

New Approaches to Intellectual Property

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Columbia University, New York, NY 10027



The Initiative for Policy Dialogue



The Transatlantic Consumer Dialogue

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WIPO Development Agenda - Monday 13 June 2005

Welcome and Introduction

Joseph Stiglitz, Initiative for Policy Dialogue, www.policydialogue.org

The intellectual basis of IP rights stands on shaky ground – many of the assertions made about its beneficial impacts are not based on economic theory, history or evidence. There are now two separate camps - those who actually think about the issue (analysis-based), and those who take one side or the other (faith-based arguments).

Innovation and legal frameworks are very important to the functioning of our economies, but rules and legislation are progressing at a very fast pace without due economic analysis. One area concerns the fast-paced negotiations on bilateral agreements, which go beyond TRIPS in a direction opposite to that agreed at Doha.

This meeting has brought together a group of people who can look at how to reverse the direction of IP, or at least change the process through which its rules are decided. From the discussions, we hope to understand what specific laws and legislation are being passed or embedded in treaties, and to see how they affect access to knowledge and healthcare. When we consider development issues around IP, we are not just referring to the transfer of research, but also about closing the information gap.

James Love, Consumer Project on Technology, www.cptech.org/jamie

TACD is a network of consumer groups, most of whom are publishers, that has started to look at IP issues in the last few years. We've become concerned that IP debates are presented as a simple choice between protecting or not protecting property - an extreme and over-simplistic framing of the debate, which is particularly harmful with regard to trade issues.

This meeting brings together economists and activists to think about the economics of IP policy. Development advocates working on this are reaching out to create a stronger intellectual and theoretical basis for what's going on. The ultimate aim of our work should be to change the way people think about IP from something merely commercial to considering how IP serves humanity - in relation to promoting innovation, protecting consumers and being consistent with human rights.

Panel 1 - Setting the Context, The WIPO Development Agenda

Chair: Klaske de Jonge, Consumentenbond, www.consumentenbond.nl

Guilherme de Aguiar Patriota, Brazil Ministry of Foreign Affairs www.mre.gov.br

The Intellectual Property system for many years remained unchanged with a trade-off at its heart –with protection came responsibilities. The rights-holder would receive a monopoly for a certain amount of time, as long as there was full disclosure, knowledge was made available to everybody, and limitations were put on the rights. It had been a system of national laws to suit national circumstances and levels of development and technology. However, in the last 20 years it has gone from a nation-state system to a global system, mimicking the development of corporations into trans-national companies. This leap from a national to a global system had an enormous impact on developing countries.

In recent years, the relation between TRIPS and WTO has been very significant since it brought a trade logic into IP protection. This is a departure from the nationally decided balance between the rights-holder and the public interest. IP is now no longer enforced only by national systems in courts, but also by economic penalties that can be brought by powerful countries. The more economically powerful the country is, the more effect its retaliation will have. It is no longer a story about equals.

The Brazil/Argentina proposal for a WIPO Development Agenda is an attempt to put a brake on the upward harmonization of IP, which is being ratcheted ever higher without differentiation between countries with

different levels of technologies and different uses of an IP system. When you raise the levels of protection, a country like Brazil is required to give more protection to ideas owned by foreigners, but this will not create innovation in Brazil.

Marta Gabrieloni, Permanent Mission of Argentina in Geneva www.mrecic.gov.ar/

The current discussions at WIPO - since the adoption of the Brazil/Argentina proposal for a WIPO Development Agenda at the October 2004 WIPO General Assembly - were unthinkable seven years ago, so this shows great development.

The Brazil/Argentina proposal was supported by 14 countries in all - Argentina, Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela – who are otherwise known as the “Friends of Development”. The proposal can be found here: http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf

The proposal aims at making WIPO and the intellectual property system more responsive to the needs and interests of developing and least developed countries. It argues that WIPO must integrate development into its activities, safeguard public interest flexibilities, and become a member-driven organization open to addressing the concerns of all stakeholders, in particular civil society.

The proposal concludes by saying that “A vision that promotes the absolute benefits of intellectual property protection without acknowledging public policy concerns undermines the very credibility of the IP system. Integrating the development dimension into the IP system and WIPO’s activities, on the other hand, will strengthen the credibility of the IP system and encourage its wider acceptance as an important tool for the promotion of innovation, creativity and development.”

Following three Inter-sessional Intergovernmental Meetings on a Development Agenda for WIPO, the Secretariat will prepare a report at the end of July 2005 on for the General Assembly Meeting in September 2005. The increasing involvement of NGOs and civil society will help raise the profile of these issues and perspectives in WIPO.

Sisule Musungu, South Centre www.southcentre.org

There has been confusion about the mandate of WIPO: A century ago there was an independent secretariat, but in 1967 it became WIPO, becoming part of the UN to provide it with legitimacy to make it a global organization. This way, it would appear more representative and attract developing countries. But, ultimately, no effort was made to make it a real UN organization whose work is underpinned by the quest to promote human rights. Instead, there has been regulatory capture and WIPO now only cares for those who finance it - industry and developed countries. WIPO negotiations are still very centered on the US and the EU. The mindset that developed countries should just approve legislation and take technical assistance to implement it threatens developing countries.

WIPO has tended to make sure that no other UN agency has dealt with IP, so UN experts dealing with substantive areas such as agricultural, culture or health, for example, have not been able to look at the impact of IP rules. In this context, the WIPO Development Agenda is a far-reaching achievement, and WIPO’s hosting of a May 2005 International Seminar, with other UN agencies, on Intellectual Property and Development shows some progress. There is a need for WIPO to now develop an evidence or science-based analysis to policy-making and look at the societal impacts of what it adopts.

In discussion, participants agreed that there was a need for more research and for an analysis-based approach. While it was agreed that WIPO, as an agency, is currently captured by rights-holders, it was felt that increasing involvement of NGOs and civil society would help raise profile of these issues and perspectives in WIPO. There is scope for change, in terms of how WIPO could operate, because dissatisfaction with WIPO felt by developed and well as developing countries. One way to generate change is to start thinking about the role of other agencies that deal with the effects of WIPO rules, such as the World Health Organization

Panel 2 – Towards a pro-development and balanced intellectual property regime

Joseph Stiglitz, Initiative for Policy Dialogue, www.policydialogue.org

There is an assumption that the market economy will promote innovation, but the basic model of efficiency of a market economy assumes that technology is fixed, which is not the case with the current economy. Therefore, asserting that market-based IP rules promote innovation is “faith-based” and does not reflect proper analysis. The whole basis of market economics is the need for competition to create efficiency, so IP rights – the granting of a temporary monopoly - undermine the very basis of the economic model we use.

The IP system does not provide a relationship between the reward granted and the (social) contribution or return given. Also, there is no attempt to assess how much earlier the ideas were introduced thanks to the person who introduced them - ideas will always be presented eventually, and the patent system just rewards the person who gets there first. The patent system is not even dynamically efficient, as it encourages people to get far enough to discourage others from trying to innovate and then stops.

There are social costs to the distortions created by these temporary monopolies, and they are very high in some cases, such as medicines in developing countries. Furthermore, once a “temporary” monopoly is established it can be easily perpetuated. Even when it is stopped benefits can continue from the monopoly established with these methods – such as the market position established through Microsoft’s anti-competitive and bundling behavior.

So what is the best way of organizing and financing research and innovation? “Strong vs. Weak” is the wrong vocabulary for this, and we must instead look at a variety of dimensions. The patent system is a self-selecting mechanism, which is more efficient than a bureaucracy having to find and choose who is best to carry out research.

It is fundamental to understand knowledge as a public good, and the privatization of a public good should only be justified if it can better produce public goods than keeping it in the public sphere. The idea of knowledge as a public good goes back to Jefferson poetically, who talked of knowledge being “like a candle – when one candle lights another it sheds more light, but the first candle isn’t diminished”, and that should be the guiding principle of a public good. Indeed, most important innovations (e.g. mathematical theorems, the human genome) are ideas that are not protected by IP rights and are not patentable. Not using an IP system therefore can and does work.

An interesting development is the use of the international arena for issues of national legislation, which has arisen because multinationals have more influence at the international level. For example, pharmaceutical companies can do internationally what they could not get away with at national level.

Reappraising intellectual property is a matter not just of equity and access to knowledge, but also of economic efficiency. We need a new lens through which to analyze every aspect of the IP regime, and we need to give greater voice to the concerns of the developing world. Unless this is done, there is the prospect of an ever-increasing gulf between the developed and less-developed world, between the owners and users of intellectual property.

Discussion touched on the strategic need to change the way people understand the economics behind IPR, and that having a strong message from economists on this would boost the help. It is important to frame the debate around how IPR impedes innovation. Professor Stiglitz is trying to establish a consensus around which most economists could agree. To get a more balanced IP regime, it is necessary to get wider acceptance of alternative frameworks and wider recognition that the commonly accepted “common sense” view – of IP always promoting efficiency and innovation - is wrong.

Panel 3 -- The role of intellectual property rights in promoting development: historical experiences and empirical evidence

Chair: Diana Barrowclough, UNCTAD www.unctad.org

Kenneth Sokoloff, UCLA www.econ.ucla.edu/people/faculty/Sokoloff.html

The framers of the US constitution thought that broadening the IP system would democratize it, allowing individuals without resources to get involved. This was in contrast to the system that was already in place in the UK, where the cost of getting a patent was 10 times the annual average income. The cost of getting a patent under the new US system was 3% of that in the UK. The results were summed up in the 1851 Crystal Palace World Fair of technology, where the US walked away with many prizes. It is no coincidence that, in the following years, the UK decided to provide a more accessible system.

In the past 20 years personal research has shown that rates of invention have been very responsive to market conditions and to changes in the patent system. People who benefited were those from lower classes who didn't have access before. For example, General Electric began from someone who didn't go to school but used the patent system to mobilize capital and get his business going. Patent institutions have a powerful impact on rates of innovation. Stronger systems do have some positive effects, even if these must be weighed against negative side.

Sudip Chaudhuri, Indian Institute of Management www.iimcal.ac.in/faculty/facpage.asp?ID=sudipc

It is claimed that stronger patent protection would benefit developing countries because multi-national companies (MNCs) would contribute more to technological and economic growth there. India's experience does not demonstrate these claimed positive impacts. In India before 1972, with patent protection in place, MNCs were not keen on manufacturing medicines and used their patents to prevent Indian companies from doing so. It was the abolition of patent protection that operated as a pull mechanism in India, with Indian companies innovating production processes and making India a global source of drugs.

With India now reinstating patent protection, some say that outsourcing by MNCs to Indian companies will more than compensate for the shrinkage of domestic opportunities in the post-TRIPS regime. But outsourcing by MNCs is still modest, and if it does increase it will not be because of TRIPS; it will be due to the technical skills acquired by Indian companies during the absence of product patent protection in the last 30 years.

Roumeen Islam, The World Bank Institute www.worldbank.org/wbi/governance/team.html

Over four decades ago, Fritz Machlup (1957) argued that it was not possible to state with certainty whether the patent system confers a net benefit or net loss upon society, and based on current empirical evidence above, the same seems true today. As does his conclusion that "If we did not have a patents system it would be irresponsible, based on our present knowledge, to invent one. However, since we do have one it would be irresponsible, based on present knowledge, to abolish it."

There is insufficient evidence as to how IPRs effect development to justify such impassioned positions on either side. A 2000 paper finds that stronger IPRs did lead to stronger R&D in 1980s but less so in the 1990s, and while some findings suggested much higher prices rises in the absence of patent protection, others showed the costs for developing countries of implementing and running such a system. Across many countries we find that richer countries have stronger IP protection regimes, and it's historically borne out that as a country becomes richer as its IP system gets stronger. In a lot of aspects there is no evidence on which to base decisions on the strength of patent protection, and in others the evidence is too mixed to provide a conclusion.

Pedro Roffe, ICTSD www.ictsd.org

IP covers many different things, and most economic analysis relates to patents, where empirical evidence is difficult to extrapolate and will have many interpretations. Latin America is an interesting case for analysis on the spread of the patent system and the movement from a laxer to a stronger system. The Paris Convention, although not containing many Latin American countries, played a major role in spreading the

system to Latin America. The countries of the Andean Group (Bolivia, Colombia, Ecuador, Peru, Venezuela) have experienced higher royalty fees since the Uruguay GATT Agreement. There has been increase in patent applications, but 85% still from non-residents – mostly from 5 countries including US, UK, Japan – so the patent system is not benefiting the people in these countries.

Lee Branstetter, Columbia University www.gsb.columbia.edu/faculty/lbranstetter

In the short term, having stronger patent rights in the South will give more profits to multinationals, but in the long term it will transfer technology and production. If multinationals are able to transfer technology to the South, stronger patent systems could speed up innovation, and while Northern production workers will suffer in the short term, innovation will happen more quickly in the long run. So, it depends crucially on the response and behavior of MNCs. Not enough evidence, but - using US Government-required reports about from multinationals about their foreign investment - it appears that inter-firm technology transfer is increasing, especially where countries are patent-intensive. MNCs seem to respond to patent reform by increasing scale and especially info-transfer. None of this should take away from the need to deal with access to AIDS medicines, but there have been some benefits from expanding strong IP to developing countries. The current system is not held up as an ideal but it is very hard to prove that it has impeded progress.

In discussion, James Love pointed out that a lot of studies referred look simply at the correlating activity with regard to strengthening or weakening IP systems, and that other approaches should also be investigated – how differently would the Internet have developed without an open source kind of approach? Does open source publishing have impacts on development opportunities in the South? Does the EU's approach to databases mean they are economically better than the US, which US decided not to adopt a sui generis approach to facts? The Chair summed up the speeches as suggesting that we need to do more research and find more empirical evidence.

Panel 4: IP open versus closed architectures

Chair: Ed Mierzwinski, Public Interest Research Group (U.S. PIRG) www.uspirg.org/consumer/edbio.html

Yochai Benkler, Yale Law School www.benkler.org

Rather than new approaches to intellectual property, the title of the conference should have been “New Approaches to Innovation” recognizing that intellectual property is only one way of promoting innovation, and not necessarily a the best, or even a good, way of doing it. In fact, once you understand that patenting is a form of regulation, you can see patent-busting as a form of deregulation.

Professor Benkler's presentation explained the concept of open architecture, the constraints it encounters and the benefits it can engender. What is “open architecture”? It is a combination of Institutional design (to what extent, and by whom, is the observation of technical affordances permitted) and industrial organization (economic constraints and conditions). Technically, it is transparent, loosely-coupled and late binding, and institutionally it permits actions to the extent that technology is able to do.

Eben Moglen, Columbia Law School emoglen.law.columbia.edu

For the past 20 years a movement has been underway to create a system of sharing that would outperform the system of property.

Software – instructions allowing humans and machines to communicate – is now primarily produced across the world by sharing rather than owning. One example is that of sourceforge.net which represents over half a million volunteer programmers. The average programmer is a software professional of 10 years experience giving over 10 hours of their time per week. This provides more input than Microsoft has – producing without property is now a dominant production model.

Multinational companies like IBM and Nokia are starting to give up patent rights, which is a positive development. IBM has now dedicated 500 patents for use in open source software, and this is just the first tranche.

The pharmaceutical sector is the *raison d'être* of the patents system – based on the notion of ownership of molecules that need to be ingested by the patient. A competing model would be to find medicines that can be ingested to prevent problem and make patient increasingly better. This model will prevail in time. In the short term, the only alternative is to destroy patents from time to time – the Public Patent Foundation last year destroyed a false patent of Microsoft. We need to support free software structure and identify where there are patents in the way.

Will Rodger, Computer and Communications Industry Association (CCIA), www.ccia.net.org/
Property is something that can be owned and protected by the law - a natural right. Unfortunately society has treated patents in the same way with a rise of ever-aggressive IP lawyers trying to convince lawmakers that patents are property. However, we must step back and identify the greater good.

An EU Software Directive would formally allow patenting of software for the first time. In theory, the European Patent Office has not allowed the patenting of software (although, in practice, many countries have allowed for this). Patents are all around us, and therefore they cannot be novel, or in merit of protection. Patents for trivial things are beginning to gum up the works and are impeding innovation.

Software is about taking tiny steps forward, “standing on the shoulders of patents”. The fact that Linux is infringing 231 patents, rather than being an indictment of Linux, gives pause to stand back and ask what’s going on. So what is industry doing about this? IBM, Sun and Nokia, for example, are moving towards Open Source software and beginning to release patents.

One perverse outcome of the current situation is the rise of defensive patents – companies taking out patents, and collecting them as chips, to protect themselves against multi-million dollar lawsuits.

In conclusion, patents are not a God-given right, and not included in the Magna Carta. Hopefully we are beginning to return to the concept of a patent as something that benefits society and not just a way of collecting rents.

Harald Alvestrand, Internet Engineering Task Force www.ietf.org
Things have changed in recent years, with the fear of patents being used as a business tool. There are many ways in which you can use a patent to get your way without actually licensing it, with the patent-owner benefiting irrespective of whether it’s a valid patent or not. People can also use the threat of a patent to influence how standards are written. So, no matter how original someone’s thought is, there are consequences they can be afraid of, and this fear creates choices - they can give up and go away; or they can stockpile arms (defensive patents). This is completely irrational from a societal perspective.

Companies are not powerful enough to break this cycle, but governments may be, because they can make rules that all companies and individuals are obliged to follow. Governments can declare that certain fields of activity are not patentable, and they can define maximum levels of patenting. This could make risk manageable, and limit the amount that inventors have to eventually pay.

Panel 5 - How should concerns about intellectual property be balanced with other concerns, e.g. competition, health and safety, and development?

Chair: Phil Evans, Which? www.which.net

Cornelia Kutterer, BEUC (The European Consumers Organisation) www.beuc.org
BEUC is lobbying for a balanced IP regime. At the moment, under EU IP regimes, compulsory licensing can be exercised but is very limited, as IP Rights (IPR) are based on property rights. The EU is as important as the US in terms of the Development Agenda at WIPO – the European Commission (EC) recently refused to answer the formal question of a European Parliamentarian as to the EC’s position on the Development Agenda. More involvement is needed from academics in Europe, in the discussion and the lobbying.

We need a moratorium on all new IP legislation in Europe - evaluations are needed for evidence-based policy, and we need to use a burden of proof when deciding whether to strengthen IP protection.

IP rights produce costs for society - enforcement, trials and lawyers are very expensive and the strategic uses of patents – i.e. patent walls etc – are detrimental to society. We must think about competition in terms of strengthening or weakening IPR. The EC recently announced that all EU regulations should be made as competition-friendly as possible, and wants this weighed as a factor in all drawing-up of regulation.

Sanya Reid Smith, Third World Network www.twinside.org.sg

High IPR protection is worse for developing than developed countries because patents in developing countries are overwhelmingly held by developed country entities, causing a huge net transfer from South to North, and administrative costs of implementing high IPR protection are prohibitive for poor countries. Furthermore, patents raise prices compared to when generic competitors are present in the market; and product and process patents can impede technology transfer and industrial development. Finally, most developing countries lack the legislation and administrative capacity to implement a strong competition law, something that provides a check on IPRs in developed countries.

Developing countries should not harmonize upwards to the level of developed countries via bilateral or multilateral pressure. Instead, they should limit the granting of patents, by keeping the scope of patentable subject matter narrow; by maintaining high standards for patentability criteria to prevent patents for discoveries, ever greening or traditional knowledge; by enabling as much opposition to patents as possible. As well as limiting the granting of patents, they should avoid TRIPS+ provisions, such as patent term extensions; use all the flexibilities they are entitled to, such as compulsory licenses, parallel importation, government/non-commercial use; and control anti-competitive practices in contractual licenses, as permitted by TRIPS.

Carlos Correa, Universidad de Buenos Aires www.netamericas.net/Paginas/ccorreaWP.asp

Compulsory licensing can introduce some competition into the system, and some evidence exists that the patent holder can retain a leading market-position. Creating such competition is important as it increases availability of the drug, and can also serve to promote technology transfer or increase the affordability of products.

Therefore, compulsory licensing could be a useful mechanism to improve balance, but why, then, are developing countries not using them, even though a large number of compulsory licenses are granted in the US, for example. Possible reasons: maybe WIPO's technical assistance is lacking? Maybe there is insufficient infrastructure in the country to manufacture the required drug? Maybe there are questions of legal uncertainty, such as how much it would cost to take action and how likely they are to succeed? Maybe there is a desire not to antagonize patent-holders but instead to work in alliance with them?

This last one is a key reason, as governments are under strong threats not to use compulsory licensing. This political problem must be solved – other countries should be permitted to use it as much as the US. In any case, compulsory licensing should be used as a second line of defense – if bad patents were no longer granted it would reduce the number of cases where compulsory licenses need to be used.

In closing, the chair, Phil Evans, said that competition authorities hate excessive pricing, which is caused by some patents, and competition is one of the few ways to keep the system in check.

Panel 6: What needs to be harmonized?

Chair: Jack Balkin, Yale Law School www.law.yale.edu/outside/html/faculty/jbalkin/profile.htm

Jorge Avila, Instituto Nacional de Propriedade Industrial, Brazil www.inpi.gov.br

On current trends, patents are becoming broader and increasingly pervasive. The rights of patent-holders are being strengthened, as are enforcement practices. Patent systems that are too broad, strong and unpredictable may become barriers to trade, as they generate strong and unregulated monopolies.

A pro-development harmonization agenda should limit patents to effective non-obvious innovation and limit the admissible scope of patent claims. It should establish minimum patterns of information disclosure and maximum standards for the rights associated to patents, and would also establish regulatory practices adequate to deal with patent-induced market-power abuse.

Jerome Reichman, Duke Law School www.law.duke.edu/fac/reichman

We should be aware that developing countries have divergent interests. Due to a distrust of harmonization, we should instead experimentally develop different approaches to stimulating innovation - valid experiments that lead to bottom-up proposals that fit with development goals.

We must ensure that developing countries are connected to the worldwide flow of scientific cooperation. Government-funded and generated scientific research should be widely distributed at affordable cost. Innovation should lead to the support of public goods. Two new resources that are valuable in looking at these issues are:

- the UNCTAD-ICTSD “Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement” (www.iprsonline.org/unctadictsd/ResourceBookIndex.htm), and ;
- “International Public Goods and Transfer of Technology Under A Globalized Intellectual Property Regime”, edited by Jerome Reichman (www.cambridge.org/uk/catalogue/catalogue.asp?isbn=0521841968)

IP propagandists want us to believe that we are at the end of history and that they should guide us. Actually we’ve entered a new threshold - unprecedented opportunities but uncharted ways of accessing them. It is precisely a time for experimenting, not a time to lock in obsolete standards that will boomerang on developing countries.

Luis Villarroel, Ministry of Education, Chile www.mineduc.cl

Chile has a proposal on exceptions and limitations of copyright at the WIPO Standing Committee on Copyright. In Latin America most countries have exceptions for quotations, news reporting, educational use, etc. However, the scope of exceptions are so different in each country that you cannot reliably exchange information as you don’t know whether it’ll be legal to use it in another country in the region. Almost none have compulsory licensing for broadcasting. A new enforcement standard introduced through the Free Trade Area of the Americas means that the situation is radically changing.

There is definitely a need to improve limits and exceptions and the way to do this is discussion in international fora. Discussion is just starting and it is too early to say exactly what the list of minimum exceptions should be, but this should be picked up along with the other Development Agenda and A2K issues being currently discussed. Also, we should look at how to promote the public domain. Identifying, in a harmonized way, who is the right holder will facilitate identification of which works are in public domain, and help track down the rights-holders of those not in the public domain.

Ronaldo Lemos da Silva, Getulio Vargas Foundation Law School www.fgv.br

In Brazil there are initiatives on free software and creative commons, but these carry political risks. The US Government says that Brazil is not doing enough to address copyright infringement and should carry out more prosecution. This creates a tsunami of enforcement actions to protect industry, leading to prosecutions, even of people photocopying books.

So where is Brazil’s thriving cultural industry? Much of Brazil’s thriving cultural industries are using pirate infrastructure (e.g. tecno-brega) to sell legitimate products by the same street vendors that also sell pirated copies. This is because it is a price infrastructure nearer to the affordability of their market. In music, for example, in the first half of 2004 four major record labels in Brazil (who represent 85% of sales) released 48

CDs, and the independent sector released over 200. Regarding free software, Cleber dos Santos has created his own distribution of Linux especially for programmes aimed at digital inclusion. Building the southern dialogue on IP, media and culture is not so much about harmonizing IP laws, but rather figuring out where they are unnecessary.

Claudio Prado, Ministry of Culture, Brazil www.cultura.gov.br

Digital culture is an iceberg with three visible tips – the Internet (a new anarchical institution where everyone has equal access), free software (it was unforeseeable 14 years ago that a group of people working for free could challenge Microsoft) and IP rights.

The Brazilian Minister of Culture, Gilberto Gil, professed himself “a defender, user and promoter of free software – the most intense manifestation of freedom of thought and creation. Digital culture is similar to the spirit of the ‘60s – a radically new system in which hacker ethics are not money-driven.”

New digital means of distribution mean that, with a click, any work can be sent instantly and at no cost to any number of people. Physical manufacture, copying, delivery seems antiquated in wake of this new digital delivery system.

The Brazilian Government is running a project aimed at bridging the digital divide - grants available for NGOs to work on these issues with access to broadband and a multimedia kit, all using free software – so that people can interact not only in text but also in graphic and audiovisual images. The aim is to jump from the 19th Century directly to the 21st cutting out the 20th Century.

Day 2 - Medical Research and Development - Tuesday 14 June 2005

Discussions addressed the thorny problem of how getting the balance right between promoting innovation and providing access.

Morning – The trade framework

Panel 1 - Current Trade framework

Chair: Rhoda Karpatkin, Consumers Union www.consumersunion.org

Carlos Correa, University of Buenos Aires www.netamericas.net/Paginas/ccorreaWP.asp

The TRIPS agreement was a major victory for the pharmaceutical industry, as for the first time it gained an international instrument for protecting and enforcing patents, and protecting test data. TRIPS left some safeguards and exceptions, such as compulsory licensing, and allowed for parallel importing. But in bilateral free trade agreement (FTA) negotiations even more protection has been, and is being, requested, especially by the US – TRIPS-plus provisions (ones that go beyond the TRIPS agreement) allow patents for secondary implications and extensions of the patent time, as well as requirements regarding test data.

Not all FTAs are identical – some countries, such as Chile, have negotiated better and have less TRIPS-plus provisions than can be found in other FTAs. So, why do developing and some developed countries (e.g. Australia) accept such stringent protections that incur significant costs, in terms of higher prices and limited access to generic medicines? One argument is that these countries will gain through other parts of the FTA that would compensate for any losses in public health. Another mooted reason is that health authorities are not informed about these negotiations, or are participating with a very weak voice.

In some cases, the FTAs provide protection that is not even available in the US (US-plus provisions), and it is unlikely that these will be applied in the US. We would then have the paradox of US pharmaceutical companies get more protection in poor countries than in the US.

In some FTA negotiations, countries have exchanged letters saying that nothing in the FTA should be understood to be against the Doha Declaration, and that if there is a public health crisis the data protection

provisions would will not come into force. However, these letters will be unlikely to have any have legal force and are just a cosmetic solution to show that FTAs are sensitive to public health issues.

One promising development is that, while some countries have signed up, others have refused – such as South Africa, Ecuador, Columbia and Bolivia, and the African Union has recently called for no TRIPS-plus provisions in any EU Partnership Agreements.

Amy Kapczynski, Yale Law School / School of Public Health www.law.yale.edu

Some mechanism is necessary to promote innovation and Research & Development, but it does not have to be the current system. There is no evidence that this system is efficient; in fact, it is highly inefficient. Since 1991, with R&D doubling and the number of patents rising every year, the number of new medicines is declining. 76% of drugs produced in 1990 showed no significant medical advances (known as “me too” drugs). The majority of drugs that do offer significant therapeutic benefit were produced with the necessary support of public sector research.

There are real problems with patent-holders using their patents to prevent further research. The public sector is moving away from open science model to private, not sharing, patent model.

The Yale proposal focuses on the role of universities that, in the US, do 50% of basic R&D. Of companies surveyed, 27% of drugs would have been substantially delayed without academic research, and 70% use some academic research. General Public Licenses are government-issued patents issued in software that encourages sharing. This is an alternative model that Yale is looking at to develop the ‘sharing’ concept that allows open competition where universities play a key role.

Sanya Reid Smith, Third World Network www.twinside.org.sg

How have countries implemented the FTAs? In particular, how have they tackled Article 39.3 of TRIPS?

In Australia the burden was put on generic producers, requiring them to make a declaration that they do not believe they infringing a valid patent. Then the opposition Labor Party added significant financial penalties (A\$10m) to patent holders who take advantage of this provision to vexatiously bring actions, as a delaying tactic. If patentees are granted injunctions that are found to be not well-founded then the patentee has to pay compensation. So Australia has put in place an unusual system of financial penalties to discourage patentees from using the clause.

Malaysia wanted to provide cheap anti-retrovirals to its public, so it tried to get voluntary price reductions from producers. The threat of compulsory licensing lead to GlaxoSmithKline reducing their prices, but the government went ahead and introduced compulsory licensing.

GlaxoSmithKline complained and threatened to withdraw foreign investment. The Malaysian government offered 4% remuneration to pharmaceutical companies, but the patent holders have not come forward to ask for it, presumably because they do not want to establish a precedent by appearing to accept and condone the action. Now they see that government are prepared to use compulsory licensing they are more likely to come to table and offer to reduce prices.

A very good resource investigating the implementation of marketing approval protection under TRIPS is Carlos Correa’s South Centre study on “Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement” www.southcentre.org/publications/protection/toc.htm .

In discussion, James Love noted that the European Commission (EC) and European governments are also intervening in this area. The EC pressured China not to issue compulsory licensing in 2003, and the EU is proud of its involvement in setting minimum price control in South Korea, even though such price controls cannot exist in EU Member States.

Ellen T’Hoen questioned the use of the term “bilateral agreements”, and proposed to instead talk about unilateral actions, as this is a more accurate description given US Government behaviour. There was agreement about the need to strengthen the multilateral system, but questions about how this can be done under the current political leadership.

It was suggested that the strategy for negotiating with the US should be not to talk to the USTR, but to negotiate with the US public in the broader sense. And you have to put something on the table that changes the nature of the negotiation – for instance, a bilateral R&D+ agreement would change the dynamic and capture the imagination.

Panel 2 -- New Trade frameworks

Chair: Sakiko Fukuda-Parr, Harvard University www.harvard.edu

Michelle Childs, Consumer Project on Technology www.cptech.org

Beginning in 2002, a number of economists, scientists, public health experts and others began work on an alternative trade framework for medical R&D. This led to a proposal for a new treaty framework that would ultimately replace existing or planned trade agreements that focus on patents or drug prices.

The new paradigm includes minimum national obligations for supporting medical R&D - all countries should support costs of R&D, contributing an agreed fraction of their GDP to avoid free-riding. There would be flexibility regarding the business models, intellectual property rules or other mechanisms (such as open source approaches) a country would use to support R&D. There are also priority setting mechanisms, including a system of tradable credits for investments in particular projects that promote social or public interest objectives. Creating markets for public goods would improve on the current system that gives incentives for lifestyle medicines rather than rare diseases, or those primarily affecting the poorest consumers.

Details of the Medical R&D Treaty proposal, and the letter to the World Health Organisation, signed by scientists, public health experts, academics, economists, government officials, parliamentarians, and NGOs, can be found here: www.cptech.org/workingdrafts/rndtreaty.html

Ellen T’Hoen, Médecins Sans Frontières www.msf.org

Médecins Sans Frontières is involved in access to essential medicines debate because of all the problems that their doctors and nurses encounter in the field. The classic 10/90 gap (where 10% of R&D money is spend on the 90% of diseases) is the core problem, but with priority-setting determined by the market we should not be surprised by the outcome.

Innovation is defined as something that represents a benefit over what we already have. In France there’s an ongoing assessment of what goes on to the market. Out of 2000 products in recent years 7 were a major breakthrough and most were “me-too” drugs. Yet the industry is one of the most profitable in the world, so they do not want to do things differently. There is a growing recognition of the huge problems and public-private partnerships are increasingly appearing for major diseases, but these do not produce new medicines – they only supply drugs.

So what should a new system look like? Governments have to be back in the driving seats, determining priorities, which must be based on health needs and not on the market needs of the pharmaceutical companies. A new system needs access to, and transfer of, knowledge, tools and technology. Finally, the issue needs to be put on the agenda of both the WHO and WIPO.

Rodrigo Salinas, Department of Health, Chile www.conicyt.cl/bases/fondecyt/personas/6/4/6415.html

The Chilean government devotes a substantial amount of money to R&D, but less than 2% is set aside for pharmaceutical R&D. Furthermore, there is a formal requirement, tied to funding, for the inventor to show

how they are patenting their invention. The Chilean Department of Health had no idea of the impact of the treaty on access to medicines before it was signed.

This is election year in Chile and the four candidates make not a single mention of patents or R&D. We are all to blame for the lack of awareness on the issue – it is a failure of political commitment. A new R&D framework urgently needed. Political commitment of authorities is a must, but the commitment of civil society is needed to make this happen. We must improve the mechanisms we use to share knowledge, both among different state agencies, and between countries. This is not a politically neutral discussion – we need a candid and social discussion of the issues.

One obstacle to solving problems is that the WHO definition of health – not just the absence of illness, but complete well-being – is so comprehensive that we can't design any instrument to measure it.

Sisule Musungu, South Centre www.southcentre.org

The WHO Commission on Intellectual Property Rights (CIPR) was created because of an acceptance at the World Health Assembly that there was a problem in medical research. So we have to think about new ways of doing it, and the Medical R&D Treaty is one way of doing this, though we should look at it more as a framework than a treaty. The CIPR has no choice but to consider this proposal, which is the most advanced proposal that has been presented (except for those that want to keep the status quo). The results of the CIPR will be a very good basis from which to mobilize and encourage governments to act, so we must focus efforts on influencing the CIPR's conclusions.

The Chair, Sakiko Fukuda-Parr, kicked off discussion and noted that, in the marketplace, using patents (essentially a monopoly) produces three problems – distorted priorities, raised costs to pharmaceutical companies of doing R&D, and raised product costs. This is not a market failure; this is actually the market working very well.

Jerome Reichmann endorsed a call for socialized clinical trials, calling them a modest but very important and achievable step that could have a positive impact. Whether or not drugs are public goods, clinical trials are public goods. One way to get more competition into the system and more drugs into the pipeline is to get more companies involved.

Rhoda Karpatkin suggested broadening the table and creating interest amongst people that would benefit by reaching out to consumer groups in developing countries, labor unions, students, teachers, nurses, and mothers. Enlarging the number of people who can address these issues from the ground up can perhaps provide more leverage for what we are trying to accomplish.

James Love explained that, to tackle the existing problems it is necessary to present a rival paradigm. You can question whether it is the best strategy, but this is a tactical proposal that is a better and more flexible alternative than TRIPS and the bilateral agreements. It is about giving flexibility for different countries to do it different ways – not about forcing one system or one view. It is also helpful to have something that is not zero-cost for the poorest countries – it's a symbolic way of persuading a US Congress that believes that everyone should pay.

Ellen T'Hoën gave the example of SARS as a very good example of public health-driven government policy - rich countries did not have confidence in the market and developed a diagnostic tool within 4 months to deal with the outbreak. Innovation must address needs, and reach the people who need it; otherwise it should not be considered innovation.

Afternoon – New thinking on the separation of markets for innovation and products

Panel 3 -- Pull and Push Methods

Chair: Nicoletta Dentico, Drugs for Neglected Diseases Initiative (DNDi) www.dndi.org

DNDi has launched an appeal looking at needs-based drug development, because of the fatal imbalance of the current drug development system. The appeal (www.researchappeal.org/) urges governments to take the lead in setting global research priorities by providing significant and sustained support, and by establishing new rules to stimulate R&D for diseases of the poor.

Terry Fisher, Harvard Law School www.tfisher.org

The appalling divergence of life expectancies is an immoral situation that drives our work. 95% of pharmaceutical revenue comes from a few western countries so it's not surprising that their priorities are thus skewed. So what are alternative tools, machinery available to create new push and pull methods for innovation?

Possible alternatives to the patent system include the following: facilitate price discrimination to reduce prices for existing products in developing countries; control drug companies' conduct; modify innovation-inducement systems in developing countries.

Two options in particular were examined. One is to use DALYs (disability-adjusted life years) as bankable and tradable measures, and each pharmaceutical firm would be required to achieve each year an aggregate DALY/revenue. This would help offset biases in current system against vaccines and diseases prevalent in developing countries. It is not a perfect system and would face enormous resistance from industry.

The other idea is to modify TRIPS so as to require all WTO Members to recognize, as inequitable conduct, the use of physical materials or knowledge obtained in violation of a member country's natural resource laws. This would be a powerful incentive to pharmaceutical companies to correct the current practice of bio-prospecting.

Barry Nalebuff, Yale School of Management <http://mba.yale.edu/faculty/professors/nalebuff.shtml>

Rather than reinventing systems from scratch, we should come up with changes that can be shown to work – problems are so large that we need to find some low-hanging fruit and show some successes. For example, we should focus on one disease, show that it works, and then do it ten more times.

One thing we know about competition is that you don't get rewarded for bringing price down, but actually, we should reward companies for helping to bring prices down. In the Hatch-Waxman Act you get rewarded for making something competitive. Whenever you show that a patent is invalid you should get a cut of the savings created.

Also, why should patents be granted for 100% of the market? Let someone patent for 50% of world and choose where they want. They will not lose a lot of incentives because they can still patent in parts of the world where all the revenue comes from (95% from the developed world).

James Love, Consumer Project on Technology www.cptech.org/jamie/

There are incremental improvements being worked upon in the U.S. Congress and around the world. This is important, but we also need an idea of where we should be at the end of the day, and tying the reward for innovation to the price of drug is not the future. A consequence of the current pricing system is that India is considered by pharmaceutical companies as a market of 50 million people, leaving 950 million Indians excluded because the logical profit point prices them out of the market.

The alternative is the Medical Innovation Prize Fund (MIPF), introduced to Congress by Representative Bernie Sanders (http://bernie.house.gov/prescriptions/rd_summary.htm). This \$60 billion fund would fundamentally restructure the prescription drug R&D system, simultaneously fostering more breakthrough drugs while dramatically decreasing the cost of these life-saving medicines. The MIPF, run by an independent Board of Trustees, would work by separating the markets for products from the markets for innovation – innovators would be rewarded from the MIPF rather than by skyrocketing prices imposed on each consumer, and, in turn, products would be subject to generic competition immediately upon FDA market approval.

The MIPF would make awards to developers of medicines, based on the incremental therapeutic benefits of new treatments, and would have minimum levels of funding for priority healthcare, such as global infectious diseases and neglected diseases primarily affecting the poor in developing countries. These prize pay-outs would be made over the first ten years of sale of a medicine and would be given to the developer of the new medicine, regardless of who actually sells the product to consumers. Investors would be free to obtain and use patents, until the FDA approves a new medicine. At that point, the patent owner would be remunerated from the MIPF, rather than from royalties on high drug prices.

Currently, the prize for innovation is a marketing monopoly, which drives the lobbying and actions of “big pharma”. If you can get past idea that a monopoly is an ordinary situation you can move to rationalize the manufacturing. It is far easier to sell a big idea to Congressman and other decision-makers, than a small technical idea, or some esoteric idea about patent extensions. CPTech will spend the next four years working on this in the U.S., because if this works then the world will follow, but we will only be able to change the system if we also change the U.S. system.

Cristina Possas, National STD-AIDS Program, Ministry of Health, Brazil <http://portal.saude.gov.br/saude>
Brazil is a good case study for evaluating the detrimental impacts of strong and non-flexible IP regimes in developing countries. Brazil’s situation is the opposite of India because it applied TRIPS immediately in 1996, whereas India built a national capacity for production and protected its industry. With India complying with TRIPS this year the prices of the drugs Brazil imports from India will rise, causing a critical situation in Brazil.

There is a human rights perspective and strong civil society participation in all the strategies and actions in Brazil, and a balance between prevention and treatment. There is an understanding in the Brazil’s Sexually Transmitted Diseases and AIDS programme that the IP regime is inefficient and that there is a need for a more balanced IP regimes.

Developing a technological network of big developing countries, and other South-South cooperation is very important to build an alternative to the current IP regimes.

Michael Behan, Representative Bernard Sanders Behan (www.bernie.house.gov/)

The extent to which Congress is paid for by the pharmaceutical industry, and the effect it has on any attempts to change USTR policies or domestic pharmaceutical policies, cannot be over-emphasized. In addition to using its profits for advertising and to field legions of sales reps to market prescription drugs in the U.S., it spends a major amount on politics. The Washington Post recorded that, two days after Republicans introduced a Medicare prescription drugs benefits Bill in 2002 ((a bill written entirely by the pharmaceutical industry), GlaxoSmithKline chaired a fundraiser and raised \$30m for the Republican party.

In 2003 the pharmaceutical industry alone spent over \$108m on lobbying on Capitol Hill, registering over 800 lobbyists (more than 1.5 for every member of Congress). This is what we’re up against. It lodged a relentless campaign to pass a Bill (which is now estimated to cost \$530billion over 10 years) that will give senior citizens a measly 10% discount, and will otherwise provide enormous subsidies to pharmaceutical companies. The Bill includes an explicit provision preventing the Secretary of Health and Human Services from negotiating price decreases.

U.S. consumers pay about 66% more for the same prescription drugs than Canadians do, according to Canadian government figures. One battle that was fought and won has allowed U.S. citizens to import drugs from outside the U.S., despite industry attempts to argue that this cannot be done safely. They are now allowed to buy from 26 different countries.

With regards to the Medical R&D Treaty, there is lot of frustration in Congress, especially among Republicans, about paying a disproportionate amount of global R&D, so there would be interest in a system that allocates R&D money proportionate to the wealth of the country. We don’t need to match the amount of

lobbyists from Pharma – if we have right arguments we just need to have endorsements from organizations and research to prove our point and help politicians and companies like GM understand what MRDT would mean to them.

Yochai Benkler, Yale Law School www.benkler.org

It is getting harder to ignore the success Free Software, and one great example is SETI (<http://setiathome.ssl.berkeley.edu/>) which is a network of people contributing unused time to create supercomputers.

About 50% of research of R&D is government-funded, through universities, and about 50% comes from the Big Pharma and Biotech industries. An interesting alternative is One World Health (www.oneworldhealth.org/), a non-profit pharmaceutical company.

An interesting strategy would be publicly-minded university licensing. Universities would be encouraged to try and persuade pharmaceutical companies to compete with generic manufacturers in lower-income countries. For instance, universities could give its research findings and IP to pharmaceutical companies on certain conditions, such as that they must distribute royalty-free in lower and middle-income countries.

Patents are broken but patent policy is mired in rent-seeking, and the political system is rotten. Universities can leverage portfolios to break the logjam.

In discussion, Jake Werksman (the Rockefeller Foundation) noted that there are changing attitudes on Capitol Hill towards developing countries, which are no longer seen as charity targets, and more as major economic competitors.

Ed Mierzwinski (U.S. PIRG) identified a shift, and said that James Love's ideas are paradigm changes that can really isolate Pharma and make changes. It is possible to make changes if you can shame Pharma, and it will be useful on the world stage to defeat them in U.S. where they are so powerful.

Panel 4 - Summary and open discussion of next steps

Joseph Stiglitz, Initiative for Policy Dialogue; www.policydialogue.org

There is a compelling case for revisiting the way that IP regimes function, in particular the framework for financing and distributing medicines – the costs of IP regimes become very high when we start talking about people's lives. IP is one of the most important issues in development and health, and talking about innovation systems is the right way of framing it.

An opportunity to revisit the way IP works is also provided by the unhappiness that the software industry is having with IP rules and that the whole world is having with Microsoft.

WIPO will discuss the Development Agenda and IPD hopes to set up a Task Force to articulate what a true development-oriented IP regime could look like.

James Love, Consumer Project on Technology www.cptech.org/jamie/

The story about the relationship between IP and innovation has not been well told at WIPO, with more focus being put on the relationship between IP and access to knowledge. We must address the concerns in the North about job loss and the transfer of technology bases.

There has not been a complete consensus today about how to go forward on medicine. More work needs to be done to find areas to agree and work on, and to then map out a political strategy as well as policy foundation.

The WIPO Development Agenda is now in play, so it is important to find ways to be supportive of process to lead it to as successful a conclusion as possible. To have more influence on the U.S. Government or European

we need to find powerful allies, such as key players in industry or proponents of competition, and motivations for them to join us.

Industry uses Geneva as way of showcasing ideas before they even have a constituency back home – the Webcasting Treaty is an example of something not being done at any national level, but Geneva is being used to establish ideas, and change the way people think about things. Rightsholder groups across sectors believe they have vested interested in locking up knowledge. For us, the relationship between people and knowledge goods is the unifying factor, so we should get together across the spectrum. We're stronger than we think we are but we need to learn how to manage our international alliance to become more effective and collaborative.

Ellen T'Hoen, Médecins Sans Frontières www.msf.org

WIPO is supposed to look at innovation, not necessarily just IP, so WIPO should be open to different methods to promote innovation if we ask the right questions. We need much more of these discussions in Geneva because the voices of this conference are not heard loudly enough there, where the propaganda and misinformation of the pharmaceutical industry is everywhere.

Cornelia Kutterer, BEUC www.beuc.org

As well as being involved in Geneva, we must think about influencing national governments too so as to influence from the ground up.

Guilherme de Aguiar Patriota, Brazil Ministry of Foreign Affairs www.mre.gov.br

The reality of negotiations at WIPO is not rational or intellectual - some are completely inflexible. It would be interesting to frame discussions less in terms of North-South, and look more at common interests, looking at innovation is one way of doing this. Diluting the developing country position to make it acceptable to the wider community is too risky as there's no assurance that support from developed countries will be forthcoming. So the North-South framework is kept, but we look for an additional segment on innovation.

Luis Villarroel, Ministry of Education, Chile www.mineduc.cl

It is impossible to get support for the Development Agenda in the countries of the North unless you can get their consumers and industry on side. It is very important to continue this discussion to keep informing people of what a more balanced approach consists of.

Marta Gabrieloni, Permanent Mission of Argentina in Geneva www.mrecic.gov.ar/

It's very difficult to see how we'll get concrete results in the near future because there is so much opposition from the Secretariat and WIPO members. But we have got the issues on the table and under discussion. It would be very helpful to receive as many substantive documents as possible to support the arguments for the Development Agenda in WIPO.

Eben Moglen, Columbia Law School <http://emoglen.law.columbia.edu/>

Talking to WIPO is a waste of time. The strategy must be about mixing our resources (fine minds) and objectives (free knowledge). The primary target is not governments but pharmaceutical companies, and the objective is to use trained minds to destroy the pharmaceutical industry. If you continue to talk about treaties as if they matter you will be in the same place in 20 years. Time and biology are on our side, but if you don't start soon you will continue to waste time and minds.

Yochai Benkler, Yale Law School www.benkler.org

There will be initial frictions in a movement of different backgrounds and interests that is just starting to understand their linkages. We are seeing that industry is not monolithic and does not necessarily share common interests. Increasingly we should use the term Access to Knowledge (A2K) to bridge development-oriented issues and the problems caused by rent-producing policies and rules.

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