

TECHNOLOGY POLICY ISSUES AT THE WTO

INTRODUCTION

UNU/INTECH Technology Policy Briefs aim to be an information and analysis resource for policy-makers, and those involved in policy debates, in developing countries. We seek to provide an overview of issues in key problem areas, with analysis, information and guides to research on central topics in technology policy for development. This first Brief focuses on technology policy issues at the World Trade Organisation (WTO), looking in particular at the debates and outcomes of the Doha ministerial meeting in November 2001. Included is an article by Ram Reddy on "WTO Declaration on TRIPS: What Does It Mean to Developing Countries?" (Page 2) followed by general comments by the Permanent Mission of Venezuela to the WTO (Page 5). Interesting results have been found in recent analysis in "Who Gains from TRIPS?" (Page 6) and commentary in "An NGO Perspective on the Declaration on TRIPS – A View From Oxfam" (Page 9). Finally, this Brief is rounded out with a book review entitled "TRIPS – A Guide for Policymakers" (Page 10). Topics for future issues are found at the end of this Brief.

Although many see the WTO as an organisation concerned only with the "rules of the game" in international trade, its agreements often have implications for technology policy actions by member countries. The most visible technology-relevant WTO Agreement is TRIPS (Trade-Related Aspects of Intellectual Property Rights). But there are many other technology-relevant dimensions of the WTO. The Agreement on Technical Barriers to Trade, for example, seeks to ensure that regulations, standards, testing and certification procedures do not create needless obstacles. But this can raise difficult information and certification issues for developing countries. Similarly, sanitary and phyto-sanitary standards for food quality can often imply difficult technological problems in reaching compliance – these are areas where the agricultural negotiations intersect with technology issues. The relationship between trade and transfer of technology is another important technology policy issue at the WTO, and the Doha ministerial meeting established a Working Group to examine this issue.

Within the TRIPS Agreement, most attention has focussed on the alterations to patent law and practice, but there are other many articles that have the potential to shape technology policy measures. These include copyright, IPRs for trademarks and geographical indications, registration of industrial designs, integrated circuit layouts and protection of trade secrets; later Briefs will address these issues. TRIPS made a major change in the patenting arrangements by changing the definition of what is patentable. The Agreement stipulates that "patents shall be available for any inventions, whether products or processes, in all fields of technology". The most important area affected by this change is pharmaceutical drugs. Nevertheless it remains possible for countries to allow exceptions to this measure on *ordre public* grounds, and this has remained an issue of controversy. It was in the forefront at Doha. Our contributors turn to the outcomes and implications of the debate.

WTO DECLARATION ON TRIPS: WHAT DOES IT MEAN FOR DEVELOPING COUNTRIES?

Rammanohar Reddy is a distinguished newspaper editor who has followed WTO developments closely for some years. He was in Doha, and writes:

The debate in Doha focused on public health. The main outcome, the 2001 Declaration on TRIPS and Public Health (DTPH), clarifies the extent of flexibility available in the 1994 TRIPS Agreement to protect public health by facilitating the provision of patented drugs at low cost. The Declaration, issued at the fourth ministerial conference of the WTO in Doha, Qatar, does not rewrite TRIPS. It is also restricted to the issue of patents in so far as they have an impact on public health, while the larger TRIPS Agreement covers all patents, copyrights, trademarks, geographical indications and other forms of Intellectual Property Right (IPR) protection. Also, since the DTPH is a political declaration, the legal value of its provisions will be known only, if and when, it is contested at the Dispute Settlement Body of the WTO.

However, the DTPH is significant because, first, it clarifies where IPR protection stands in relation to government measures to protect public health. Second, the WTO statement ends certain ambiguities in the TRIPS Agreement by delineating how and when countries can override patents for addressing public health concerns. Third, the declaration modifies one clause of TRIPS relating to the transition period available to the Least Developed Countries (LDCs). Fourth, there is a commitment to further discuss the particular issue of how to enable countries with limited manufacturing capacities to use the flexibility in TRIPS that have now been delineated. And, finally, it makes statements of intention regarding transfer of technology.

■ IPRs and Public Health

The issue of how much flexibility there is in TRIPS, and whether or not it contains a balance between the producers of intellectual property and its users goes back many years. The immediate background to the adoption of the Declaration

followed the feeling among a number of developing countries that the high prices of patented medicines that were used for anti-retroviral therapy were standing in the way of their ability to tackle the HIV/AIDS epidemic. While recognising the importance of IPRs for development of new medicines, the DTPH, first of all, recognises that patents do have an impact on prices and, second, that the TRIPS Agreement "does not and should not prevent" WTO members from taking measures to protect public health.

Articles 7 and 8 of the TRIPS Agreement, which list the Objectives and Principles, do recognise the freedom of countries to adopt measures to protect public health. In that sense, the new WTO Declaration does not give countries any new freedom or additional flexibility in implementing TRIPS. However, what it does do is state that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all". Such explicit mention of implementation in the context of public health concerns is not contained in the TRIPS Agreement.

The DTPH is also explicit in stating that the Declaration does not apply only to public health concerns like HIV/AIDS and such pandemics. Besides HIV/AIDS, the Declaration refers to public health problems resulting from "tuberculosis, malaria and other epidemics". Policy-makers should be able to interpret this as the ability of governments to implement TRIPS with flexibility in situations other than crises and emergencies.

■ TRIPS and Compulsory Licences

Article 31 of the 1994 TRIPS Agreement covers "Other Use Without Authorisation of the Right Holder", some clauses of which were understood to refer to the issue of compulsory licences by governments to third parties to increase availability or reduce prices of the patented medicines. Compulsory licences are generally seen as an important tool to check anti-competitive

practices of the holders of IPRs. However, there were in the first instance, two sets of ambiguities in the Agreement. The term Compulsory Licence (CL) was not mentioned in Article 31 (or anywhere in the TRIPS Agreement), nor were the grounds for issue of CLs outlined in the treaty. This raised the possibility that the issue of CLs by any developing country government for production of a drug under patent would be contested by the government of the patent holder at the WTO.

The DTPH now explicitly states that "Each Member has the right to grant compulsory licences". This removes one ambiguity. The new Declaration also affirms that the countries have the freedom to decide the grounds, which warrant issue of a CL. For the policy-maker these are extremely important clarifications of the TRIPS Agreement. They mean that governments can incorporate in their legislation all the public health situations when they would need to consider the issue of a CL for expanding access to patented medicines at a reasonable cost, in case these drugs are either in short supply or priced very high.

Another important clarification for policy-makers is about what constitutes a "national emergency or other circumstances of extreme urgency" when, under the TRIPS Agreement, a CL can be issued even without making efforts to obtain authorisation from the patent holder. While the 1994 treaty did not define such emergencies, the decision at Doha states that, here as well, governments have the right to decide what constitutes such an emergency. It also states that public health crises like HIV/AIDS, tuberculosis and malaria are examples of such emergency situations.

In practical terms, these two affirmations in the 2001 Declaration mean that developing countries, to meet their public health concerns, can issue CLs to those pharmaceutical companies who can supply generic versions of patented drugs at low prices.

Parallel Imports

Another important ambiguity in the TRIPS Agreement related to "exhaustion of rights", which can directly impact on the freedom of countries to import the patented drugs at the best possible price without the authorisation of the patent holder. Since drug companies usually charge different prices

for their products (patented and non-patented) in different national markets, governments should be able to import drugs from the market where they are sold at the lowest prices. They should be able to do so even if the patent holder is producing/ selling the drug locally. The ability of governments to arrange for such "parallel imports" could in some situations serve as a check on anti-competitive practices. This, however, depends on whether or not the right of the patent holder has been "exhausted" when the medicine under IPR protection is first sold in a market, an issue that has been subject to various interpretations in the reading of the TRIPS Agreement. According to Article 6 of the TRIPS Agreement, signatories were, under certain conditions, protected from being taken to the WTO's Dispute Settlement Body if they exercised their rights on exhaustion. However, there was no explicit reference to "parallel imports" in the TRIPS Agreement nor did Article 6 speak of "domestic" and "international" exhaustion.

The DTPH has clarified that countries are "free" to establish rules and procedures for exhaustion and that this will not be challenged by other WTO members, as long as the regime respects in the Most-Favoured Nation (MFN) and national treatment provisions of the TRIPS Agreement. This political reaffirmation of the rights conferred by Article 6 means that, in practice, governments can, if they want to, arrange for parallel imports of patented medicines without worrying about the decision being contested at the WTO.

Extension of the Implementation Period for LDCs

In the 1994 TRIPS Agreement, the LDCs were given a transition period up to January 2006 to bring their national laws into conformity with the clauses of the treaty that deal with patents. The DTPH extends this implementation period for another decade, up to 2016. This, in effect, gives these countries more freedom on IPRs.

Countries without Manufacturing Capacities

A CL is a useful tool to check anticompetitive practices if governments can arrange alternative sources of supply of a drug granted a patent in their market, through domestic production or imports. Countries with well-developed manufacturing capacities in pharmaceuticals - like Brazil, India and Argentina - can, if they need to, issue CLs to generic producers to augment supply at low cost. Countries, which do not have such manufacturing capacities, will naturally not be able to use a CL to produce generic variants of the patented drug. The question is if such countries can import a generic version from another country, which has a developed pharmaceutical industry, where a CL may have, been issued to produce the pharmaceutical product at low cost. The problem is that Article 31(f) of the TRIPS Agreement states that "any such use (i.e. CL) shall be authorised predominantly for the supply of the domestic market of the Member authorising such use". This means that generic drug producers in, say, India, can export the product to a country which does not have sufficient manufacturing capacities only if consumption within India is more than 50 per cent of production. This also means country-specific requirements cannot be met by generic producers in third countries. For governments of countries, which do not have a well-developed industry, Article 31(f) is in effect a binding constraint on the use of CLs to control anti-competitive practices. A related issue – on which there is a lack of clarity in the TRIPS Agreement - is if the government of one country can issue a CL to a producer in another country, which could be of importance to countries with an undeveloped pharmaceutical industry.

The new affirmation of the flexibility in TRIPS does not therefore have any operational content for countries with insufficient or no manufacturing capacities. Proposals were made before and at Doha to get round this problem by giving such countries the right to import all or the predominant part of such production from generic manufacturers by recourse to the provisions of Article 30 of the TRIPS Agreement, which covers "Exceptions to Rights Conferred" on the patent holder. However, the DTPH did not sanction such a right.

What the Declaration has done is only to recognise the problem and instruct the TRIPS Council "to find an expeditious solution and to report back to the General Council before the end of 2002". There is no guarantee that a satisfactory solution will be found or that it will be found quickly. This is one important limitation of the 2001 Declaration which could seriously impact on the ability of some governments – likely to be of small or very poor countries – from effectively using the tool of compulsory licensing.

Technology Transfer

While the TRIPS Agreement is understood to be one that protects the rights of the holders of IPRs, the objectives and principles of the Agreement, as contained in Articles 7 and 8, have other aims as well. For instance, protection and enforcement of IPRs, according to Article 7, "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology". While transfer of technology is an integral part of the TRIPS Agreement, in practice, the discussions at the WTO since the Agreement began to come in to force on 1 January 1995 has entirely been on the obligation of member-countries to enforce the rights of the holders of IPRs. The objective of technology transfer has been lost sight of.

The DTPH makes two statements of intent in this respect. First, it states that all provisions of the TRIPS Agreement "shall be read in the light of the objects and purpose of the Agreement" which are expressed in Articles 7 and 8. This will mean placing technology transfer, among other issues, more squarely in the centre of implementation of TRIPS. But there is no concrete direction in this respect. Second, with reference to the least developed countries, the 2001 Declaration refers to Article 66.2 of the TRIPS Agreement according to which "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members". However, here again there is no operational content to this direction.

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GENERAL COMMENTS ON THE "WTO DECLARATION ON TRIPS: WHAT DOES IT MEAN FOR DEVELOPING COUNTRIES?"

We invited comments, and a Latin American perspective, on Ram Reddy's account of the WTO Declaration on TRIPS from the Permanent Mission of Venezuela to the WTO. Ms Virginia Perez and colleagues wrote the comments below; they reflect their personal positions, and should not be taken as representing official Venezuelan positions. Nevertheless the comments indicate a high degree of accord with Dr. Reddy's analysis: differences among the countries of the South may be more apparent than real when it comes to TRIPs.

A basic comment was that "The political value of the Declaration is that is has had a clear impact on international public opinion. The fourth paragraph of the Declaration should be taken to read that nothing should prevent countries protecting public health. This will also reduce uncertainty for countries when making use of the flexibilities of the Agreement. For future studies, it would be interesting to highlight other articles of TRIPS relating to technology transfer and issues". Some specific comments are summarized below:

Points by Ram Reddy

"The declaration, issued at the fourth ministerial conference of the World Trade Organisation in Doha, Qatar, does not re-write TRIPS."

"Another important clarification for policy-makers is about what constitutes a "national emergency or other circumstances of extreme urgency" when, under the TRIPS Agreement, a CL can be issued even without making efforts to obtain authorisation from the patent holder. While the 1994 Treaty did not define such emergencies, the decision at Doha states that, here as well, governments have the right to decide what constitutes such an emergency. It also states that public health crises like HIV/AIDS, tuberculosis and malaria are examples of such emergency situations."

"Extension of the Implementation Period for LDCs: In the 1994 TRIPS Agreement, the LDCs were given a transition period up to January 2006 to bring their national laws into conformity with the clauses of the treaty that deal with patents. The DTPH extends this implementation period for another decade, up to 2016. This, in effect, gives these countries more freedom on IPRs."

"TRIPS and Compulsory Licences"

"Technology Transfer"

Comments by the Permanent Mission of Venezuela to WTO

It confirms the flexibility and reduces external pressures to interpret and apply the Agreement at the national level.

Here it is convenient to highlight that there remains no clear definition of what is a "national emergency or other circumstances of extreme urgency". This would have been very negative for developing countries because it would have limited the scope for action. However, the Declaration widens the scope of what could be an emergency or extreme urgency. There was an explicit reference that illnesses different to HIV-AIDS may constitute a national emergency.

With this extension LDCs does not necessarily achieve more freedom on IPRs, but just a temporal extension in order to improve the observance of the Agreement (...) The ultimate goal of WTO in general remains unchanged.

The Declaration left an unresolved task regarding countries with low production capacity to effectively make use of these licences. This is a pending issue that goes beyond the confirmation of export capacity of some countries (...) The problem is more related to imports.

The observance of IPRs, in the absence of technology-related development policies, is widening the development gap. Developing countries have been constrained to apply policies that help them to transform their productive apparatus with the hope of being capable of benefiting from trade. Notwithstanding TRIPS Article 7, the right possibilities have not been put in place for attracting foreign investment in R & D. Furthermore, developed countries have not yet taken advantage of the flexibility offered by TRIPS with regards to technology transfer. These possibilities have yet to be operationalised.

WHO GAINS FROM TRIPS?

Many developing countries believe that a strict enforcement of all the provisions of TRIPS would yield considerable rents to developed countries, based on a significant negative net transfer from the developing countries. But who really gains and who really loses? A recent analysis by Philip McCalman, of the University of California at Santa Cruz, has made possible a deeper understanding of the distribution of the direct gains and losses from TRIPS. McCalman estimated, using econometric methods, the present value of patents in 1988 (pre TRIPS) for a variety of developed

and developing countries, and the geographical structure of the payments that support those values. The World Bank (2001) has updated these using 1995 data. The results are presented in Figures A and B. Figure A shows that only nine developed countries would have positive net receipts if TRIPS were to be fully enforced. What is striking is that US alone would receive a net transfer greater than all other countries combined – about US \$19 billion per year. The US would be followed by Germany, Japan and France, countries which own substantial number of income-yielding patents abroad.

Figure A: Net Rent Transfers-Positive

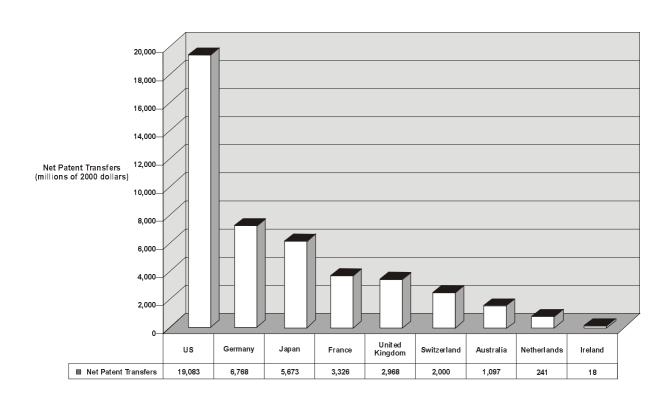
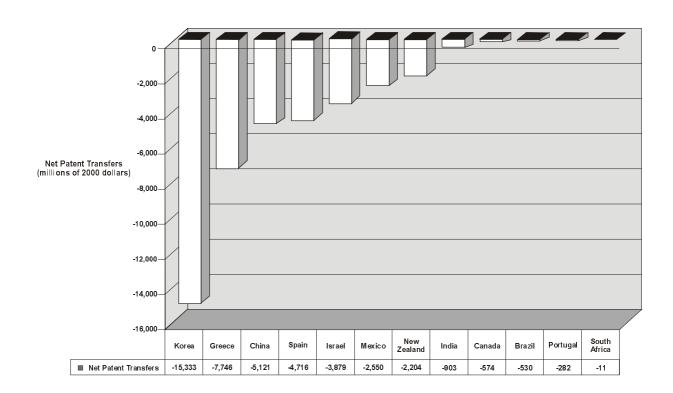


Figure B shows the net losers in terms of fee income. It is interesting to note that within this "negative list", there are both developing and developed countries. Canada is a notable member from the developed world in this category. The biggest loser is Korea with a large negative net transfer of US \$15 billion per year. This is particularly interesting since Korea is a large owner of patents: Korean inventors have managed to secure a substantial number of patents in the US, on an average of about 3000 patents per annum. But these patents are yet to be yielding actual royalties and this is

further indicated by the growing technology trade balance of Korea as it has increased from (-) \$1.3 billion in 1990 to (-) \$ 2.11 billion in 1998. On the contrary, if we were to relate the size of the net patent transfer of each of the losers to their respective Gross Domestic Product, the ranking is entirely different (Figure C) with Greece, Israel and New Zealand at the top with Brazil, India and South Africa at the bottom.

Figure B: Net Patent Transfers-Negative



It must, however, be borne in mind that these estimates are based on a number of restrictive assumptions, and the results should be taken only as broad trends. Nevertheless they go a long way towards reinforcing the arguments of developing countries with respect to the economic effects of TRIPS. But they undercut the idea that the impact of TRIPS can be seen purely in terms of an opposition between developed and developing countries.

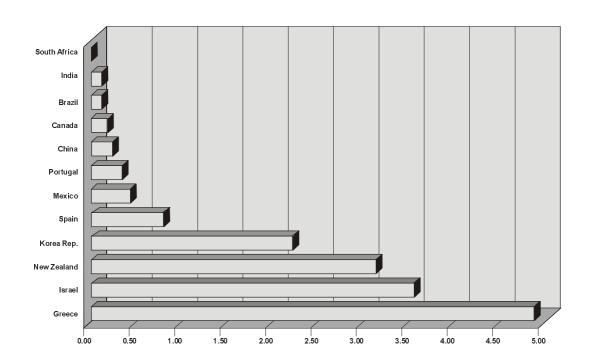
Sources:

Mc Calman, Phillip. 2001. Reaping What You Sow: An Empirical Analysis of International Patent Harmonization. *Journal of International Economics* 55:161-186.

World Bank. 2001. *Global Economic Prospects* 2002. Washington, DC: World Bank. 129-150.

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Figure C: Net Patent Transfers-Negative (as a per cent of GDP, PPP (Current International \$)



	Greece	Israel	New Zealand	Korea Rep.	Spain	Mexico	Portugal	China	Canada	Brazil	India	South Africa
Net Patent Transfers as a per cent of GDP (PPP, Current Prices)	4.77	3.45	3.03	2.08	0.66	0.32	0.18	0.11	0.07	0.04	0.04	0.00

AN NGO PERSPECTIVE ON THE DECLARATION ON TRIPS – THE VIEW FROM OXFAM

The Doha meeting attracted considerable attention from governments, NGOs and the press. How did NGOs view the outcome? Discussion and commentary focussed heavily on the TRIPS-related aspects of the meeting,

rather than the agricultural negotiations. One of the largest and most influential of these organizations is Oxfam, which reflected the widespread view that TRIPS was the key issue of the meeting, and commented as follows:

"The Doha declaration includes a separate declaration, which unambiguously reaffirms the primacy of public health concerns over patent rights in the TRIPS agreement. The fact that patents/medicines was by far biggest single issue at the Doha [meeting] is a huge achievement. It reinforces a political climate where it is hard for companies and governments to push countries around on patents. Countries can feel more confident in using safeguards and resisting 'TRIPS plus', i.e. bilateral or regional agreements imposing more stringent patenting rules.

The future challenges now are:

- to counter negative messages from selected governments (including the US, Canada and Switzerland) and the pharmaceutical industry, which are trying to downplay the political importance, and negate the legal value, of the declaration.
- to emphasize that the problem of TRIPS is far from being resolved. Next year's scheduled review must look at the basics of the problem, in particular the length and scope of pharmaceutical patenting in developing countries, and transition periods for the implementation of the agreement. Other problematic areas include the implementation of TRIPs in the agricultural sector in developing countries, as well as the mechanisms to make operational existing technology transfer provisions in the TRIPs agreement.
- to ensure that the 'expeditious solution' of the specific issue of compulsory licensing by countries without manufacturing capacity – which was not resolved at Doha – is done quickly and without restrictions or conditions."

Source:

Edited from the Oxfam commentary at http://www.oxfam.org/what_does/advocacy/papers/

TRIPS - A GUIDE FOR POLICYMAKERS

Watal, Jayashree. 2001. Intellectual Property Rights in the WTO and Developing Countries. The Hague/London/Boston: Kluwer Law International

Although many aspects of WTO rules have implications for technology development and policy, by far the most prominent has been the TRIPS Agreement. The provisions of TRIPS – what it covers, what it permits and excludes – are central constraints for technology policy formation in developing countries. So it has become essential, not just for negotiators, but also for technology policy-makers in a wide variety of fields, to have a working knowledge of the law and economics of TRIPS. This recently published book is the definitive guide for policy-makers to "the most wide ranging and far reaching international treaty on the subject of intellectual property". It is essential reading for those seeking a detailed analysis of TRIPS.

The headline-grabbing conflict around TRIPS has been related to product patenting in pharmaceuticals, and particularly AIDS drug treatments. But TRIPS goes far beyond this, and Watal's book reflects its breadth. There is of course a full treatment of patent protection, but the book also covers such topics as exclusive marketing rights, trade secrets (so-called "protection of undisclosed information"), copyright, trademarks and geographical indications, industrial design protection, and the specific protection of integrated circuit design. Each of these topics gets a full discussion.

If implemented in full, this array of agreements would immeasurably strengthen the protection of technologies emanating mainly from rich countries. But implementation of TRIPS is closely linked to interpretation. Watal argues that negotiation of the treaty was along opposed North-South lines, with a co-ordinated Northern position being pitched against fundamentally disunited South negotiators who nonetheless achieved much against considerable odds. A key point is that conflicts were often resolved by "constructive ambiguity", leaving scope for alternative

interpretations. Combined with the absence of an official negotiating record, and with lack of clarity in both drafting and implementation measures, the impact of TRIPS is by no means cut and dried. So, long after the signing of the agreement, there remain serious options and alternatives for policymakers in developing countries with respect to TRIPS.

These points lead naturally to two substantial chapters discussing limits to intellectual property protection in TRIPS, and future policy issues. Watal stresses the balancing effects of Articles 7 and 8 in TRIPS. The first of these Articles establishes the principle that TRIPS should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology" while being to the mutual advantage of producers and users. The second allows WTO signatories to take measures in the public interest, particularly with respect to nutrition and health. These limits have been the basis of decisions in Doha, discussed elsewhere in this Brief.

In Watal's interpretation, TRIPS is far from fixed and complete, and much remains for future negotiation. In part, TRIPS has a 'built-in agenda' for future discussions, including biotechnology inventions and the patenting of living organisms; important issues concerning agricultural biotechnology remain unresolved. Similarly there are unfinished discussions regarding geographical indications. Perhaps more important, and certainly more challenging for developing countries, is the question of IPR and technology issues in other WTO discussions – on trade and the environment for example, or on trade and investment. A key issue in the latter is whether "the definition of investment should include IPRs". Discussions on global electronic commerce will certainly incorporate IPR questions, as will those on competition policy. Future TRIPS revision is likely to include negotiations of patent law and procedure, on parallel trade, on compulsory licencing and on patent term extension. These are just the issues with respect to patenting. Other areas of TRIPS will raise issues concerning protection of test data, enforcement effectiveness, and technology transfer.

For developing countries, the WTO is not of course the only IPR-relevant forum, and it is not obvious that the WTO is the right place to fight out IPR issues. WIPO too is of great importance, and Watal concludes with a brief but excellent discussion of interactions between these agencies, and in particular the role of WIPO as a provider of detailed technical advice to developing countries. This covers interpretive issues around TRIPS, and specific legislative advice. But "WIPO will need to rise to the challenge of helping developing countries in interpreting TRIPS in ways that align with their national objectives", and this means more study of developed-country IPR practice, with economic analysis of implications for developing countries.

This is by no means the only good book available on TRIPS – works by Maskus* and Correa** should certainly be mentioned, and are each valuable to policy-makers – but it is a first rate "user's manual" that provides essential information for every trade or technology policy-maker across the developing world.

*Maskus, Keith. 2000. Intellectual Property Rights in the Global Economy. Washington, DC: Institute for International Economics. (Under translation to Spanish for publication by Oxford University Press, Mexico.)

** Correa, Carlos M. 2000. Intellectual Property Rights, the WTO and Developing Countries: The Trips Agreement and Policy Options. London, New York, and Penang: Zed Books.

Book Review by: Professor Keith Smith, UNU/INTECH smith@intech.unu.edu

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FUTURE

TECHNOLOGY POLICY BRIEFS

Future Technology Policy Briefs will address issues in agricultural biotechnology, health and biopharma, energy and environment, ICT and transnational corporations and innovation.

Future issues on the WTO will focus on: trade and technology transfer, and particularly the work of the WTO Working Party on this topic; the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement); and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement).

The next Brief will be published in March 2002 and will focus on agricultural biotechnology. Topics to be covered will include company strategies in agro-biotechnology, organisation of research in biotechnology, the biotechnology development programme in Ghana, and the dicussions on agricultural biotechnology at the World Social Forum which takes place at Porto Alegre, Brazil in February 2002.

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