TRIPs Flexiblities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements

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Introduction

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") contains in-built flexibilities that can be used to ensure access to medicines in developing countries. These include: compulsory licensing; exceptions to the exclusive right conferred by a patent; the status of test data submitted for the purpose of obtaining regulatory approval; and parallel importation. Yet, despite recent calls from the UN Commission on Human Rights for its member countries to consider taking full advantage of TRIPs flexibilities in order to ensure access to the medicines needed to fight diseases such as HIV/AIDS,[1] developing countries have been slow to do so.

This article suggests two reasons why this is the case. The first is an absence of the institutional capacity and local technical expertise required to put TRIPs flexibilities into practice. The second is the effect of bilateral pressure, particularly when exerted through free trade agreements, the intellectual property provisions of which often go far beyond what is required by the TRIPs Agreement. This article argues that, in order to take full advantage of TRIPs flexibilities, developing countries should be given the freedom to introduce measures appropriate for local conditions. Technical assistance can help achieve this. But, although a significant amount of technical assistance has been made available already from a range of developed country and institutional donors, assistance given so far has not generally focused on the use of TRIPs flexibilities. Instead, donors have preferred to highlight the need to safeguard the interests of right holders through technical assistance designed to achieve improved IPR enforcement standards. The article argues that, for TRIPs flexibilities to be used effectively by developing countries to ensure access to medicines in the future, technical assistance needs to be appropriate for local conditions, while developed countries must avoid imposing TRIPs-plus constraints.

Compulsory licensing as a TRIPs flexibility

The TRIPs Agreement contains flexibilities in Art.31 which allow for the grant of a compulsory licence by a competent national authority in order to permit that national authority or a third party to manufacture a patented product without the authorisation of the right holder, in doing so creating a mechanism under which generic medicines can be made available at a lower cost than the equivalent patented products.[2] Grounds for the issuance of compulsory licences under Art.31 TRIPs are set out in very broad terms, allowing developing countries wide discretion over their use as a means of ensuring access to medicines.[3] But, although developing countries have substantial discretionary powers to grant compulsory licences in accordance with Art.31 TRIPs, use of this provision remains problematic,[4] not least because procedures for issuing compulsory licences remain complex to an extent that may go beyond the existing institutional capacities of developing countries.[5] Put simply, the use of TRIPs flexibilities in relation to compulsory licences requires not only a willingness to amend domestic legislation in developing countries, but also technical expertise and institutional capacity to understand the complexity of the TRIPs provisions concerned and to put those flexibilities into practice locally.

A specific example illustrates why technical assistance is needed to overcome the complexity of compulsory licensing arrangements. On the face of it, the second sentence of Art.31(b) TRIPs provides an important flexibility, namely that the requirement that "the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions", and that a compulsory licence may be granted if "such efforts have not been successful within a reasonable period of time" can be waived in the event of a "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". However, it is not necessarily straightforward for a developing country to determine the precise meaning of

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1 As reported in *ICTSD Bridges Weekly Trade News Digest*, April 20, 2005, available at: *www.ictsd.com/weekly/05-04-20/inbrief.htm#1* (visited May 3, 2005).

2 For a more detailed discussion of these provisions see Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: A Solution to the Access to Medicines Problem?" (2004) 7/1 *Journal of International Economic Law* 73 at p.76.

3 See also Brook K. Baker, *Processes and Issues for Improving Access to Utilise TRIPS Flexibilities in Non-Producing Countries* (DFID Health Systems Resource Centre, London, 2004), p.23.

4 See also S. F. Musungu, S. Villanueva and R. Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* (South Centre, 'South Perspectives' series, Geneva, 2004), p.xiii.

5 See also the statement from India's Affordable Medicines and Treatment Campaign, MSF, Lawyers Collective HIV/AIDS Unit and the Alternative Law Forum, reported in *The Lancet*: "India's New Patent Laws May Still Hurt Generic Drug Supplies", 365; 9468: April 16, 2005, available at *http://lists.essential.org/pipermail/ip-health/2005-April/007765.html* (visited April 18, 2005).

what constitutes the Art.31(b) requirement that use of a compulsory licence be only permitted "if, prior to such use, the proposed user has made efforts to obtain the authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". Nor is it necessarily easy for a developing country to know how to determine the "adequate remuneration" that the right holder must receive "taking into account the economic value of the authorisation" in each case, within the meaning of Art.31(h). Calculating the appropriate level of compensation payable to the right holder when compulsory licences are issued remains difficult for many developing countries.[6]

There are also concerns that developing countries will be reluctant to use compulsory licensing owing to the possibility that costly litigation will result should right holders seek recourse to judicial review or other independent review by a distinct higher authority in that WTO member under the provisions of Art.31(i).[7]

Uncertainty about the scope and applicability of Art.31 TRIPs may well help explain why, in practice, there are very few instances of developing countries using compulsory licences to ensure access to medicines. A rare example was the announcement, on September 21, 2004, that the Republic of Zambia's Ministry of Commerce, Trade and Industry had issued a compulsory licence in accordance with Art.31(b) TRIPs. The Zambian compulsory licence recognises that HIV/AIDS constitutes a national emergency and grants a compulsory licence to a local generic drug producer, Pharco Ltd, for the local manufacture of a triple compound of anti-retroviral drugs Lamivudine, Stavudine and Nevirapine for the treatment HIV/AIDS.[8] But, despite the recent Zambian initiative, elsewhere a lack of institutional capacity and an absence of the technical expertise needed to utilise TRIPs flexibilities may be constraining the wider use of compulsory licences by developing countries seeking to ensure access to medicines.

The Art.31(f) problem

While developing countries that possess local pharmaceutical manufacturing capacity have been reluctant to use compulsory licensing as a public policy instrument, developing countries with insufficient or no domestic pharmaceutical manufacturing capacity have been in an even more difficult situation. These countries were initially uncertain whether they were able to follow the strategy adopted by Zambia, even when a pandemic such as the HIV/AIDS virus was declared a "national emergency" within the meaning of Art.31(b). This uncertainty arose because Art.31(f) provides that any such use of compulsory licences must be "authorised predominantly for the supply of the domestic market" of the country authorising such use.[9] The wording of Art.31(f) raised concerns among developing countries that, following the end of transitional arrangements set out in Art.65(4) TRIPs on January 1, 2005, and the resultant extension of patent protection for pharmaceuticals in all but a few least-developed countries, developing countries with insufficient or no domestic pharmaceutical manufacturing capacity would be unable to import generic versions of essential medicines under compulsory licensing terms without breaching Art.31(f).

The Doha Declaration

In response to these concerns, the Doha Declaration on the TRIPS Agreement and Public Health[10] acknowledged, in para.5(b), the existence of flexibilities in the TRIPs Agreement with respect to the right to grant compulsory licences and that each WTO member has the freedom to determine the grounds on which such licences are granted. Paragraph 6 of the Declaration went on to recognise 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.[11]

The Doha Declaration set in train the process of negotiations that resulted in the WTO Decision on the Doha Declaration, the TRIPS Agreement and Public Health on August 30, 2003.[12] As a result, the flexibilities in relation to compulsory licensing for non-producing developing countries are now more clearly set out. Some developed countries, in particular Canada and Norway, have already put in place measures to implement the Decision by introducing legislation to allow the grant of compulsory licences for the manufacture and sale of patented pharmaceutical products intended for export to countries with insufficient or no manufacturing

6 Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (Commission on Intellectual Property Rights, London, 2002), p.149.

7 Comments made by Kevin Watkins, Head of Research, Oxfam, at the Conference Commemorating the 10th Anniversary of the TRIPs Agreement, hosted by the European Commission, DG Trade, on June 23–24, 2004. See *The TRIPS Agreement—Ten Years Later*: A Report of the Conference, p.53, available at *http://europa.eu.int/comm/trade/issues/sectoral/intell_property/pr110604_en.htm* (visited April 18, 2004).

8 Compulsory Licence No.CL01/2004 will expire as soon as the conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic come to an end in Zambia, or upon expiry of the period of emergency stipulated in Statutory Instrument No.83 of 2003, titled the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations of September 2, 2004. Statutory Instrument No.83 declared HIV/AIDS as an emergency for a period of five years, commencing in August 2004 and expiring in July 2009. Compulsory Licence No.CL 01/2004 is available at: *http://www.cptech.org/ip/health/c/zambia/zcl.html* (visited April 18, 2005).

9 On the meaning of "predominantly" see Frederick M. Abbott, "Compulsory Licensing for Public Health Needs: the TRIPS Agreement at the WTO after the Doha Declaration on Public Health", Quaker United Nations Office—Geneva, Occasional Paper 9 (2002).

10 The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, November 14, 2001, available at *www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm* (visited April 18, 2005).

11 Sandra Bartelt "Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health" (2003) 6/2 *Journal of World Intellectual Property* 283 at p.296; Matthews, n.1 above, at p.82.

12 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405, August 30, 2003, *www.wto.org/english/tratop_e/trips_e/implementation_para6_e.htm* (visited April 5, 2005).

capacity in the pharmaceutical sector, while the EU is in the process of doing so.[13]

But, for non-producing developing countries, the procedures set out in the August 30 Decision are still complex and administratively burdensome.[14] This may be an important reason why no developing country has yet used the new mechanism to allow the importation of generic medicines following the issuance of a compulsory licence in a developed country prior to patent expiry. A list of WTO members wishing to take advantage of the waivers contained in the WTO Decision of August 30, 2003 will apparently be made available on the WTO website as soon as a member country seeks recourse to the new procedure but, to date, no developing country has actually taken advantage of this opportunity.[15] Although still at an early stage, doubts remain about the extent that non-producing developing countries have the institutional capacity and technical expertise to take full advantage of WTO arrangements in favour of compulsory licences. This, in turn, lends further weight to the argument that there is a great need for technical assistance and capacity building initiatives to empower developing countries.

Remedying anti-competitive abuses

In fact, leaving aside the Art.31(f) problem, even before the long and detailed negotiations that began with the Doha Declaration and led to the August 30 Decision, little had been offered by way of technical assistance focused on other flexibilities in Art.31 TRIPs that can be used by non-producing developing countries seeking to use compulsory licences to ensure access to medicines. Article 31(k) TRIPs, for example, has always provided that the conditions set out in Art.31(b) and (f) (which, prior to the August 30 Decision, appeared to constrain the ability of non-producing developing countries to use compulsory licensing provisions) do not apply where measures are necessary to remedy anti-competitive patent abuses and the need to correct anti-competitive practices. But, despite the existence of Art.31(k) as an exception to the "predominantly for the supply of the domestic market" requirement of Art.31(f), there is no evidence that developing countries were made aware of the opportunities presented by this TRIPs flexibility to introduce legislation providing for the granting of compulsory licences on grounds of remedying anti-competitive abuses, such as excessive pricing, refusals to license or the denial of an essential facility.[16] The fact that Art.31(k) has not been used by developing countries is particularly surprising given that there is little evidence to support the argument that granting compulsory licences based on anti-competitive practices will discourage foreign direct investment, hinder transfer of technology or discourage research into neglected diseases.[17]

Exceptions to the exclusive right conferred by a patent as a TRIPs flexibility

Article 30 TRIPs provides a further flexibility, under which WTO members "may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". Examples of permissible exceptions to the exclusive rights that a patent shall confer on its owner under Art.30 TRIPs are experimental use, fair use and research exemptions. There have been suggestions that Art.30 could also provide a mechanism for producing countries to export medicines to non-producing developing countries, without having to use compulsory licensing measures at all.

In 2002, a joint letter to the WTO TRIPs Council from NGOs CPTech, Essential Action, MSF, Oxfam International, Health Gap Coalition and the Third World Network advocated the use of Art.30 TRIPs to ensure access to medicines in developing countries on grounds that it was the most direct, administratively simple and least contentious approach in that an activity falling within a Art.30 exception is not an infringement of the patent and did not need permission from the patent holder—or even notice to be given to the patent holder or compensation to the patent holder arranged, as under the Art.31 compulsory licensing provisions.[18] Similarly, submissions to the TRIPs Council by both the EC[19] and Brazil, on behalf of a group of developing countries,[20] endorsed a broad interpretation of Art.30 that would permit its use to meet the public health needs of developing countries that do not have the capacity to manufacture medicines locally.

In practice, however, Art.30 TRIPs has not been used as a limited exception for the exportation of medicines to non-producing developing countries. This is because there has been strong opposition from the US administration and the research-based pharmaceutical industry,[21] while the WTO Dispute Settlement Panel decision on ss.55.2(1) and (2) of the Canadian Patent Act[22] also created uncertainties by stressing the limited

13 Paul Vandoren and Patrick Ravillard, "A New EC Initiative to Allow Export of Medicines under Compulsory Licences to Poor Countries" (2005) 8/2 *Journal of World Intellectual Property* 103.

14 For explanations of procedural requirements set put in the August 30 Decision see Baker, n.3 above, at p.29, and Matthews, n.2 above, at p.95.

15 Notifications will be made available at *www.wto.org/english/tratop_e/trips_e/public_health_e.htm* (visited on April 16, 2005).

16 See also Baker, n.3 above, at p.26.

17 See *ibid.*, at p.27.

18 The full text of the joint letter from CPTech, Essential Action, MSF, Oxfam International, Health GAP Coalition, and the Third World Network to the WTO TRIPs Council of January 28, 2002 is available at *www.cptech.org/ip/health/art30exports.html* (visited May 8, 2005).

19 *Concept Paper Relating to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, Communication from the European Communities and their Member States to the TRIPs Council, IP/C/W/339, para.24.

20 *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, Communication received from the Permanent Mission of Bolivia, Brazil, Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/355.

21 See Baker, n.3 above, at p.27.

22 WTO Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS/114/R, adopted March 17, 2000.

nature of exceptions to exclusive rights conferred by a patent under Art.30.[23] But, despite continued opposition and the uncertainties surrounding the use of Art.30, it is regrettable that technical assistance has so far not even explored the potential for this TRIPs flexibility to be used to ensure access to medicines in developing countries.

Understanding why developing countries do not use TRIPs flexibilities

Of course, there may be good reasons why developing countries have not made use of TRIPs flexibilities to ensure access to medicines, having made an informed decision not to do so, but the UK Commission on Intellectual Property Rights is correct to point out that the availability of TRIPs flexibilities must be real and practicable for the countries most in need.[24] The suspicion is that those in charge of the legislative process in developing countries are simply unaware of the flexibilities available, or possess insufficient technical expertise to utilise those flexibilities. While developing countries receive technical assistance from a wide variety of national and international institutions, much of the emphasis on the part of providers of technical assistance is on raising intellectual property enforcement standards. Far less attention is being paid to technical assistance designed to assist developing countries in utilising TRIPs flexibilities.

Technical assistance from bilateral sources

At a bilateral level, most developed country initiatives undertaken by way of providing technical assistance fall within the remit of fulfilling obligations under Art.67 TRIPs.[25] Article 67 places an obligation on developed country WTO members to provide, on request and on mutually agreed terms and conditions, technical and financial co-operation in favour of developing and least-developed WTO members. The type of technical co-operation to be provided by the Art.67 mechanism includes assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights, as well as the prevention of their abuse, and support regarding the establishment or enforcement of domestic offices and agencies relevant to these matters, including the training of personnel.[26]

However, there are in-built limits to Art.67 that have important consequences for the quantity and quality of technical assistance provided. First, by requiring developing countries to request assistance from developed country WTO members, and by requiring the providers and recipients of technical assistance to mutually agree terms and conditions, there is a risk that Art.67 perpetuates a dependency culture, with developing countries required to ask developed countries for assistance in a manner that may be inappropriate locally. Those responsible for wider trade policy issues in developing country governments have tended not to favour relying on assistance from developed world sources, even if this would improve their own government's technical capacity with respect to TRIPs flexibilities. Secondly, by making explicit reference to the fact that technical co-operation under Art.67 "shall include" the provision of assistance associated with the protection and enforcement of intellectual rights,[27] Art.67 fails to place an explicit obligation on developed nations to assist developing countries in utilising TRIPs flexibilities such as those in relation to compulsory licensing that could help to ensure access to medicines. As a result, developed countries have largely limited their technical assistance activities to protection and enforcement activities.

A closer examination of the US IPR Training Coordination Group, which provides a mechanism through which the United States aims to fulfil its technical assistance obligations under Art.67 TRIPs, illustrates this point. The IPR Training Coordination Group, comprising government agencies and industry associations representing right holders[28] aims to provide information, training and technical assistance to foreign officials and policy makers. As such, the US IPR Training Coordination Group has two characteristics. The first is a focus on activities designed to enhance implementation and enforcement procedures in developing countries, paying little regard to wider issues of how best developing countries can utilise TRIPs flexibilities. The second is a high profile for private sector organisations representing right holders, with a vested interest in ensuring high standards of IPR enforcement, which are consequently likely to emphasise a narrow focus on compliance with Art.67 TRIPs provisions rather than engaging with the wider agenda of public health imperatives and focusing on how best to ensure access to medicines

23 For a discussion, see Matthews, n.2 above, at p.91.

24 Commission on Intellectual Property Rights, n.6 above, at p.160.

25 See also Kirsten M. Koepsel, "How Do Developed Countries Meet their Obligations under Article 67 of the TRIPS Agreement?" (2004) 44/2 *IDEA: The Journal of Law and Technology* 167.

26 Information on the technical and financial co-operation programmes provided by developed country members and intergovernmental organisations under Art.67 TRIPs can be found on the WTO website at *www.wto.org/english/tratop_e/trips_e/intel9_e.htm* (visited May 3, 2005).

27 See also Musungu *et al.*, n.4 above, at p.24.

28 The following departments and agencies of the US Government are represented in the IPR Training Coordination Group: US Department of State; US Department of Commerce (International Trade Administration and Commercial Law Development); US Department of Justice (Office of Overseas Prosecutorial Development Assistance & Training Criminal Division and the Computer Crime and Intellectual Property Section, Criminal Division); the US Department of Homeland Security (Bureau of Customs & Border Protection); the Federal Bureau of Investigation; the US Agency for International Development; the Office of the US Trade Representative; the US Patent and Trademark Office; and the Copyright Office of the Library of Congress. In addition, the following private sector organisations are also represented in the Group: the Coalition for Intellectual Property Rights ("CIPR"); the Interactive Digital Software Association ("IDSA"); the International Anti-Counterfeiting Coalition ("IACC"), the International Intellectual Property Institute ("IIPI") and the Pharmaceutical Research & Manufacturers of America ("PhRMA"). See Intellectual Property Rights Training Database, sponsored by the Bureau of Economic and Business Affairs of the US Department of State, at *www.training.ipr.gov/index.cfm?fuseaction=content.about* (visited April 17, 2005).

in developing countries through compulsory licences. NGOs and academics with the knowledge and expertise to redress the balance by highlighting the scope for TRIPs flexibilities alongside issues of protection and enforcement of intellectual property rights are excluded from the US IPR Training Coordination Group altogether and, even though the UK Commission on Intellectual Property Rights has cautioned against policy decisions on intellectual property in developing countries being influenced principally by domestic industrial and commercial interest groups in the developed world,[29] this appears to be exactly what has happened in the case of the US IPR Training Coordination Group.[30]

So, at a bilateral level, the reality is that technical assistance tends to emphasise intellectual property protection and enforcement objectives that are priority areas for foreign right holders operating in developing countries and, while developed countries are quick to provide assistance and to give examples of best practice on how to protect intellectual property rights, they rarely offer technical assistance on how best to use TRIPs flexibilities such as those on compulsory licensing.[31] Emphasising protection and enforcement as priority areas has simply had the effect of downgrading the need for assistance designed to ensure that developing countries make appropriate use of TRIPs flexibilities.

Technical assistance from multilateral sources

In addition to the bilateral technical assistance initiatives provided under Art.67 TRIPs, a number of multilateral organisations also have either a specific or a non-specific mandate in the area of intellectual property technical assistance. These organisations include: the World Intellectual Property Organization ("WIPO"); the World Bank; the United Nations Development Programme ("UNDP"); and the United Nations Conference on Trade and Development ("UNCTAD").[32] The type of technical assistance provided by these multilateral institutions includes: general and specialised training; legal advice and assistance with preparing draft laws; support for modernising intellectual property administration offices and collective management systems; access to patent information services (including search and examination); exchange of information among lawmakers and judges; and the promotion of local innovation and creativity.[33]

By far the largest provider of multilateral technical assistance is WIPO,[34] the role of which is formalised by the WTO-WIPO Cooperation Agreement which provides for enhanced co-operation between the International Bureau and the WTO Secretariat in their legal-technical assistance and technical co-operation activities relating to the TRIPs Agreement for developing countries, so as to maximise the usefulness of those activities and ensure their mutually supportive nature.[35] WIPO's website is at pains to point out that, in providing assistance to developing countries, it takes into account all flexibilities that are available under the TRIPs Agreement including those confirmed in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001 ("the Doha Ministerial Declaration") and that, furthermore, WIPO's advice takes into account the unique situation of each country, given that Member States have different legal systems and different political and cultural structures.[36]

But, despite WIPO's own assertions, it remains a multilateral organisation with an explicit mandate to promote intellectual property protection, with Art.3(i) of the Convention Establishing the World Intellectual Property Organization setting out that an objective of WIPO is to "promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization" and, in order to obtain this objective, Art.4(i) of the WIPO Convention then provides that the organisation "shall promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field". It is in this context that Art.4(v) of the WIPO Convention envisages that the organisation "shall offer its cooperation to States requesting legal-technical assistance in the field of intellectual property".[37]

WIPO is, of course, a relatively rich organisation financially and, since about 90 per cent of its funding comes not from member governments but from the private sector in the form of fees paid by patent applicants made under the Patent Cooperation Treaty ("PCT"), it has the resources to undertake a range of technical assistance projects in developing countries that are far in excess of anything offered either bilaterally or by other multilateral organisations in this field.[38] But, with its resources derived principally from right holders,

29 Commission on Intellectual Property Rights, n.6 above, at p.163.

30 See also Elena Ghanotakis, "How the U.S. Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries" (2004) 7/4 *Journal of World Intellectual Property* 563.

31 A view corroborated by Musungu *et al.*, n.4 above, at p.25.

32 See also Christopher May, "Capacity Building and the (Re)production of Intellectual Property Rights" (2004) 25/5 *Third World Quarterly*; and Tom Pengelly, "Technical Assistance for the Formulation and Implementation of Intellectual Property Policy in Developing Countries and Transition Economies", Geneva: ICTSD Programme on IPRs and Sustainable Development, Issue Paper No.11 (2004), p.8.

33 See also Commission on Intellectual Property Rights, n.6 above, at p.149.

34 See *ibid.*, at p.160.

35 Art.4(2), Agreement Between the World Intellectual Property Organization and the World Trade Organization, December 22, 1995, available at *www.wto.org/english/tratop_e/trips_e/wtowip_e.htm* (visited April 18, 2005).

36 Legislative Assistance Provided by the World Intellectual Property Organization (WIPO) in Relation to the Implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) and the Doha Declaration, *www.wipo.int/cfdiplaw/en/trips/index.htm* (visited March 15, 2005).

37 *www.wipo.int/treaties/en/convention/trtdocs_wo029.html #P68_3059* (visited March 11, 2005).

38 Commission on Intellectual Property Rights, n.6 above, at p.157.

WIPO has been characterised as a firm advocate of stronger intellectual property protection in developing countries,[39] as characterised by the now infamous publication *Intellectual Property—Power Tool for Economic Growth*, still available on the WIPO website, which maintains that arguments that patents are incompatible with economic objectives in the developing nations are "pernicious myths".[40] As such, WIPO would appear to have a pre-determined agenda in terms of the type of technical assistance that it provides. The UK Commission on Intellectual Property Rights has rightly raised concerns about whether the assistance provided by WIPO, through its model laws and the nature of the technical assistance that it provides, has always been appropriately tailored to the circumstances of developing countries.[41]

As Cambodia was preparing to join the WTO, for instance, the NGO Médecins Sans Frontières ("MSF") found, in March 2002, that the draft patent law submitted by WIPO to the government did not take account of TRIPs flexibilities, that WIPO had not informed Cambodia of the existence of the Doha Declaration on the TRIPS Agreement and Public Health, and that the government had not been made aware that, as a least-developed country, it was not required to grant or enforce patents for pharmaceutical products until 2016.[42] Similar concerns were raised at a meeting to consider how to achieve appropriate technical assistance in relation to the TRIPs Agreement and public health, organised jointly by MSF, the Consumer Project on Technology ("CPTech"), Oxfam International and Health Alliance International ("HAI"), where participants reported that WIPO's mandate to strengthen intellectual property protection worldwide may not be consistent with the need for more nuanced levels of intellectual property protection to take into account varying stages of economic development and local conditions in developing countries.[43]

Against this background, there have been calls recently for WIPO to become more sensitive to the health needs of people in developing countries, to ensure that the technical assistance provided fully reflects the provisions of the Doha Declaration on TRIPS and Public Health and that all available options are presented to safeguard the best public health interests of the population and, in particular, to ensure access to essential medicines for all.[44] Discussions on the establishment of a Development Agenda for the WIPO should, therefore, make the provision of appropriate technical assistance a priority.

The impact of TRIPs-plus regional and bilateral free trade agreements

But, even if sufficient quantities of appropriate technical assistance are available, bilateral pressures also limit the scope for developing countries to make effective use of TRIPs flexibilities. Frequently driven by the interests of research-based pharmaceutical companies in developed countries,[45] these bilateral pressures take the form of threats to withhold trade concessions where the intellectual property regimes of developing countries are deemed not to meet the expectations of developed country governments,[46] and regional or bilateral free trade agreements. Free trade agreements are often asymmetric in the sense that they are made between developed and developing country nations that possess unequal bargaining power, and TRIPs-plus to the extent that they require developing countries to implement intellectual property provisions in excess of those required by the TRIPs Agreement.[47] The result is that developing countries are bargaining away TRIPs flexibilities and that new barriers to access to medicines are being raised.[48]

In the United States, negotiation of TRIPs-plus standards is explicitly mandated by the Trade Promotion Authority Act 2002, which grants the President of the United States fast-track authority to enter into and conclude trade negotiations with other countries. Among the negotiating objectives of the Act is ensuring that the provisions of any multilateral or bilateral agreement governing intellectual property rights entered into by the United States reflect a standard of protection similar to that found in US law.[49] But there is also a potential conflict of objectives in the Act, since the amended version of the same provision now also requires respect for the Doha Declaration on the TRIPS Agreement and Public Health[50] and, because the Doha Declaration explicitly acknowledges that a key flexibility contained in the TRIPs Agreement is the right of each WTO member to grant compulsory licences and the freedom to determine the grounds on which such licences are granted,[51] the United States has not surprisingly been

39 See, for instance, Sisule F. Musungu and Graham Dutfield, "Multilateral Agreements and a TRIPS-Plus World", Quaker United Nations Office, Geneva, TRIPs Issues Papers 3 (2003).

40 *www.wipo.int/about-wipo/en/dgo/abstract_ip_pub.htm* (visited March 15, 2005).

41 Commission on Intellectual Property Rights, n.6 above, at p.160.

42 Médecins Sans Frontières, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines* (2003), p.5.

43 *Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance—How to Get it Right*, organised by the MSF Campaign for Access to Essential Medicines, the Consumer Protect on Technology, Oxfam International and Health Action International, March 28, 2002, Geneva. Conference report available at *www.haiweb.org/campaign/access/ReportPostDoha.pdf* (visited on March 15, 2005).

44 Médecins Sans Frontières, Comments on WIPO Patent Agenda, February 15, 2005, available at *http://lists.essential.org/pipermail/ip-health/2002-February/002690.html* (visited April 19, 2005).

45 See also Baker, n.3 above, at p.7.

46 See also Commission on Intellectual Property Rights, n.6 above, at p.162.

47 See also Peter Drahos, "BITS and BIPS. Bilateralism in Intellectual Property" (2001) 4/6 *Journal of World Intellectual Property* 786 at p.799; and Anthony D. So, "A Fair Deal for the Future: Flexibilities under TRIPS" (2004) 82/11 *Bulletin of the World Health Organization* 813.

48 See also Baker, n.3 above, at p.8.

49 19 U.S.C. 3802 Sec.2102 (b)(4)(A)(i)(II). Full text available at *www.bilaterals.org/article.php3?id_article=151* (visited April 18, 2005).

50 19 U.S.C. 3802 Sec.2101 (b)(4)(C), ibid., at p.27.

51 Art.5(b) of the Doha Declaration on the TRIPS Agreement and Public Health, November 14, 2001, available at

criticised for not achieving a single provision in bilateral trade agreements that respects the Doha Declaration.[52]

Limiting TRIPs flexibilities through data exclusivity

A particular feature of recent US trade policy has been an enthusiasm for data exclusivity provisions in regional and bilateral trade agreements. These provisions generally prevent, for a period of at least five years, generic drug manufacturers from using the first producer's data submitted for regulatory approval to establish the safety and efficacy of a bioequivalent medicinal product. This goes beyond what is required under Art.39.3 TRIPs, which deals with the protection of data submitted for the purposes of obtaining regulatory approval to market a product. Despite assertions to the contrary,[53] Art.39.3 is narrowly drawn and allows developing countries substantial flexibilities in implementation.[54] In particular, Art.39.3 requires the protection of undisclosed test data from unfair commercial use and but does not explicitly require a period of data exclusivity.[55]

TRIPs-plus data exclusivity provisions in US regional and bilateral free trade agreements have the potential to severely constrain the ability of developing countries to use TRIPs flexibilities because such provisions can prohibit access to essential medicines by delaying significantly the registration of a generic drug, even if a compulsory licence is issued,[56] because generic manufacturers will not be able to rely on data submitted by the original applicant for regulatory approval of the second-comer drug. In addition, there is a risk that, if generic companies are not able to rely on drug approvals based on the brand-name data, the financial incentives may be insufficient for them to meet the demand created by compulsory licences at all.[57] Data exclusivity provisions first entered regional international law in Art.1711 of the North American Free Trade Agreement of 1992 ("NAFTA")[58] and are now also contained in the US–Central America Free Trade Agreement ("CAFTA")[59] and in US bilateral trade agreements with Australia, Bahrain, Chile,[60] Jordan, Morocco and Singapore.

Although the Office of the US Trade Representative ("USTR") argues that including data exclusivity provisions in bilateral agreements is simply an opportunity to clarify Art.39.3 TRIPs as the United States understands it, elsewhere, it is generally considered unfair that developing country WTO members are put under pressure to adopt substantive TRIPs-plus standards that are not adapted to their level of development.[61] In the words of former EU Trade Commissioner Pascal Lamy, "flexibility should not be taken away through the back door".[62]

Limiting TRIPs flexibilities by restricting parallel importation

Some US regional and bilateral trade agreements have also denied developing countries the opportunity to use TRIPs flexibilities in the form of parallel importation. Parallel trade, which occurs when national law allows importation, without the authorisation of the patent holder, of a product sold more cheaply in another market,[63] is permitted under Art.6 TRIPs, which provides that "nothing in the Agreement shall be used to address the issue of the exhaustion of intellectual property rights". Although most developed countries have placed restrictions on parallel importation of medicines,[64] by permitting intellectual property rights to be internationally exhausted on first sale, developing countries can allow parallel importation and, in doing so, retain the flexibility to source patented medicines at the lowest price. The potential for WTO members to operate a regime of international exhaustion in this way was confirmed by Art.5(d) of the Doha Declaration

www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (visited April 18, 2005).

52 On February 16, 2005, for instance, Senator Edward Kennedy made a statement for the Senate Record on the meaning of the amendment to the Trade Promotion Authority Act of 2002 requiring the United States to respect the Doha Declaration on the TRIPS Agreement and Public Health in all trade negotiations The text of Senator Kennedy's statement is available at *http://lists.essential.org/pipermail/ip-health/2005-February/007498.html* (April 18, 2005).

53 See, for example, Ingo Meitinger, "Implementation of Test Data Protection According to Article 39.3 TRIPS. The Search for a Fair Interpretation of the Term 'Unfair Commercial Use'" (2005) 8/2 *Journal of World Intellectual Property* 132.

54 Carlos Maria Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (South Centre/WHO, 2002), available at *www.southcentre.org/publications/protection/protection.pdf* (visited April 27, 2005).

55 See also Karin Timmermans, "Intertwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals" (2005) 8/1 *Journal of World Intellectual Property* 67 at p.69.

56 "WOA Joins NGOs in Letter to US Trade Representative Robert Zoellick Regarding Access to Medicines and Trade Agreement Restrictions", the Washington Office on Africa, May 27, 2004, available at *www.woaafrica.org/AIDS77.htm* (visited July 20, 2004).

57 See also Baker, n.4 above, at p.6; and Robert Weissman, "Dying for Drugs: How Cafta Will Undermine Access to Essential Medicines", *Health Now*, March 2, 2004, available at *www.health-now.org/site/article.php?menuId=12&articleId=75* (visited April 18, 2005).

58 Jerome H. Reichman, "Undisclosed Clinical Trial Data Under the TRIPS Agreement and its Progeny: A Broader Perspective", UNCTAD-ICTSD Dialogue on *Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning*, Bellagio, November 29, to December 3, 2004 at p.4. Available at *www.iprsonline.org/ictsd/bellagio/docs/Reichman_Bellagio4.pdf* (visited April 27, 2005).

59 The following Central American countries became signatories to the US–CAFTA Free Trade Agreement in May 2004: Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua.

60 See Pedro Roffe, "Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement", Quaker International Affairs Programme, TRIPS Issues Papers 4 (2004), p.25. Available at *www.intech.unu.edu/events/seminar_series/2005_5_issuepapers.pdf* (visited April 27, 2005).

61 For example, see Commission on Intellectual Property Rights, n.6 above, at p.162.

62 Comments made by Pascal Lamy at the Conference Commemorating the 10th Anniversary of the TRIPS Agreement, see n.7 above.

63 See also Nick Gallus, "The Mystery of Pharmaceutical Parallel Trade and Developing Countries" (2004) 7/2 *Journal of World Intellectual Property* 169.

64 See also Baker, n.3 above, at p.21.

of November 14, 2001, which sets out that the "effect of the provisions of 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. . .".[65] But, by securing provisions in bilateral trade agreements with Australia, Morocco and Singapore that can be used to block parallel trade with both developed and developing nations, the United States has effectively closed off the possibility of using the Art.6 TRIPs flexibility for medicines sourced from these countries.[66]

Concluding remarks: the challenge for the future

Although the TRIPs Agreement contains important flexibilities that can help ensure access to medicines, many developing countries have failed to take advantage by incorporating appropriate provisions into national law.[67] One reason for this is lack of institutional capacity and technical expertise—a problem often compounded, not alleviated by, the provision of insufficient or inappropriate technical assistance from developed country and multilateral donors. Added to this is the burden of bilateral constraints, particularly when driven by US policy objectives, which undermine the opportunities for developing countries to utilise TRIPs flexibilities.

Enabling developing countries to act in their own interests is crucial and, to this end, a first step towards improving this situation should be ensuring that technical assistance donors provide advice that is appropriate for the needs of developing countries.[68] But a major problem is that there is so little information about the quality or appropriateness of the technical assistance currently available. Improving transparency through an enhanced role for the TRIPs Council in evaluating the quality of technical assistance programmes would help to overcome this information deficiency,[69] while greater involvement of NGOs and experts in technical assistance initiatives would also act as an important counterbalance to the pro-right holder advice often provided by developed countries and multilateral organisations such as WIPO.[70] The World Health Organization ("WHO") may also be well placed to play a role in providing balanced policy advice so that the overall impact of a range of technical assistance advice can take account of TRIPs flexibilities.[71]

Further potential to enhance the quality of technical assistance lies with the prospect of enhanced South–South regional or bilateral co-operation, with developing countries breaking their dependency on advice provided by developed nations and instead drawing upon each other's experience,[72] sharing information on how to use compulsory licensing provisions to ensure access to medicines. There have even been suggestions that joint compulsory licensing applications could also be made by a group of developing countries acting collaboratively, rather than on an individual basis.[73]

These are clearly options for the future but, for the present, the immediate challenge is to monitor the quality of technical assistance and to take stock regularly to ascertain what is required by way of appropriate technical assistance, tailored for local conditions, so that TRIPs flexibilities, particularly those capable of ensuring access to medicines in developing countries, are fully utilised.

65 Full text of the Doha Declaration available at *www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm* (visited May 8, 2005).

66 See also Senator Edward Kennedy, n.52 above, and The Doha Declaration, n.10 above *www.bilaterals.org* (visited May 8, 2005).

67 See also Musungu *et al.*, n.4 above, at p.24.

68 See also Commission on Intellectual Property Rights, n.6 above, at p.156.

69 See also comments made by Elizabeth Ponsolle de Portes, CEO of Comité Colbert, France at the Conference Commemorating the 10th Anniversary of the TRIPS Agreement, see n.7 above, at p.30.

70 See also Pengelly, n.32 above, at p.8; and Jerome H. Reichman, "Managing the Challenge of a Globalised Intellectual Property Regime", ICTSD-UNCTAD. Paper prepared for the Second Bellagio Series of Dialogues, September 18–21, 2003.

71 See also Commission on Intellectual Property Rights, n.6 above, at p.139.

72 See also Musungu *et al.*, n.4 above, at p.24.

73 Baker, n.3 above, at p.8.