. Abbott, 'The WTO TRIPS Agreement and Global Economic Development', in F. Abbott and D. Gerber (eds), *Public Policy and Global Technological Integration* (Kluwer, 1997).

[12] For example, Bermudez, *et al*., have calculated substantial increases in dollar outflows from Brazil based on implementation of pharmaceutical product patent protection. See J.A.Z. Bermudez, R. Epszstejn, M.A. Oliveira and L. Hasenclever, *The WTO TRIPS Agreement and Patent Protection in Brazil* (ENSP/WHO, 2000), at 75–77.

[13] World Bank, Global Economic Prospects and the Developing Countries 2002, Ch 5 and Table 5.1. See also J. Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round*, Study for the Asian Development Bank 2002, at 13–19, 25. Finger notes that for six countries (United States, Germany, Japan, France, United Kingdom and Switzerland) the net increase in patent rents

TRIPS Agreement reflects past and continuing patterns of ownership of IP assets by Northern Tier enterprises.[14]

The US-EC-Japan-Swiss alliance that drove the Uruguay Round negotiations presented a case that their intention also was to serve the interests of the Southern Tier because strong IP regimes would generate benefits for developing countries.[15] These were not empirically-supported arguments, and they were not understood to be the basis for the negotiations. If developing countries concluded that stronger IP protection was in their own interests, they did not need the Northern Tier to force them to adopt it. And, the empirical evidence to this point does not add significant support for the premise that stronger IP protection would benefit the developing countries.

China is a paradigm case. It has pursued a policy of technology appropriation much like those pursued earlier by Japan, Taiwan and Korea, and has enjoyed explosive economic growth and development. Only a revisionist might attempt to correlate China's rapid economic growth to the introduction of strong IP protection. To the contrary, China has been under constant attack by the United States and EU for its IP protection failings.[16] There is nothing new, different or surprising about this. In a decade or so, China will likely reach a cross-over point when it will decide that interests in collecting technology rent outweigh its interests in technology appropriation, and it will

from TRIPS implementation is estimated by the World Bank at $40 billion per year. Total net payment outflows (including other forms of IP) based on full implementation are estimated at $60 billion per year. These estimates are based on full collection, and need to be discounted based on the level of compliance.

[14] A recent study by the OECD confirms that the overwhelming proportion of patent applications filed under the Patent Cooperation Treaty (PCT), and at the US Patent and Trademark Office (PTO), European Patent Office (EPO) and Japan Patent Office were from developed country inventors. OECD, Compendium of Patent Statistics 2004 (OECD 2004). In 2001, for example, the United States, European Union and Japan accounted for 86.3 percent (86.3%) of PCT applications, Korea, Canada, Switzerland and Australia accounted for nine percent (9%), China for 0.8%, Russian Federation 0.6% and rest of world 3.3%. Id., at 20, Graph 7. Brazil and China have experienced substantial increases in the number of patent applications filed locally, but foreign applicants account for the bulk of the increases. Id., at 35–36.

[15] See Protecting First World Assets, above at 10, citing at note 16 to R. M. Gadbaw and T. Richards (eds), *Intellectual Property Rights: Global Consensus, Global Conflict* (1998) 20–21 (and Robert Sherwood, *The Benefits Developing Countries Gain from Safeguarding Intellectual Property* (June 1988); and see for further discussion on this point, Frederick M. Abbott, 'The Enduring Enigma of TRIPS: A Challenge to Global Economic Development', 1(4) JIEL (1998) 497.

[16] See, e.g., USTR, 2003 Report to Congress on China's WTO Compliance, available at http://www.ustr.gov, reserving its harshest criticism of China for its IPRs-related policies, stating:

> In 2003, IPR infringement in China continued to affect products, brands and technologies from a wide range of industries, including films, music, publishing, software, pharmaceuticals, chemicals, information technology, consumer goods, electrical equipment, automotive parts and industrial products, among many others. This situation not only has had an enormous economic impact, but also presents a direct challenge to China's ability to regulate many products that have health and safety implications for China's population and, as an increasing amount of counterfeit and pirated products are being exported from China, for others around the world. Id, at 51.

shift from an appropriation regime to a protection regime.[17] Some signs of this already are emerging.[18] Still, whether it is in five, ten or fifteen years, the cross-over point will be reached and China will likely begin to demand stronger IP protection for its inventions and expressive works.

An asserted correlation to promotion of foreign direct investment remains highly elusive.[19] Again, the most significant growth in FDI is in Asia, where IP protection regimes have been weak.[20] Yet there are examples of countries using strong IP as part of their industrial policy to attract investment to targeted sectors, such as Singapore and its development of a biotech research complex, the Biopolis.[21]

There has been a pronounced trend in the pharmaceuticals sector for production facilities to be shut down and consolidated – a policy of export substitution – affecting places such as South Africa, where entry into force of the TRIPS Agreement was followed by the closing of local production affiliates of foreign multinationals.[22] It is hard to reconcile the pattern of consolidation in the pharmaceutical sector with a promise of increased direct

[17] During the earlier stages of the industrial development cycle, for structural and cost reasons, the national interest lies in 'borrowing' and imitating foreign technology. At a certain cross-over point, there are enough local innovators seeking to protect their investments in technology that the country's interest in protection begins to outweigh its interest in appropriation, and industrial policy shifts. Keith Maskus has empirically illustrated this phenomenon in what is now commonly referred to as the 'Maskus curve'. See Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (IIE, 2000), Ch 4.

[18] Although the number of patent applications by Chinese nationals has increased substantially over the past several years, a presentation by the Chinese Patent Office at a WIPO meeting in March 2002 suggested that many of the applications filed to that point were 'weak' in the sense of not fully appreciating the requirements attached to patentability. WIPO, Conference on the International Patent System, 25–27 March 2002 (author's notes of presentation).

[19] See Maskus, above n 17, and Carlos A. Primo Braga and Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 Duke J. Comp. & Int'l L. (1998) 163.

[20] South Korea has progressively strengthened its IP regime in response to US and other OECD demands, but as with China there is not a 'cause and effect' relationship between the strengthening of the regime and economic development. Rather, as South Korea became a stronger competitor in the world market and its products challenged OECD dominance, the OECD demanded that South Korea cease its pattern of appropriation. History of bilateral IPRs relations between the United States and South Korea are in Congressional Research Service, Report for Congress, South Korea-US Economic Relations: Cooperation, Friction, and Future Prospects, updated 3 Jan. 2002, Code RL30566.

[21] See reports regarding research conducted at the Singapore Biopolis presented at Medecins Sans Frontieres, Neglected Diseases Group Meeting, Penang, Malaysia, 6–7 Feb. 2004, Dr. Alex Matter, Director, *Novartis Institute for Tropical Diseases*, Singapore, Novartis Institute for Tropical Diseases, and Dr. Ee Chee Ren, Deputy Director, Genome Institute of Singapore and Principal Investigator, SARS Research Kit, *Harnessing Research Capacity for Public Health: A Diagnostic Test for SARS – What lessons for neglected diseases?* Note, however, that Singapore is classified as a high-income country by the World Bank.

[22] See W. Kaplan, *et al., Ways to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda*, Boston University School of Public Health, 23 April 2003 (draft), at p 13, section 3.6.1, citing to LABAT AFRICA/CMCS, Pharmaceutical Manufacturing Sector Study 2001, p 34, reporting the closing of nine local production facilities (five subsidiaries of multinational companies and four local companies through acquisition and closure by multinationals).

investment for countries that introduce stronger protection regimes. The reality appears more heavily weighted toward rent collection. This may be rational enterprise policy – that is, to use a more protective environment as a means to consolidate and achieve increased economies of scale – but rational commercial reality should be acknowledged. Until some evidence is brought forward to support a correlation, strong patent regimes should not be promoted as the means to secure direct investment in areas such as pharmaceuticals.[23]

This is not to suggest that improvements by developing countries in their IPRs regimes may not generate benefits from increased local R&D and enhanced licensing opportunities.[24] There is, however, substantial evidence to suggest that when and how such changes are introduced will play an important role in determining the net benefits to the country implementing the policies. Within three broad categories – developed, developing and least developed countries – the TRIPS Agreement accounted for different levels of economic development in establishing transition arrangements. For the developing countries, that transition has effectively ended (with the last window set to close on Indian pharmaceutical producers).[25] While passive resistance to TRIPS enforcement among developing countries will doubtless continue, as of 1 January 2005, 'policy space' in IPRs will have dramatically narrowed from the pre-Uruguay Round situation. It is likely to be some time before increases in local wealth generation from increased investments in innovation will offset static technology rent outflows even with a heavy discounting of rent obligations based on incomplete enforcement.

Looked at purely from the standpoint of the Northern Tier and the objective of information and technology rent collection, the first ten years of the TRIPS Agreement have been a success. Implementation and enforcement is far from perfect, but no one expected perfection. Because investments in information and technology are sunk costs, each additional dollar, Euro, yen or Swiss Franc collected is a net gain, and the net gains have been substantial. That, of course, is only a part of the story, but a good jumping-off point.

II. WTO TRIPS JURISPRUDENCE

It is fitting to say a few words about TRIPS in WTO dispute settlement. I have recently published a detailed survey and analysis of the TRIPS case law to date.[26] There have not been any great surprises. The AB has pursued a

[23] Of the pharmaceutical producers I have met over the past years, the most enthusiastic are based in Bangladesh where patents are ignored, and where foreign direct investment is increasingly flowing.

[24] See, e.g., World Bank Global Economic Prospects, above n 13, at Ch 5.

[25] India's implementation of pharmaceutical product patent protection on 1 January 2005 will be one of the single most significant events triggered by the TRIPS Agreement, with consequences yet to be determined. This subject is treated in some detail in Abbott, *The WTO Medicines Decision*, above n 2.

[26] Frederick M. Abbott, 'WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Intellectual Property Rights', in F. Ortino and E.-U. Petersmann (eds), *The WTO Dispute Settlement System 1995–2003* (2004) 421–53.

cautious approach, warning against expansive interpretation of TRIPS obligations. The most important TRIPS decision from a social welfare standpoint was decided only by a panel – chaired by Bob Hudec – the *Canada – Generic Pharmaceuticals* case.[27] This was a finely crafted decision that gave us a nuanced interpretation of Article 27.1 of the TRIPS Agreement and its use of the term 'discrimination', while providing a somewhat over-narrow interpretation of Article 30. The AB's doctrine of evolutionary interpretation may eventually help rectify any excess rigidity.[28] It is of some interest that the AB in the *EC – GSP* case effectively supported the *Canada – Generic Pharmaceutical* panel's approach to the term 'discrimination', though in a trade-in-goods context.[29]

The most troublesome AB TRIPS jurisprudence is found in the *US – Havana Club* case where, in this author's view, the AB adopted an excessively strict standard for evaluating national treatment and MFN obligations that allow neither the AB nor the Members any 'wiggle room' under these concepts, which flexibility is likely to be needed. Yet this is perhaps a technical point, and the lawyers on the AB should be able to work their way out of this jam.

Civil society groups worried over threats from industry on the basis of TRIPS Agreement rules may find a modicum of comfort in the appointed guardian of the TRIPS Agreement – the WTO Appellate Body. There is a difference between threatening countries on the basis of unwarranted interpretations and the reality of persuading the AB. However, just as the US Supreme Court does not intervene on each occasion an accused is improperly imprisoned, so the AB is not involved in the daily implementation of the TRIPS Agreement. Its influence is somewhat remote and symbolic.

There may be some high-profile cases brought before the AB in the next several years. Given the scale of India's 2005 transition obligations there is substantial room for domestic patent litigation, and this could indirectly spill into the WTO. If Argentina's dispute with the United States concerning interpretation of Article 39.3 reignites, or if Brazil's provisions on local working are used, the AB may find itself in the global TRIPS spotlight.

III. THE ALLOCATION OF INSTITUTIONAL RESPONSIBILITY

John Barton recently observed that patents are too important to be left to patent lawyers.[30] We might similarly say that regulation of the international IPRs

[27] WT/DS114/R, 17 March 2000. Frederick M. Abbott, 'Bob Hudec as Chair of the *Canada – Generic Pharmaceuticals* Panel – The WTO Gets Something Right', 6 JIEL (2003) 733.

[28] See United States – Import Prohibition on Certain Shrimp and Shrimp Products, AB-1998-4 WT/DS58/AB/R, 12 Oct. 1998, at para 130, and id.

[29] See European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries, AB-2004-1, WT/DS246/AB/R, April 7, 2004, e.g., at paras 173–74.

[30] John H. Barton, 'Issues Posed by a World Patent System', in K. Maskus and J. Reichman (eds), *International Public Goods, The Public Domain, and the Transfer of Technology after TRIPS* (Cambridge Univ. Press, forthcoming 2004).

system is too important to be left to the WTO and WIPO. That is the arrangement largely contemplated by the TRIPS Agreement.[31]

According to Article 27.1 of the TRIPS Agreement, patent rights should be available and enjoyable without discrimination as to field of technology. This does not, however, mean that a patent with respect to an Internet search engine must be treated the same as a patent on a steam turbine. In the *Canada – Generic Pharmaceuticals* decision, the panel made clear that the pejorative concept of 'discrimination' must be distinguished from differentiation for legitimate reasons. Inventions are not neutral with respect to field of technology. The invention of a new variety of disease-resistant rice has fundamentally different implications than the development of a new microprocessor or machine tool. IPRs are not only trade-related. They are also education-related, health-related, nutrition-related, defense-related, environment-related, energy-related and so on. Multilateral organizations such as the Food and Agriculture Organization and the World Health Organization have important interests in the way rights granted with respect to inventions within the scope of their regulatory mission are used. It is therefore not remarkable that these organizations have sought to play a more significant role in the implementation of the TRIPS Agreement and in the formulation of new rules.

Industries potentially affected by a broadened scope of multilateral regulatory authority do not endorse the wider contextual view of IPRs, and resist efforts by 'non-trade' multilateral institutions to affect the exercise of what they argue are effectively unlimited rights in property.[32] This is nothing new. It is reflective of the historical tension between the regulator and the regulated. This brief article will not attempt to analyze in depth the question of sharing inter-institutional regulatory responsibility in the field of TRIPS.[33] As a broad observation, the regulated industries so far have been largely successful in lobbying governments to keep the center of IPRs power at the WTO and WIPO (as far as multilateral institutions are concerned). As we will see, multilateral institutions are only a part of the overall IPRs and TRIPS context.

[31] See, e.g., final clause of Preamble to TRIPS Agreement.

[32] This perspective has been particularly pronounced in respect to the pharmaceutical sector, where the industry has resisted WHO involvement in regulation of IPRs. This is reflected in recurring debates at the World Health Assembly regarding proposed references to the TRIPS Agreement in WHA resolutions. Conflicts between pharmaceutical industry representatives and NGOs promoting access to medicines are regularly reported by many NGOs, including Medecins Sans Frontieres at its Campaign for Access to Essential Medicines website, at http://www.accessmed-msf.org. Tobacco industry representatives were active during negotiation of the WHO Framework Convention on Tobacco, pressing for elimination of proposed controls on cigarette advertisements based on asserted trademark holder rights. Report by Allyn Taylor to Third ASIL Human Rights and International Economic Law Conference, Georgetown University Law Center, 4–5 April 2004. During negotiation of the International Treaty on Plant Genetic Resources for Food and Agriculture at the FAO, there was substantial lobbying by biotechnology-intensive plant and seed producers to eliminate provisions regulating patenting of inventions derived from materials withdrawn from the multilateral system.

[33] See for details, *Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance*, 3 JIEL (2000) 63, and Frederick M. Abbott, *Coherence, Co-Option, Flanking and Containment: Distributed Governance Revisited*, paper presented at ASIL Human Rights and Trade Conference, Georgetown, Washington, DC, April 2004.

IV. TRIPS AND SOCIAL POLICY: THE MEDICINES DEBATE

The public face of the TRIPS Agreement has been largely defined by the medicines debate. It is not difficult to trace the genesis of the debate, and why it became so heated. And, I believe I am on safe ground when I offer you the prediction that the controversy is not over.

The subject of patenting of pharmaceutical products was one of the most intensely fought over during the Uruguay Round. There were many countries in the developing world that did not provide pharmaceutical product patent protection. India, which was and remains the major producer of generic versions of medicines on-patent in the OECD, led resistance on this question, with Argentina, Brazil and other developing countries with some capacity in this sector in support. The TRIPS Agreement ultimately encompassed pharmaceutical product patents, but with a complex transition arrangement involving a 'mailbox' and 'exclusive marketing rights'. The principal rule of patent obligation impacts India as of 1 January 2005.

But the public controversy over TRIPS did not arise from these rules. It arose from industry and government misbehavior – that is, the action by the Pharma companies and their supporting governments (the United States and European Union) against the government of South Africa. A few details are important to an understanding of the situation today.

The subject matter of the dispute was the Medicines and Related Substances Control Amendment Act of 1997.[34] The public face of the complaint by Pharma was that Section 15C of the Act violated the TRIPS Agreement because it authorized parallel imports, and did so in a non-elegant way from a drafting standpoint. On these basic points the complaint made little sense since (a) the TRIPS Agreement manifestly permitted each Member to authorize parallel imports – a matter on which none of the leading experts on TRIPS has ever disagreed,[35] and (b) the complained-of language came from a WIPO Committee of Experts Report.[36] The US government eventually conceded the essential TRIPS-consistency of the legislation and left that particular arena.

The problem is that the industry was not mainly after parallel imports or the drafting of Section 15C, but was instead concerned about certain more basic aspects of medicines regulation: that is, the introduction of mandatory generic substitution and a system of price controls based on a so-called 'single

[34] At the recommendation of the WHO, this author served as adviser on TRIPS and IPRs matters to the South African government as the case came to trial in the High Court of Pretoria. For additional details on legal issues, see Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, Study Paper 2a*, Commission on Intellectual Property Rights, United Kingdom, Feb. 2002, available at http://www.iprcommission.org/text/documents.htm.

[35] See, e.g. Declaration Regarding the Exhaustion of Intellectual Property Rights and Parallel Trade, adopted by the International Law Association on recommendation of the Committee on International Trade Law, July 2000 (London Conference).

[36] Language used in Section 15C had been transmitted by WIPO to the government of South Africa during development of the legislation.

exit price'. The problem from Pharma's standpoint was that the TRIPS Agreement did not address the questions of generic substitution or pharmaceutical price controls, nor did any other WTO Agreement. These regulatory matters did not entail international legal responsibility for South Africa. So the TRIPS complaint was essentially an effort to block the implementation of legislation that would adversely affect Pharma's regulatory interests in South Africa through an untenable allegation of TRIPS-wrongdoing.

Unfortunately for everybody concerned, and particularly the HIV-infected community, Pharma's attack coincided with a mushrooming pandemic which demanded the immediate attention of the South African government, the industry, the WHO, and so forth. The net consequence of the attack on South Africa's medicines legislation was to completely divert attention from the core problem, and effectively paralyse the government. Today everyone involved on the Pharma side can say this was all just an unhappy coincidence, but the reality is tragic.

And so, the Doha Declaration was born out of the abuse of TRIPS Agreement rules and the tragedy in South Africa, not out of the TRIPS Agreement rules themselves. That is why developing countries were largely satisfied with a Doha Declaration that principally restated existing rules, but confirmed the right of Members to use them.

The Doha Declaration included in its Paragraph 6 a directive to the TRIPS Council to recommend a solution to the problem of effective use of compulsory licensing by countries with insufficient or no manufacturing capacity in the pharmaceutical sector. Close to two years of negotiations were required to address the minor adjustment of two clauses (Articles 31(f) and (h)) of the TRIPS Agreement. The result is the subject of considerable controversy, having satisfied none of the major negotiating constituencies.[37] There is a substantial amount of activity ongoing to implement the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in both developed and developing countries. It is too early to say whether it will be adequate to address the situation for which it was intended.

But why does the South Africa case remain relevant today? There are a number of reasons, including the need to remain vigilant against misuse of WTO rules. From the standpoint of present trends in IPRs-related negotiations, it is because Pharma was made to recognize that the TRIPS Agreement did not, in fact, allow it to effectively intervene in the development and implementation of medicines regulation, whether in South Africa, Australia, Chile, Central America, Morocco, Canada, France or Germany. There is a campaign underway to change the rules to allow that. But the problem is that those rules changes could not be negotiated in a multilateral forum where there is relative transparency and a high level of interaction among government delegations. US PhRMA is following a different approach: pressing for bilateral and regional free trade negotiations

[37] See Abbott, 'The WTO Medicines Decision', above n 2.

as the mechanism to bring about change.[38] Before discussing that, reference should be made to a development related to the Doha Declaration, and that is the emergence of the G20+ and other South–South alliances.

V. EMERGENCE OF THE G-20+ AND SOUTH–SOUTH ALLIANCES

The G-20+ is associated with negotiations on agriculture. However, the development of the G-20+ has roots in the Doha Declaration, and more particularly the Paragraph 6 negotiations as Brazil, India, South Africa and other developing country delegations spent a great deal of time in close quarters hammering out negotiating positions in a very concrete way. We begin to see a shift in the post-Cold War paradigm. Until recently, OECD countries had a relatively free hand to drive the GATT-WTO agenda. There is no question but that China is becoming a dominant economic force in Asia,[39] and it will gradually begin to chart a more assertive economic agenda. As Brazil, India and South Africa solidify their new trilateral relationship, and if China becomes more closely linked to form a Southern Quad, we may begin to see negotiations at the WTO take on a different character. There is a risk of over-anticipating future events, but as we consider variable geometries at the WTO, it is important to factor in that the dynamic markets of the next two decades may not be the OECD, and that unilateralist trade policies may begin to hit against serious limits. This will, of course, be important in relation to TRIPS, because the interests of the Southern Quad may be significantly different from those of the Northern Tier.

VI. REGIONAL AND BILATERAL TRIPS-PLUS AGREEMENTS AND WTO-BASED MULTILATERALISM

A. Toward formal TRIPS impact assessments

While Members at the WTO were preoccupied with negotiations on Paragraph 6, the United States was pursuing another TRIPS agenda. This agenda is being carried out in the context of bilateral and regional free trade agreement

[38] See PhRMA Special 301 Submission to USTR 2004 ('PhRMA 2004 Submision'), at Appendix B, FTAs – Challenges and Opportunities, observing that FTA negotiations are a 'second best' to multilateral agreements, but that 'deliberations in the TRIPS Council call into question the current value of the WTO as a venue for improving the worldwide protection of intellectual property.'

[39] See WTO Committee on Trade and Development, Participation of the Developing Economies in the Global Trading System, WT/COMTD/W/1, 9 Nov. 2004, at paras 3, 25, and Table 1.

> 'The most dynamic large economy in the [Asian] region in terms of its trade performance between 2000 and 2003 was China, with average annual merchandise export growth of nearly 21 per cent and import growth of 22 per cent. China's exports in 2003 were led by machinery and transport equipment (including office machines and telecom equipment), as was also the case for China's imports. India experienced strong growth in its trade performance during 2000–03, with exports and imports respectively growing at 10 per cent and 11 per cent per year on average. India's exports were led by manufactures, the most important of which were clothing and textiles.' Id, at para 29.

Regarding the growing importance of China in world markets, including as an importer of raw materials and destination of foreign direct investment, see Larry Rohter, *China Widens Economic Role in Latin America, NY Times*, 20 Nov. 2004, http://www.nytimes.com.

negotiations with developing and developed countries. Agreements are in force or signed with Singapore, Chile, CAFTA, Australia and Morocco,[40] and negotiations are underway with several Andean countries, the Southern Africa Customs Union (SACU), Thailand and others. The objective is realized in chapters setting out extensive commitments on intellectual property rights, including specific provisions addressing 'certain regulated products'.[41]

With reference to the regulation of pharmaceutical products, the intellectual property chapters of these agreements vary in their specific terms.[42] The common objectives of the United States, achieved to different degree, are to limit potential exclusions from patentability,[43] require the grant of patents for 'new uses' of known compounds,[44] require patent term extension under certain conditions,[45]

[40] This refers to negotiations completed subsequent to adoption of the Doha Declaration on the TRIPS Agreement and Public Health, adopted 14 Nov. 2001.

[41] The provisions on 'certain regulated products' address pharmaceuticals and agricultural chemicals. For a technical discussion of the provisions on pharmaceutical regulations, see Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Quaker United Nations Office, Occasional Paper 14, April 2004 (at http://quno.org).

[42] Parts of this paragraph describing the provisions of the FTAs also appear in Abbott, 'The WTO Medicines Decision', above, note 2. The texts of the FTAs are available at http://www.ustr.gov. The World Bank has compiled tables of IPRs-related provisions in the various bilateral agreements, see Trade Note (forthcoming 2004, in author's files). A number of NGOs have also compiled tables showing the TRIPS-plus provisions adopted on an agreement-by-agreement basis. See, e.g., Oxfam Briefing Note, *Undermining access to medicines: Comparison of five US FTAs*, May 2004, available at http:// http://www.oxfamamerica.org/pdfs/fta_comparison.pdf) and CPTech, *Table of selected provisions related to healthcare in the Free Trade Agreement texts that have been made public*, available at http:/ /www.cptech.org/ip/health/trade. See also MSF Briefing Note, *Access to Medicines at Risk Across the Globe: What to Watch Out for in Free Trade Agreements with the United States*, May 2004, available at http://www.accessmed-msf.org. An excellent analysis of the US-Chile FTA is Pedro Roffe, 'Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement', TRIPS Issues Paper No. 4, Quaker International Affairs Programme, Ottawa.

[43] Some agreements, for example, preclude the exclusion of plants and animals from patentability, eliminating the flexibility in Article 27.3(b) of the TRIPS Agreement to exclude such subject matter, and to provide only a *sui generis* form of plant variety protection. See US-Chile FTA, art. 17.9(2)(best efforts), CAFTA, art. 15.9(2)(best efforts), and US-Morocco FTA, art. 15.9(2).

[44] The grant of patents for 'new uses' is not permitted in a number of countries. See, e.g., Andean Community, Decision 486, art. 21 ('Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.') In a typical case, a pharmaceutical compound known to be effective for treating one form of disease may be found to treat another disease, and a person seeks a patent on the 'new use' (sometimes referred to as a 'second medical indication' patent in that context). The TRIPS Agreement is silent regarding whether such patents should be granted, leaving countries with flexibility to decide the question. See US-Morocco FTA, art. 15:9(2), and US-Australia FTA, art. 15:9(1).

[45] The United States provides a limited patent term extension based on the period during which a product undergoes regulatory review. Country practice varies on this matter, and it is not regulated by the TRIPS Agreement. See Panel Report in *Canada – Generic Pharmaceuticals* case, above note 27, describing US system and deciding that patent term extension based on regulatory review is not required by TRIPS Agreement. The terms of the FTA base the exception on unreasonable delays in granting patents. See US-Australia, art. 15.9(8), CAFTA, art. 15.9(6), US-Chile FTA, art. 17.9(6), US-Morocco FTA, art. 15.9(7), US-Singapore FTA, art. 16.7(7)–(8).

prevent parallel importation,[46] limit the grounds under which compulsory licenses may be granted,[47] and allow for the prosecution of non-violation nullification or impairment claims.[48] In addition, the United States is securing periods of marketing exclusivity, covering patented and non-patented products, based on the submission of data in the regulatory approval process. The new provisions eliminate important flexibilities of the TRIPS Agreement.[49] Marketing exclusivity is based not only on data submitted in the country where regulatory approval is sought, but is also based on data submitted in foreign countries, and is based on the fact of marketing approval in foreign countries.[50] Furthermore, patents are linked to the marketing approval process, and preclude a country from giving effect to marketing approval prior to the expiration of the patent term without the 'consent or acquiescence' of the patent holder.[51] Because the patent holder is given the right to block marketing approval by the medicines regulatory authority, read literally this provision would prevent the effective use of compulsory licensing. The patent-marketing approval link adds a complex layer to the typical medicines approval process, requiring the medicines regulatory authority to become involved in determining patent status.[52] In the case of Australia, the United States negotiated so that pharmaceutical companies are newly able to challenge decisions by Australian regulators as to whether drugs will qualify for reimbursement

[46] The Doha Declaration, at para 5(d), confirmed the right of each WTO Member to adopt its own policy and rules with respect to parallel imports. Some FTAs preclude parallel importation of patented products, thereby eliminating this flexibility. See US-Morocco, art. 15.9(4), and US-Australia FTA, art. 17.9(4).

[47] Some FTAs limit the grounds for granting compulsory licensing, for example, to national emergencies and circumstances of extreme urgency, or to remedy anticompetitive practices. See US-Australia, art. 17.9(7), and US-Singapore FTA, art. 16.7(6).

[48] See CAFTA, art. 20.15(2) and Annex 20.2, and US-Australia, ch 21.

[49] Article 39.3 of the TRIPS Agreement requires Members to provide protection against use of confidential information with respect to 'new chemical entities' submitted during the regulatory review process against 'unfair commercial use'. The provisions in the FTAs establish strict 'marketing exclusivity' periods following approval based on submitted data (initially five years) and do not allow exception for fair or non-commercial uses, such as use by government authorities in public health-systems. Several do away with the limitation to 'new chemical entities' See US-Australia, art. 17.10(1), CAFTA, art. 15.10(1), US-Chile, art. 17.10(1), US-Morocco FTA, art. 15.10(1), and US-Singapore, art. 16.8(1). Some of the agreements allow the renewal or 'evergreening' of marketing exclusivity periods. See US-Australia, art. 17.10(2), US-Morocco FTA, art. 15.10(2). These provisions taken together dramatically limit TRIPS flexibilities.

[50] The United States is apparently concerned with countries that do or may accept registration in the United States or other countries, or approval by the WHO prequalification program, as sufficient evidence of the safety and efficacy of medicines, extending the basis of marketing exclusivity to actions taken outside the country where exclusion is sought. See text of articles formulated in various ways, id.

[51] See US-Australia, art. 17.10(5), CAFTA, art. 15.10(3), US-Chile, art. 17.10(2), US-Morocco FTA, art. 15.10(4), US-Singapore, art. 16.8(4), and discussion below.

[52] The operation of the complex Orange Book-based system for challenging accelerated new drug applications is described in US Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

under its Pharmaceutical Benefits Scheme (PBS).[53] The PBS is the principal mechanism by which Australia controls drug prices.[54]

Earlier I suggested that the action threatened by US and EU trade authorities against South Africa remained relevant today. In that action, WTO Members were over-reaching under the TRIPS Agreement, and Members and their private sector constituency were forced to withdraw. The new bilateral and regional arrangements are providing the legal basis for the reduction of critical policy space within developing countries, and in the case of Australia, a developed country. The United States has made clear that it is implementing an agenda to force other countries to follow its lead on medicines policy. Its PhRMA industry constituent has stated that its objective is forcing the abandonment or modification of price control systems that are ubiquitous outside the United States.[55]

The countries of Europe that control pharmaceutical prices are the most highly valued target on the price control issue because the potential aggregate financial rewards to PhRMA are much greater than those from other regions. At the same time, the prospects for success are relatively low since Europeans are not anxious to see their health care budgets increase, particularly in the face of aging populations. Increases in price-controlled exports from Canada to the United States doubtless raise PhRMA's level of concern with Canada's medicines regulatory regime.

The medicines export industries of India and China supply a large portion of the world's supply of generic medicines, and are rapidly evolving on the research side. By imposing restrictive new rules on the marketing approval of medicines in importing countries, the expansion of competition from India and China can be slowed.

PhRMA argues that without relief from price controls and without protection against competition from India and China, it will not be in a position to provide new medicines based on very costly research. This line of argument has complicated underpinnings. Below are a few counter-points:[56]

(1) The PhRMA companies in the United States benefit from an enormous public subsidy. The NIH has a budget of $28 billion per year,

[53] US-Australia FTA, Annex 2-C Pharmaceuticals, at para 2(f).

[54] This aspect of the US-Australia FTA was the subject of intense political controversy in Australia. See discussion text at n 66, below.

[55] On OECD price control systems, see generally 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 Feb. 2001. Regarding PhRMA position, see PhRMA 2004 Submission, at Introduction (i), Canada (at 2, 7–8), New Zealand (at 34), Italy (at 57–58), Egypt (at 62), India (at 68), Saudi Arabia (at 84), Brazil (at 94) Ecuador (at 99), Venezuela (at 104–5), Russia (at 121), CAFTA (regarding Honduras, Nicaragua and Panama) (at 143), and especially at Appendix A, Foreign Government Price Controls Are a Major Trade Issue, referring to other countries, including Australia, Japan and Taiwan.

[56] For a critical perspective on the research contribution of the Pharma companies by the former editor-in-chief of the New England Journal of Medicine, see Marcia Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do About It* (Random House, 2004). This book, published after this paper was initially presented in Berne, makes points very similar to those made here concerning the complexities of the pharmaceutical R&D arguments.

most of which goes into funding research into medical technologies. The results of that research are channeled back to the PhRMA companies which pay very limited royalties for its use. The PhRMA industry is the beneficiary of a tremendous amount of basic research being conducted at universities, teaching hospitals and research institutes.[57]

(2) The PhRMA companies today have a weak record of innovation, and this phenomenon appears to be driving a trend toward consolidation. Few new chemical entities are being discovered.[58]

(3) The PhRMA companies focus their attention on blockbuster discoveries — drugs with a market potential of over $1 billion per year – and heavily promote drugs such as Viagra and Cialis based on potential market demand, rather than public health requirements.[59]

(4) The major expenditures and risk for the PhRMA industry lie in clinical trials – part of the process in which new drugs obtain marketing approval from the US FDA and foreign regulatory authorities. This is where investors risk their capital. PhRMA plays the role of determining what drug candidates will be put forward for the costly testing process, and thus acts to allocate financial risk. But this role should be disaggregated from 'basic research' – that is, where new medicinal properties are discovered. The 'golden goose' of pharmaceutical innovation is cooked only partly in PhRMA laboratories. It is mainly cooked elsewhere.

None of this is to say that the US PhRMA industry does not play a useful role in the development of new medicines. It is rather to say that one should be cautious about over-simplifying the situation by reducing it to a phrase like 'killing the goose that lays the golden eggs'.[60]

The use by the United States of bilateral and regional trade negotiations to obtain concessions from developed countries on the issue of price controls and related regulatory matters raises important questions. The international community must finance innovation in the pharmaceutical sector. The optimum way to finance R&D very likely involves a combination of mechanisms, including public research expenditure, targeted subsidy and use of the patent. The idea that governments should eliminate price

[57] See references in Abbott, 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines', in K. Maskus and J. Reichman (eds), *International Public Goods, The Public Domain, and the Transfer of Technology after TRIPS* (Cambridge Univ. Press, forthcoming 2004).

[58] See NIHCM Foundation, 'Changing Patterns of Pharmaceutical Innovation (2002) relied on by the US Federal Trade Commission in its report on patents and competition' (see US FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003, at Chapter 3, Part II).

[59] See Report of British Commission on Intellectual Property Rights (2002).

[60] PhRMA spokespersons have routinely used the phrase 'killing the goose that lays the golden eggs' to counter suggestions for pharmaceutical industry regulation. See, e.g., statement of Dr. Michael Horan, MD, Vice President for Clinical Affairs, PhRMA. US FDA, Anti-Infective Drugs Advisory Committee, Meeting of Pediatric Subcommittee, 23 Apr. 1999, available at http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3506t1.rtf.

controls, leave the Pharma companies to determine the direction of research and charge the price the market will bear seems an unlikely way to achieve a satisfactory result when there is such high risk of and from market failure. There is widespread dissatisfaction in the United States and elsewhere with respect to prices of prescription medicines. Yet for the OECD countries it is not a question of whether they can afford access to medicines for their citizens. It is a question of priorities and policy choices.[61] If Australia and Canada are willing to relinquish control over the price of medicines in exchange for market access in agriculture that is a policy choice – whatever its wisdom – these countries can afford to make.

A large segment of the world's population cannot, however, afford to pay the medicines bill. Throughout the developing world people live without adequate access to medicines, and their governments have very limited capacity to reallocate resources to help them. The provisions of FTAs being signed by developing countries address the pharmaceutical sector with extensive new requirements: adding periods of marketing exclusivity; extending the scope and term of patent protection; facilitating evergreening; blocking parallel imports; limiting compulsory licensing. These provisions are designed to inhibit the marketing of generic products. The known economic consequence of such inhibition is to raise prices.[62] All other things being equal, the FTAs will increase the price of medicines in developing countries.

For the rationale as to why countries are signing these agreements one can go back to the Uruguay Round. In those negotiations, developing countries made concessions on TRIPS in exchange for OECD commitments to reduce agricultural export subsidies and textile quotas. Today, textile producers in Central America hope to obtain a more competitive position in the US market *vis à vis* Chinese textile producers. Chile will gain on exports of agricultural products. But the idea of bargaining for gains in textile exports by offering concessions in pharmaceuticals and health care only works if certain preconditions are met. What are those preconditions? The gains to textile exporters must be transferred into public health systems. Most importantly, increased payments to textile producers must be used to fund general increases in public health budgets to offset the increases in pharmaceutical prices. At the very least, individuals working in textile factories must see improved health care benefits. But these kinds of preconditions are not built into FTAs. The owners of the textile factories gain,

[61] The author appreciates that a significant number of Americans are facing serious difficulties from the high prices charged for prescription medicines, and of course these consumers are not 'rich'. The point is that United States and other OECD countries are 'rich' by relative standards (see World Bank Data and Statistics on global wealth and income distribution at, e.g., http://www.worldbank.org/data/countryclass/countryclass.html), and if the governments of these countries choose policies intended to make medicines generally available, it is well within the national means. This is not true for developing countries.

[62] There is extensive evidence that generic competition in the pharmaceutical sector lowers prices. See, e.g., Canada, Patented Medicines Price Review Board, Prices of the Top Selling Multiple Source Medicines in Canada, Nov. 2002.

there are some gains in local employment, and therefore a segment of the population may be better off. But it is most likely that a wider segment of the population will be worse off, and governments may not make policy adjustments to rebalance the system.

In the TRIPS bargain developing WTO Members obtained concessions on agriculture and textiles and granted concessions on pharmaceuticals and videos. However, while developed countries prepared quasi-empirical reports of losses their industries suffered as the result of inadequate protection of IPRs,[63] there were no comparable assessments of the impact that TRIPS rules would have on developing country public health sectors.

The year 2004 saw an idea emerge from various quarters and begin to take root.[64] That is, the idea of subjecting new agreements on intellectual property rights to objective impact assessment.[65] In May 2004, a distinguished group of economists and lawyers in Australia presented an assessment of the pharmaceutical sector impact of the US-Australia FTA to a Senate Select Committee.[66] In November 2004, an assessment for Colombia of a prospective free trade agreement with the United States was published by the Pan American Health Organization (PAHO) and the Fundacion instituto para la investigacion del medicamento en los systemas de salud/Institute for the investigation of medicines in public health systems (IFARMA).[67] This assessment was requested by the Colombian Congress.

The independent assessment of the impact of the US-Australia FTA suggested substantial increases in the price of medicines, with a corresponding negative impact on the private sector and government provision of health care services.[68] The principal problem identified in the assessment was the FTA's

[63] See, e.g., the 1988 report of the US International Trade Commission prepared at the request of USTR, referred to in Abbott, 'Protecting First World Assets', above, n 10, at 699–702.

[64] Before he left his post, UNCTAD Secretary General Ricupero began to speak in these terms. See, e.g., presentation at UNCTAD/ICTSD, above, n 4.

[65] So far, this idea has been discussed principally in relation to public health and medicines, but it may obviously be extended to cover other subject matter areas.

[66] P. Drahos, T. Faunce, M. Goddard and D. Henry, *The FTA and the PBS: a submission to the Senate Select Committee on the US-Australia Free Trade Agreement*, 2004. See also Parliamentary Library Research Department (Australia), Research Note, The PBS and the Australia-US Free Trade Agreement, 2004–05, No. 3, 21 July 2004. This assessment was submitted to the Senate Committee at about the same time the FTA was signed.

[67] This report assesses the potential impact of an FTA involving the United States and Colombia (including also Ecuador and Peru), based in substantial part on the terms of FTAs recently negotiated by the United States. See Miguel Ernesto Cortes Gamba, Alvaro Zerda Sarmiento, Devis Sarmiento and Gerardo Augusto De La Hoz Pinzon, 'Modelo Prospectivo del Impacto de la Proteccion a la Propiedad Intelectual sobre el Acceso a Medicamentos en Colombia', PAHO and IFARMA, Bogota, Nov. 2004 ('PAHO/IFARMA Assessment').

[68] The main conclusions of the Drahos *et al*. report are:

–The FTA will substantially increase the cost of the PBS. We will be paying more for the same drugs.

–It is plausible that the cost to the government of the PBS is likely to rise by around 30 percent as a result of the FTA. For calendar 2003, this would have meant an extra cost of around $1.5 billion with no increase in the health benefit to Australian patients. We believe this to be a conservative estimate.

–Other drug buyers, including public and private hospitals, will also have to pay more.

provisions granting rights to American pharmaceutical companies to challenge determinations regarding medicines that are subject to reimbursement under Australia's Pharmaceutical Benefits Scheme (PBS).[69] The assessment was a significant factor leading the Australian Parliament to amend legislation implementing the FTA. The amendment imposes liability on parties attempting to block introduction of generic products by improper use of patents. US PhRMA has objected to the amendment on grounds of inconsistency with the TRIPS Agreement.[70] USTR has reserved rights to address the matter further with the Australian government.[71]

The independent Australian impact assessment shows both promise and limitation. The Australian executive was impelled to address evidence that the FTA would have an adverse effect on the Australian public health system. Changes to implementing legislation were demanded and secured by the opposition party. Yet the amendments adopted by the Parliament did not address the principal problem identified in the assessment, that is, changes in the way the PBS will be administered.

The assessment of a prospective US-Andean FTA on Colombia predicts a substantial adverse impact on access to medicines, disproportionately burdening the poor.[72] It is difficult at this early stage to predict its impact on the

–To compensate for this drain on their budgets, public hospitals are likely to cut back on drug availability and on non-drug services such as elective surgery.
–Private hospitals will pass costs onto patients and insurance funds.
–Private health insurance premiums will rise. Id. at 7.

[69] Drahos *et al.*, id, at, e.g., 4–6.

[70] See 'PhRMA Memo Concludes Australian FTA Amendments Violate TRIPS', *Inside U.S. Trade*, 24 Sept. 2004

[71] See Letter of 17 November 2004, from USTR Zoellick to Australian Trade Minister Vaille, at para 6, and Letter of 17 November 2004 from Vaille to Zoellick, third paragraph from end.

[72] This assumes acceptance of terms comparable to those in other recently concluded FTAs. Some of the conclusions of this assessment are:

(1) Measures already adopted in Decision 486 as a consequence of TRIPS Agreement adherence have had a very significant impact on Colombia. By 2005, this will affect 6.68% of the pharmaceutical market with an equivalent cost of 110 million US dollars. Expressed in terms of the impact on the population, 900,000 people or 2% of the population will not have access to medicines.
(2) Data protection rules (Decree 2085) already adopted will have an impact estimated at 280 million dollars by 2010, equivalent to 400,000 individuals without medicine.
(3) Extending the term of patent protection under the US-Andean FTA will have an estimated cost beginning in 2025 of $400 million, corresponding to 13% of the market, with a health impact on 2.5 million people not having access to medicines.
(4) Extending the scope of patent protection (for new uses, minor modifications and combinations), for the year 2014 will have a cost of 1.2 billion dollars, or 23% of the value of the market.
(5) The increased cost of medicines will have a major impact on the system of public health, raising costs by 6.61% in 2008 if the same level of pharmaceutical access is provided. Unless expenditures are increased, 300,000 people will need to be removed from the system. The impact will be much greater on the poor. Because of cost increases, about 10,000 people will lose access to HIV/AIDS treatment, leading to about 4,000 additional deaths per year by 2014.

Id. at pp 7–8. The report is in Spanish and the conclusions above are based on translation by this author.

US-Andean negotiations.[73] Since the assessment was requested by the Colombian Congress, it is reasonable to assume that it will be given serious consideration as terms of the FTA are further negotiated and considered.

The results of the US-Australia FTA negotiations suggest that expectations regarding the positive effects of public health impact assessments should be tempered by recognition of the many interests at stake in FTA negotiations and the relative bargaining power of the government actors. Nevertheless, the results in Australia were preferable to what likely would have happened in the absence of the assessment. Also, there may be lessons for future use of assessments in the negotiating process. For example, the Australian assessment was transmitted to the Senate at about the same time the FTA was signed. If assessments can be prepared before agreements are signed, as has happened in the case of Colombia, this may make it easier to persuade government officials regarding the direction of negotiations. Also, it may be useful if governments are at least indirectly involved in these assessments – for example, as commissioning parties – because disclosure of information from industry might be mandated.[74] If disclosure is mandated, this might facilitate obtaining more complete and accurate information. Of course, assessments should be publicly disclosed, with due account for confidentiality of proprietary information.

The public might find out from these assessments that the anticipated effects are very modest. The public might find out they are very large. The effects may be quite different from country to country. One of the major benefits of such a system is that there would be a benchmark under which all sides could be held accountable. If the price effects turn out to be substantially greater than the assessment predicted, an adjustment to the terms of the deal could be made. Moreover, governments would be encouraged to explain to their own people how they intend to address the consequences of the agreement.

This is not a radical idea. In fact, it is in keeping with traditional GATT-WTO practices in trade-in-goods where the Members and the Secretariat calculate in advance the value of tariff and quota concessions. While calculating the effects of new rules on the pharmaceuticals trade may be somewhat more difficult, these difficulties should not be exaggerated.[75] Everyone involved in the bargain should know what they are trading, and what internal adjustments might be required.

Up till now, stakeholders have been groping in the dark, and forced to recycle ideas of the 1970s and 1980s in endless loops. It would be useful to learn

[73] This assessment was released very shortly before the publication deadline for this article.

[74] For example, regarding present and projected sales by product, pricing, patent and registration status in different markets, and so forth.

[75] IMS maintains a vast amount of data on the pharmaceutical industry, and while the numbers tend to be somewhat less complete for the developing countries than the developed, there would be many advantages to putting together more complete benchmarking numbers. *See* IMS website at http://www.ims-global.com/.

what disadvantages would be perceived in 'demystifying' these issues. There will likely be objections. The Pharma companies have been reluctant to provide data on patent status at request of UNAIDS and the Global Fund. There may be some concerns that provision of data on pricing and market demand will give unfair advantages to competitors. However, American and European competition authorities are able to assess market share and the prospective impact of mergers and acquisitions. European, Australian and Canadian regulatory authorities conduct detailed investigations of medicines pricing and market demand. There are ways to deal fairly with these problems.

B. MFN and regional arrangements in TRIPS

The US push toward dealing with perceived deficiencies in TRIPS-based regulation outside the WTO creates a very complex legal environment. Governments are bound to one set of rules in their dealings with the United States and its FTA partners, and another set of rules in dealing with other WTO Members. The most-favored-nation-principle in Article 4 of the TRIPS Agreement says that any IPRs protection advantage granted to one Member will be immediately and unconditionally granted to other Members.[76] The special regulatory rules regarding pharmaceuticals raise important MFN questions.

In an FTA, two or more countries may agree to raise IPRs standards or regulatory requirements. So, for example, in the US-Morocco FTA the parties agree to provide extensive marketing exclusivity rights based on submissions of regulatory data and foreign marketing approval, and to preclude the exercise of marketing approval without the consent of the patent holder. These rules principally benefit pharmaceutical patent holder-originators. We may assume that the United States and Morocco are willing to extend these same 'privileges' to European, Japanese and even Chinese and Indian pharmaceutical companies. In other words, if Indian or Chinese producers conduct clinical trials on new drugs and obtain the first marketing approvals, thereby constituting themselves as 'originators', they will be able to exclude generic competitors from the market. In that regard, the principle of nondiscrimination among WTO Members would be respected.

But what is the real effect of the new 'higher' regulatory standards? Indian and Chinese producers are very rarely 'originators'. Instead, they are efficient producers of generic drugs. The rules in the FTAs block Indian and Chinese

[76] Article 4 of the TRIPS Agreement provides:

> With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.

The WTO Appellate Body has referred to the MFN principle as a fundamental element of TRIPS (See WTO Appellate Body, United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R, 2 January 2002 ('US – Havana Club'), at para 297), although prior to the TRIPS Agreement MFN was not a principle of the international intellectual property system. On an historical basis, there is little international precedent for applying MFN in the field of IPRs.

generic producers from entering the Moroccan market. The new standards preclude the registration of bioequivalent medicines that are off-patent and, taken literally, preclude effective approval and registration of on-patent medicines in connection with compulsory licensing. This effectively establishes a trade barrier – a new quota – against Indian and Chinese products.

There is a considerable amount of WTO-GATT jurisprudence concerning the use of facially neutral measures as disguised trade barriers. It is worth examining whether India and China may be suffering *de facto* MFN discrimination as a consequence of these new rules.[77] The US would presumably argue that the TRIPS Agreement permits Members to adopt higher standards of protection, and that the relevant measures are TRIPS-consistent. However, in the typical *de facto* discrimination case the measure under scrutiny is facially neutral and, absent an impermissible modification of competitive conditions, appears to be 'legal'. The question in such cases – and in this case – is whether a measure pursues a legitimate and proportionate regulatory aim, or unjustifiably discriminates.[78]

VII. THOUGHTS ON WTO VARIABLE GEOMETRY IN TRIPS

Research and analysis over the ten years under the TRIPS Agreement suggests two basic principles. First, all subject matter is not created equal. Society has very different interests in inventions depending on their field of use. From the standpoint of IPRs law, this insight can be dealt with in a number of ways. It can be approached from the standpoint of (a) exceptions to the grant of IPRs, (b) variations in the terms of the grant of IPRs, and (c) variations in the scope of regulatory authority with respect to the use of IPRs.

The second basic principle is that all levels of development are not equal. Countries at different stages of economic development have different interests insofar as the value to society of protecting IPRs is concerned. If encouraging development is a high priority of the WTO, more leeway for use of technology by developing countries would likely benefit those countries.

The problem set is how to encourage local developmental uses of technology without undermining innovation in the developed countries. The TRIPS

[77] See, e.g., Canada-Generic Pharmaceuticals, at para 7.101, and cases cited at note 436. See also United States – Section 337 of the Tariff Act of 1930, Panel Report, adopted 7 Nov. 1989, BISD 36S/345 ('US – Section 337').

[78] The *Canada – Generic Pharmaceuticals* panel framed the matter as follows:

> . . . de facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable. Two main issues figure in the application of that general concept in most legal systems. One is the question of de facto discriminatory effect – whether the actual effect of the measure is to impose differentially disadvantageous consequences on certain parties. The other, related to the justification for the disadvantageous effects, is the issue of purpose – not an inquiry into the subjective purposes of the officials responsible for the measure, but an inquiry into the objective characteristics of the measure from which one can infer the existence or non-existence of discriminatory objectives.' (id., at para 7.101)

Agreement recognized differential interests in technology needs only through the incorporation of transitional arrangements, but without any clear picture as to how differential needs would be accounted for after the transitional periods ended. To be realistic, we must also take into account the fact that the United States and some other Northern Tier countries consider some TRIPS rules are not strong enough to protect large-scale investments in certain fields of technology.

The basic principles regarding differential subject matter and development interests suggest a potential restructuring of the way the TRIPS Agreement is administered and the way it might evolve. Within the TRIPS Council, sub-committees could be established for expressive industries, industrial producers, chemical and pharmaceutical producers and others. Within each subject matter or sector area, developmental interests could be addressed according to objective criteria of development, taking into account both the producer and the consumer side of the equation. The extent of market penetration into developed country markets could be a factor in determining the extent to which rules might be relaxed to accommodate developing country interests. Negotiations on new and different rules could be conducted much as negotiations are conducted within the GATS (i.e. Banking, Telecommunications, etc.), that is, along sector subject matter lines.

There are significant obstacles to the establishment of such an arrangement. The most serious are political, but there are legal questions as well. On the political side, could industrialists in the Northern Tier be persuaded of advantages to giving up gains won in TRIPS, and accept that some new rules may be TRIPS-minus? In addition, how could negotiations be undertaken in an environment more or less insulated from the pressures exerted during bilateral and regional negotiations? Despite the best intentions of the policy community, any new set of TRIPS negotiations could be turned into a platform for ratcheting up obligations on the weaker economic actors.

One way to address the political obstacles would be to create a 'shadow' negotiation undertaken by non-governmental persons under the auspices of a neutral institution. This shadow group of negotiators could be asked the question, what would a variable format TRIPS Agreement and administration look like, leaving aside political interests, and instead focusing on economic and developmental interests? To put it another way, the shadow group would be asked to posit an outcome that specifically encouraged growth in the weaker economies, while seeking a globally optimum (or quasi-optimum) outcome under that condition. The group would have to address not only efficiency of outcome from the global standpoint, but distributive outcome in terms of balancing global development.

Assuming for the sake of argument that the political obstacles could be overcome, legal questions must still be addressed. Operation of the foundation principles of the WTO and TRIPS Agreement – national treatment and MFN – would need to be re-evaluated. If large OECD-based multinational

enterprises must be treated the same way as small and medium-sized developing country producers, the large established enterprises would take advantage of preferences and we might be back where we started. Similarly, unless changes to the MFN principle are adopted in this context, it would not be possible to adopt a set of country specific variable rules.

Finally, however, before initiating an ambitious exercise in restructuring the TRIPS Agreement and the way it is administered, governments and policy makers would need to be persuaded that the wheel is broken. Otherwise, why fix it? A period of benign neglect in TRIPS might instead be encouraged. Benign neglect may be a logical outgrowth of increased South–South cooperation at the WTO. Developed countries face difficulty executing their TRIPS agendas there. The consequence is an effective multilateral stalemate.

We are not, however, in a period of benign neglect. We are in a period in which tremendous pressure is exerted at the bilateral and regional level for new and more restrictive rules that eliminate policy space in developing and developed countries. A presumed objective is to force the multilateral system to accommodate to a new reality or face the prospect of irrelevance. Benign neglect does not appear to be a constructive option. The question is whether preferable and viable alternatives will be proposed.