

Intellectual Property, Bilateral Agreements and Sustainable Development:

A STRATEGY NOTE

Ellen ‘t Hoen

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ABOUT THE INTELLECTUAL PROPERTY, BILATERAL AGREEMENTS AND SUSTAINABLE DEVELOPMENT SERIES

This series was produced as part of a feasibility study funded by the MacArthur Foundation and the Rockefeller Foundation. As part of the study, CIEL commissioned four papers to provide guidance on the landscape of procedural and substantive challenges posed by bilateral and regional intellectual property negotiations. The four papers are:

"Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation", by Pedro Roffe. This paper examines the development of strategies for developing country officials, civil society organizations, and other stakeholders with respect to the implementation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper aims to raise awareness of the continuing pressure for higher intellectual property protection during the implementation and annual review of bilateral trade agreements, as well as to outline the opportunities created by the diverse options for implementation to "claw back" policy space.

"Intellectual Property, Bilateral Agreements and Sustainable Development: A Strategy Note", by Ellen 't Hoen. This paper examines strategic considerations for developing country officials, civil society groups, and other stakeholders with respect to upcoming challenges and opportunities in the negotiation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper uses the example of the access to medicines issue to provide tangible and realistic recommendations for the next steps that could be taken by civil society groups working on bilateral and regional intellectual property and sustainable development issues.

"**Intellectual Property, Bilateral Agreements and Sustainable Development: Intellectual Property in the US-Peru Trade Promotion Agreement", by Luis Alonso García**. This paper was written under the auspices of the Sociedad Peruana de Derecho Ambiental (SPDA). It examines a specific free trade agreement, the US-Peru Trade Promotion Agreement, as an example of the challenges and opportunities presented by such negotiations. The paper aims to provide lessons for developing countries and civil society organizations to consider in their future work.

"**Intellectual Property, Bilateral Agreements and Sustainable Development: US Trade Policy-making in Intellectual Property", by Robert Weissman.** This paper presents an analysis aimed at providing developing country officials, civil society groups, and other stakeholders with critical information as to challenges and opportunities in the U.S. trade policy-making process as it relates to intellectual property discussions in bilateral and regional free trade agreements. The paper provides a clear and comprehensive overview of this process, touching upon the key institutions and players and providing concrete possibilities and suggestions to increase the influence of developing countries, civil society groups, and other relevant stakeholders in bilateral intellectual property discussions.

The analyses and findings of the papers form the inputs to CIEL's **Framework for Future Action in Bilateral and Regional Trade Agreements**, which recommends specific methodologies and priority areas for civil society work in the bilateral and regional arena.

ABOUT THE CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL)

CIEL is a nonprofit organization that uses international law, institutions, and processes to protect the environment, promote human health, and create a just and sustainable world. Through our offices in Europe (Geneva) and North America (Washington D.C. and Berkeley, California), we provide advice and support to partners in civil society, government and intergovernmental organizations.

CIEL's Intellectual Property and Sustainable Development Project works with non-governmental organizations and developing country governments to include sustainable development concerns in current multilateral and bilateral rules on intellectual property.

ABOUT THE AUTHOR

Ellen 't Hoen is a lawyer and Director for Policy Advocacy at MSF Campaign for Access to Essential Medicines of Médecins Sans Frontières.

In 1981 she was one of the co-founders of DES Action the Netherlands where she worked as a coordinator until 1990. From 1990 until 1996 she was a project coordinator at the European office of the consumer network Health Action International. From 1996 until 1999 she was the coordinator of the International Society of Drug Bulletins (ISDB) and consultant to the editorial board of the independent French pharmaceutical journal *La revue Prescrire and Prescrire International.* She joined MSF in 1999. She has worked as a drug policy consultant for a number of institutions, including the World Health Organization.

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I. INTRODUCTION

This paper will address the main threats of the intellectual property (IP) chapters in the bilateral and regional agreements with the United States of America (US) for access to medicines, give an overview of the reactions from different sectors to these agreements, and outline some strategic considerations for future action.

The effects of Free Trade Agreements (FTAs) on access to medicines are of course only one area of concern. Others have documented concerns in other areas of intellectual property such as patenting of life forms, which has consequences for agriculture, software patenting to the detriment of open source developers, and the extension of copyright affecting education and libraries.[1] In addition, the intellectual property chapters of the FTAs cover only a relatively small area. Other areas of concern are the effects of FTAs on agriculture, competition policies, the environment, investment policies, labour and others.

The scope of this paper is however limited to the effects that IP provisions in FTAs have on access to medicines. In part, this is because the access to medicines case is rather well documented and has generated the largest amount of both empirical and analytical work on intellectual property and sustainable development issues. An examination of the effect of bilateral and regional FTAs on access to medicines may provide some insights, strategic considerations and lessons to the benefit of others who work on broader issues in relation to the FTAs, such as Food Security and Biodiversity. A recent example of this is the Side-letter on Biodiversity that Peru obtained in its FTA with the US, an extension of the use of previous side-letters on Public Health.

II. THE PROBLEM OF ACCESS TO MEDICINES

The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Over 40 million people are infected with HIV. Of that group, 4.7 million people are in urgent need of treatment with antiretroviral medicines. Today only 1.3 million[2] have access to treatment. The reasons for the lack of access to essential medicines are manifold.

In many cases, however, high drug prices are the main barrier to needed treatments. Prohibitive drug prices are often the result of the fact that there is no competition in the market. Often a single producer's monopoly sustained through patent protection or other intellectual property rules dictates the rules of the game. This leads to high prices but also to lack of availability of medicines when a company holds the patent but does not make the product available.

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[1] *See* http://www.bilaterals.org/rubrique.php3?id_rubrique=33.
[2] 2006 Report on the Global AIDS Epidemic. UNAIDS. Page 151.
http://data.unaids.org/pub/GlobalReport/2006/2006_GR_CH07_en.pdf

Pharmaceutical product patenting has become a widespread practice as a result of the implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS agreement globalized western IP standards and practices.

By adopting the Doha Declaration on TRIPS and Public Health in 2001, the WTO recognised some of the concerns raised by developing countries regarding access to medicines. However, in recent years, we have seen a systematic dismantling of the Doha Declaration through bilateral trade agreements with the US, which include so-called "TRIPS-plus" provisions. These "TRIPS-plus" provisions annul the achievement of the Doha Declaration and confirm the lack of political support by the US for the use of TRIPS flexibilities.

II.1 The Doha Declaration on TRIPS and Public Health

The Doha Declaration on TRIPS and Public Health established the primacy of public health over commercial interests. Crucial language for the Declaration is contained in paragraph 4; it reads:

> *"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."*[3]

In paragraph 5, the Declaration lays out the key measures and flexibilities within TRIPS that can be used to overcome intellectual property barriers to access to medicines. The discussions at Doha and the Doha Declaration itself make it unambiguously clear that the use of compulsory licenses is in no way confined to cases of emergency or urgency; in fact, the grounds for issuing a compulsory license are unlimited. Members who proposed language that would have limited measures like compulsory licensing to emergency situations, pandemics, or specified diseases such as HIV/AIDS were unsuccessful. In addition, the Declaration leaves Members free to determine for themselves what constitutes a national emergency or urgency, in which case the procedure for issuing a compulsory license becomes easier and faster because no prior negotiation with the patent holder is required. The Declaration also resolves the question of whether TRIPS authorizes parallel trade once and for all by noting in paragraph 5 (d), "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge." In paragraph 7, the Declaration grants Least Developed Country (LDC) Members an extra ten-year extension – until 2016, instead of 2006 – to implement pharmaceutical product patent protection and test data protection.

[3] Doha Ministerial Declaration on TRIPS and Public Health, (available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.)

III. US OBJECTIVES FOR IP IN BILATERAL TRADE AGREEMENTS

After having been forced to compromise in multilateral negotiations the US has stepped up its efforts to increase IP standards through bilateral and regional trade agreements. These agreements have, until fairly recently, attracted little attention. They are highly technical and have generally been negotiated in secret without draft texts being available for public scrutiny. In addition, a significant problem is that at the negotiating table one finds the trade ministers and not the health ministers. Often health authorities find out after the fact that the agreement has consequences for health and pharmaceutical policies.

The US is seeking to secure, and has already secured, the inclusion of several intellectual property provisions in its regional and bilateral trade agreements that are particularly detrimental to the objective of achieving access to medicines for all. All of these features can be characterized as "TRIPS plus". These include:

- rules which will give national drug health and safety regulatory authorities a new and strong role in the enforcement of patents on medicines;
- obstacles related to the use of pharmaceutical laboratory and clinical test data for drug regulatory purposes, which will delay the registration and thereby the marketing of generic medicines ("data exclusivity");
- extensions of the patent term for pharmaceuticals beyond the 20 years required by the TRIPS Agreement, which will further delay generic competition;
- measures which will allow known substances to be patented for each "new use"; and
- restrictions which will limit countries' abilities to use compulsory licenses as effective measures to ensure access to low-cost medicines.

Some or all of these provisions appear in concluded agreements such as the Central American Free Trade Agreement[4] (CAFTA), the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, the US-Morocco Free Trade Agreement, Peru and other agreements which have already been signed[5] and reappear or are likely to reappear in trade agreements being negotiated with Thailand, Panama, the Andean countries (Bolivia, Colombia, Ecuador) and the countries of the Southern African Custom Union[6] (SACU) and have also appeared in accession agreements with new WTO Members, for example China and Cambodia.[7]

[4] CAFTA originally included Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua, but the Dominican Republic agreed in March 2004 to sign on to CAFTA as well.
[5] NAFTA (US, Canada, Mexico) as well as several bilateral investment agreements with the US.
[6] SACU includes Botswana, Lesotho, Namibia, South Africa and Swaziland.
[7] WTO working party reports and protocols of accession of China and Cambodia, available at http://www.wto.org/English/thewto_e/acc_e/completeacc_e.htm.

Since 2001, an increasing number of countries have used the flexibilities to allow for production of generic versions of patented essential medicines, to import from countries where pharmaceutical product patents do not exist or as a bargaining tool in price negotiations with multinational pharmaceutical companies.

The proliferation of the TRIPS-plus rules through FTAs pose a very serious threat to the effective use of safeguards. It also establishes a globalisation of new IP norms, which the US would not be able to obtain in multilateral negotiations.

IV. RESPONSES TO THE US-STYLE FTAS

Civil society and access campaigning groups have been key in raising awareness of the threats posed by IP chapters in trade agreements with the US. They have been successful in gaining attention and increasingly the health sector, academia, international institutions and the legal profession are sharing their concerns.

The involvement of the public health community in particular has been important in the debate, highlighting the negative effects of the IP clauses in trade agreements with the US.

IV.1 World Health Assembly

The World Health Assembly (WHA) has passed several resolutions that have warned against provisions in FTAs that negatively affect countries' ability to make full use of the Doha Declaration.[8] A resolution of the World Health Assembly in 2004 urged Member States:

> "...to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health."

The report of the World Health Organization (WHO) Commission on Intellectual Property Innovation and Pubic Health (CIPIH) published in April 2006 has the following recommendations with regard to trade agreements:[9]

> *"4.21 In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation. Bilateral*

[8] World Health Assembly resolution No WHA 57.14, 2004, available at http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf.

[9] WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) report on "Public Health, Innovation, and Intellectual Property Rights, April 2006, available at http://www.who.int/intellectualproperty/documents/thereport/en/index html.

trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries."

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The WHO Country representative in Thailand, Dr William Aldis, warned about the negative effects a FTA with the US could have on the Thai national AIDS programme and its much praised "30 baht" universal health care scheme in an article in the Bangkok Post.[10] He urged the Thai government not to give up its sovereign right to use, to the fullest extent, all available flexibilities contained in the TRIPS Agreement of the World Trade Organization and reaffirmed by the Doha Declaration.[11]

IV.2 United Nations

Concerns about the FTAs have also been raised by the UN's Human Rights Committee and by the Special Rapporteur on "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", Paul Hunt, who said on 13 July 2005 during the US-Peru negotiations:[12]

"I am concerned that the US-Peru free trade negotiations could lead to higher protection of patents than is currently required under the rules of the World Trade Organization (WTO). Higher protection of patents could restrict Governments from taking action to protect the right to health in the future,"

"A year ago, I indicated my deep concern that the US-Peru trade agreement would water down internationally agreed health standards, leading to higher prices for essential drugs that millions of Peruvians would find unaffordable. I continue being concerned today as negotiations on key issues draw to a close."

IV.3 Legal Profession

[10] Aldis, William L., "*Opinion: It could be a matter of life and death"*. Bangkok Post, 9 January 2006, available at http://www.bilaterals.org/article.php3?id_article=5072.

[11] However it must also be said that WHO came under tremendous pressure from the US after the publication of Dr Aldis' opinion piece which was nothing more than a public statement of the established WHO position on the use of the TRIPS flexibilities. As a result Dr Aldis was removed from his post by the WHO leadership. Simon Montlake, "*Bitter Medicine",* South China Morning Post, 12 July 2006, available at http://lists.essentials.org/pipermail/ip-health/2006-July/009839/.html. This incident shows that despite several WHA resolutions that cautioned against TRIPS plus provisions in FTAs the WHO still needs to be a target of access campaigners and civil society groups.

[12] UN News Centre, "*UN Expert concerned US-Peru free trade accord could deprive poor of medicine"*, 13 July 2005, available at http://www.bilaterals.org/article.php3?id_article=2282.

The International Trade Law Committee of the International Law Association (ILA) at its annual assembly in June 2006 adopted a resolution stating:[13]

> *Governments are urged to refrain from using bilateral and regional trade negotiations and agreements to limit or eliminate flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights which are recognized in the Doha Declaration on the TRIPS Agreement and Public Health to support the protection of public health and to promote access to medicines for all.*

Taking into account that this particular committee of the ILA includes members of the legal profession that are engaged in WTO litigation this is a rather significant move and evidence of the fact that the global concerns about the effects of FTAs on countries ability to make full use of the Doha Declaration is growing.

IV.4 Responses in the US

The United States codified its formal commitment to Doha in its 2002 Trade Promotion Authority (TPA) Act, which specifies "respect for the [Doha] Declaration" as one of the objectives of the TPA.[14]

Nevertheless the Bush administration has also come under criticism from US politicians for its TRIPS plus stance in FTA negotiations. In June 2005 the United States House of Representatives Committee on Government Reform in an 18-page report prepared for Rep. Henry Waxman concludes:

> *In 2001, the United States joined the international community in adopting the Doha Declaration, which recognized that trade agreements should not impede the efforts of developing nations to obtain essential drugs at affordable prices. Since then, the Bush Administration has negotiated multiple trade agreements with developing nations, including the CAFTA agreement now pending before Congress. Contrary to the principles of the Doha Declaration, the Administration has used these trade agreements to restrict the access of developing nations to low-cost generic drugs. By delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, the trade agreements undermine the safeguards outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations.*

Pressure in the US has lead to the so called side letters to FTAs with developing countries that state that the IP chapter of the FTA does not affect any "party's ability to take

[13] Resolution No. 3/2006 International Trade Law Committee. The 72nd Conference of the International Law Association, Toronto, Canada, 4-8 June 2006, available at http://www.ila-hq.org/pdf/Trade%20Law/Resolution%203%202006%20Trade%20Law%20English.pdf.
[14] http://www.cptech.org/ip/health/trade/ip-hr3009 html

necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency." While the legal and practical usefulness of these side letters is doubtful it does show that the USTR has felt under pressure to at least make a gesture.[15]

While there is a wealth of evidence, documentation and political statements that address the serious detrimental effects of the TRIPS-plus chapters in FTAs with the US, progress on influencing the negotiations has been lagging behind. This calls for a rethinking of the strategy. The next section will provide some strategic suggestions.

V. SOME STRATEGIC CONSIDERATIONS FOR CIVIL SOCIETY GROUPS

The suggestions for strategies are listed under two headings: actions that are ongoing or that are focussed on immediate results and strategies that have a more long-term perspective. The recommendations are not mutually exclusive.

V.1. Immediate actions:

V.1.1. Continue to raise public awareness.

It is important to continue to raise awareness among the public about how the new IP standards in FTAs affect access to medicines. This should be based on solid analysis. It is advisable to use concrete examples to illustrate the potential negative effects of TRIPS plus provisions in the countries that are (or planning) negotiating with the US. This also requires working with the media.

V.1.2. Ministers of Health

It is imperative that the ministers of health are briefed about the effects of IP requirements in FTAs and that they play a much more active role in the negotiations. In particular the medicines regulatory agency – which often resides in the Ministry of Health – is affected by US demands to increase its role in patent enforcement and the prohibition on the of use clinical test data to register generic medicines for five to ten years. It is therefore key to involve the medicines regulatory agencies in the debate. Civil society groups should engage with ministries of health and drug regulatory agencies. The WHO should also be pressured to increase its technical assistance at the country level with the ministries of health.

V.1.3. Raise awareness in the USA

[15] Center for Policy Analysis on Trade and Health (CPATH), "*Brief: CAFTA side letter does not protect access to medicines"* 30 September 2004, available at http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/CAFTASideLetterDoesNotProtectAccessToMedicines.pdf

While civil society mobilization against the TRIPS plus provisions in developing countries is increasingly vocal, in the US the awareness amongst the public is still relatively limited. Compared to global media coverage, there has been relatively little media attention to what the US government (USG) is pursuing in FTA negotiations and what the consequences for access to medicines in the developing world may be. We have seen the USG respond to complaints from members of Congress. However, the USG seems immune to concerns expressed outside its territory. It is therefore crucial to bring the debate to the US and raise awareness among the public and policy makers.

It may in particular be useful to point out that the demands the US makes to other countries to curtail their ability to control medicines prices may come back to haunt US citizens. The US itself is plagued by high drug prices and many of its citizens cannot afford the medications they need. This is particularly the case for the elderly, some of whom have resorted to parallel imports from Canada and Mexico to save on their drug bill. Many of the measures the US wants to see abolished are or will be necessary in the US to control escalating drug costs.[16]

V.2. Strategies with a longer term perspective

V.2.1. Moratorium on TRIPS plus provision in FTAs

On 17 December 2005 during the WTO Ministerial summit in Hong Kong, NGOs issued a joint Statement on the Need for a WTO Moratorium on Regional and Bilateral Trade Agreements and Policies Undermining Access to Health. The demand reads as follows:[17]

> *"We ask that Members agree to a moratorium on any new bilateral and regional trade agreements that include provisions involving intellectual property rights and medicines, and that all WTO Members agree they will not enforce any provisions in such agreements that are contrary to the 2001 Doha Declaration on TRIPS and Public Health."*

This call needs to be translated into a global campaign. One entry point could be the European Commission's publicly stated position, which is against TRIPS-plus and in favour of the protection of the Doha Declaration. However this publicly stated position does not translate into action on the FTA front. Civil society groups should call the Commission to task. It would be quite appropriate to ask the Commission to take action at the WTO level to stop the further hollowing out of the Doha Declaration on TRIPS and Public Health.

V.2.2. Engage in the wider debate on IP, Innovation and Access.

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[16] In a letter to USTR Barbara Weisel about the FTA negotiations with Korea, James Love director of the Consumer Project on Technology wrote: "everything Korea will do to avoid paying high prices will have a counterpart in the US. State governments, the Veterans Administration, private insurance companies, and eventually, the US federal government, will manipulate co-payments and reimbursement schedules to avoid paying for expensive drugs. How are we supposed to tell Korea this is wrong, when we do?", available at http://www huffingtonpost.com/james-love/ustrs-ftas-and-a-new-ap_b_25261 html.

[17] For full text of the statement please see: http://www.cptech.org/ip/wto/ngos12172005.html.

Make health innovation the focus, e.g. health R&D investments instead of higher levels of IP protection.

It is no coincidence that during the 59th World Health Assembly, which was largely devoted to discussion of the Commission on Intellectual Property, Innovation and Public Health (CIPIH) report,[18] and in particular the need for new mechanisms for stimulating health needs driven R&D, that concerns about FTAs were raised.

The CIPIH report is particularly important as it introduces a new definition of innovation, which includes delivery: the CIPIH talks about the 'triple D', discovery, development, and delivery.

The justification for increasing IP levels is that it will stimulate R&D. However evidence is becoming increasingly available that the implementation of TRIPS has done little or nothing to encourage innovation to address health needs in developing countries.

In its report published in April 2006 the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) came to the conclusion that:

"There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on TYPE II and particularly Type III diseases. Insufficient market incentives are the decisive factor."[19]

A May 2006 article in the medical journal *The Lancet* shows that there has been no increase in R&D outcomes for the so-called neglected diseases – diseases that predominantly affect people in developing countries. Between 1975 and 2004, of the 1,556 new chemical entities marketed globally, only twenty new drugs - a mere 1.3% - were for tropical diseases and tuberculosis, diseases which account for 12% of the total disease burden.[20] This 1% ratio has been steady over the last three decades.

Patent protection has increased over the last twenty years, but the main innovation rate has fallen, with an increase in the number of 'me-too drugs' of little or no therapeutic gain. This global crisis in innovation has a disproportionately heavy impact on the needs of people in developing countries - but is not confined to the developing world.

A survey published in April 2005 by *La Revue Prescrire*, concluded that 68% of the 3,096 new products approved in France between 1981 and 2004, brought 'nothing new' over previously available preparations.[21] *The British Medical Journal* published a study

[18] Report of the Commission on Intellectual Property, Innovation and Public Health, available at http://www.who.int/intelectualproperty/en/.
[19] Ibid at 58.
[20] Pierre Chirac and Els Torreele, "*Global framework on essential health R&D*", The Lancet, 13th May 2006, 367:1560-1.
[21] *"A review of new drugs in 2004: Floundering innovation and increased risk-taking"*, Prescrire International, April 2005, vol.14, n. 76 pp 68-73.

rating barely 5% of all newly patented drugs in Canada as 'breakthrough.'[22] Furthermore, a breakdown of over one thousand new drugs approved by the US Food and Drug Administration between 1989 and 2000 revealed that over three quarters have no therapeutic benefit over existing products.[23]

The UK government-sponsored Commission for Intellectual Property Rights supported the view that higher levels of intellectual property protection have not resulted in increased drug R&D for global health needs.[24] Worse, in some cases R&D may actually be hampered by IP, either through the complexities of dealing with large numbers of patents (some human genes are patented as many as twenty times for example), or because follow-on innovation is rendered impossible. An example is the problem of developing fixed-dose combinations (e.g. the "three-in-one" pill for AIDS treatment) when different companies hold the patents on the individual components.

In May 2006 the World Health Assembly adopted a resolution titled: "Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action".[25]

WHA resolution 59/24 states that the WHO:

Decides to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. Such a strategy and plan of action aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Indeed, the immediate result of the resolution is that the governments of member states of WHO start talks based on - but not limited to - the CIPIH report's recommendations about the aspects of a health needs driven R&D system. These talks could lead to short term deliverable agreements, as well as to new legally binding agreements between countries. The intergovernmental working group will make recommendations to other bodies including for example the WTO and the WHO. In sum, the key feature is that the discussions on what a system for health research and access to the results of this research will look like is likely to be driven again by health considerations, and not by commercial concerns, as is the case in the WTO, nor by the pro-IP lobby, as is the case in WIPO.

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[22] Morris L Barer, Patricia A Caetano, Charlyn D Black, Steven G Morgan, Kenneth L Bassett, James M Wright, & Robert G Evans, *"Breakthrough drugs and growth in expenditure on prescription drugs in Canada"*, British Medical Journal, 2nd September 2005, 331:815-6.

[23] *"Changing Patterns of Pharmaceutical Innovation"*, The National Institute for Health Care Management Research and Educational Foundation,. Washington, DC, NIHCM Foundation, May 2002, available at, http://www nihcm.org/innovations.pdf.

[24] http://www.iprcommission.org/graphic/documents/final_report.htm

[25] http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf

The relentless drive for higher IP standards is justified by promises of innovation. At the same time there is increasing evidence that the current 'high price-patent' model for health innovations is not delivering on need. The recent WHO resolution offers an opportunity to move away from the IP based model as the single model for innovation and start talks about an R&D system that is driven by health needs, with assuring access as one of its core components.

If the debate moves from IP to R&D this is likely to affect countries' abilities to change the dynamics in trade agreements. When the talks are no longer about how high IP standards should be but rather how can each contribute to essential health innovation the power dynamic is likely to change.

VI. IN CONCLUSION

Civil society should step up its advocacy and raise awareness in the countries presently negotiating, or planning to open talks with, the US. At the same time there is a need for an international game plan that condemns the pursuit of TRIPS plus norms and that moves the debate on IP standards to a debate on essential health R&D. The growing opposition to TRIPS plus demands in FTAs and recent political moves at the WHA seem to offer openings to do this.

Access to medicines is only one area of concern that helps to illustrate how FTAs can affect people's lives and health. However it will be important for those working on FTAs to compare notes and align strategies. At the very least this paper suggests that it is important that countries negotiating FTAs need principles or declarations such as the Doha Declaration on Public Health to help frame their response. In addition, the issues must be addressed in the multiple fora where IP issues arise, such as the WIPO, WHO and the FAO International Treaty on Plant Genetic Resources. The involvement of stakeholders from other government departments in negotiations is also significant, as is sharing of negotiating texts with civil society. While the Access to Medicines issue remains an essential entry point for action on FTAs, it is clear that the strategy applied to such interventions can be extended to other issues such as biodiversity and food security.

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INTELLECTUAL PROPERTY, BILATERAL AGREEMENTS AND SUSTAINABLE DEVELOPMENT SERIES

For Further information contact:

Dalindyebo Shabalala
Director, Intellectual Property and Sustainable Development Project
Center for International Environmental Law
15 Rue des Savoises, 1205
Geneva, Switzerland
Phone/: +41-22-321-4774; Fax: 41-22-789-0739
e-mail: dshabalala@ciel.org

Nathalie Bernasconi-Osterwalder
Managing Attorney
Center for International Environmental Law
15 rue des Savoises, 1205
Geneva, Switzerland
Phone: 41-22-789-0500; Fax: 41-22-789-0739
e-mail: nbernasconi@ciel.org

Marcos Orellana
Senior Attorney-Director of Trade and Sustainable Development Program
Center for International Environmental Law
1367 Connecticut Avenue NW, Suite 300
Washington D.C., U.S.A.
Phone: +1 - 202 785 87 00; Fax: +1 - 202 785 87 01
e-mail: morellana@ciel.org