

The Fourth Bellagio Series of Dialogues on Development and Intellectual Property

ICTSD-UNCTAD Dialogues:

“Moving the pro-development Intellectual Property agenda forward: Preserving Public Goods in Health, Education and Learning”

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FINAL REPORT

1. As part of the Rockefeller Foundation's Frati Series on Intellectual Property Policies and Development, the ICTSD-UNCTAD joint Project¹ has organized since 2002 dialogues focusing on a Development-Oriented Intellectual Property Policy.² A fourth dialogue, “*Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning*“, considered options and solutions to two critical issues in the current deliberations on intellectual property (IP): the protection of undisclosed information related to pharmaceutical products and the challenges to education and learning posed by new developments in copyright protection. The unifying theme was the preservation of public goods in these two key social sectors.
2. The main objectives of the Dialogue were to:
 - Discuss and analyze recent developments;
 - Consider the social and economic impact of new trends;
 - Examine relevant comparative experiences in developed and developing countries;

¹ The UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, launched in 2002. For details, see <http://www.iprsonline.org/unctadictsd/description.htm>

² "Towards Development-Oriented Policy: Setting an Agenda for the Next Five Years" (October 2002); "Advancing the Reform Agenda" (September 2003); and "Policy Options for Ensuring Affordable Access to Essential Medicines" (October 2004).

- Move forward the IP development-oriented agenda by exploring policy options for developing countries in the negotiations of new standards at the multilateral and bilateral level;
 - Set a follow-up plan to implement the conclusions reached including ongoing collaboration of a core network of individuals and institutions to contribute to monitoring developments and enhance capacity building in developing countries.
3. The main body of the report summarizes the discussions of the various issues. The two accompanying annexes reflect the brainstorming nature of the Dialogue and list in detail the several ideas and recommendations discussed and made by participants for future policy action and research.

(a) Overview of recent IP trends with emphasis on the protection of information³

(i) General trends

4. Participants were of the view that the TRIPS Agreement has represented a major shift in international IP rule making. It has considerably limited WTO Members' discretion with respect to the use of IP as a tool for the promotion of innovation. This development is characterized by the privatization of knowledge and the corresponding shrinking of the public domain. For example, the TRIPS Agreement has introduced a general obligation to provide patent rights for pharmaceutical products, thereby reducing the possibilities for early market entry of generic drugs, price competition and follow-on innovation through third parties. Also, the TRIPS Agreement has extended restrictions on copyright exceptions, making access to published material more difficult (for details, see below). Recently, the trend to privatize knowledge has even been deepened through the move from TRIPS to TRIPS-plus, as illustrated by recent WIPO initiatives and in particular free trade agreements (FTAs), including regional trade agreements (RTAs). As a response to this trend, participants emphasized the need to re-establish the necessary balance between producers and users of technical knowledge.
5. In more concrete terms, the recent trend to enclose essential basic information in the realm of IP can be illustrated by looking at the object of IP protection. Historically, IP law focused on the protection of outputs rather than inputs, and access has been assured through the limitation of subject matter, and the development of exceptions. At both the domestic and international level, a process of gap filling has taken place to reduce IPRs limitations and exceptions. At the same time, in some areas there is a tendency to shift the focus of IP law to the inputs themselves. In this respect, a new IP order is emerging. This development may be illustrated by: i) rules on data exclusivity; ii) protection of non-original databases (i.e. information including essential inputs); iii) patenting of research tools (i.e. building blocks of scientific

³ The discussion was based on papers presented to the Dialogue by Carlos Correa, Peter Jaszi, Clemente Forero, and Jerome Reichman. The papers are available at http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004-2/bell4_documentation.htm

knowledge that traditionally have been in the public domain); and iv) anti-circumvention regimes applying to information in its entirety as a consequence of trends in the USA and WIPO treaties. Participants underlined that this was not a healthy development and that affirmative strategies needed to be developed by stakeholders to secure access to knowledge.

6. In the light of the trend to move beyond the protection of creative and innovative ideas towards protection of economic activities constituting simple investments, participants raised the question if it was still appropriate to continue talking of trends in the IP system proper. They stressed the need to revisit the discourse.
7. With respect to the flexibilities permitted in national law under TRIPS, participants observed a lack of implementation by developing countries. In addition, concern was expressed about the danger of future compromises in the case of Africa, with respect to exemptions for public health.
8. Finally, a general observation was made on the role of developing countries in the international IP law making and on the need to re-assess their involvement and participation. Are they mere spectators? Is there a parallel between the evolution of general principles of international law in the colonial period and the present evolution of IP law? At the same time and paradoxically, as this great transformation of the system and marginalization of developing countries are taking place, there is greater awareness on the implications of these recent trends. In this latter context, participants highlighted the role being played by new civil society actors, as is the case in the health debate.

(ii) Public health: undisclosed information and clinical trials

9. With respect to public health, reference was made to the virtues and flaws of the Doha Declaration of November 2001 and the 30 August 2003 Decision. As one positive aspect, participants considered that the Decision had provided some negotiating leverage for governments in their dealings with the multinational pharmaceutical industry.
10. In the public health context, participants discussed in detail the issue of undisclosed information and the scope of Article 39.3, TRIPS Agreement, which provides that test data must be protected under the discipline of unfair competition, in the context of the Paris Convention. Test data do not imply any innovative activity, and its protection does not necessarily serve the purpose of promoting creativity but rather that of protecting investments. During the Uruguay Round, attempts by developed countries failed in expanding data protection to exclusive rights as done under NAFTA. Article 39.3, TRIPS, provides protection only against the unfair use of data by commercial competitors. Thus, Article 39.3, TRIPS, does not prevent governments from permitting production of relevant products or the manufacture of bio-equivalent products on the basis of regulatory decisions by other national authorities or the data underlying them. As to the implementation of Article 39, it was observed that there was no single model for data protection, with different approaches existing in the EU, the USA, Japan, and various developing countries. Reference was also made to the case of Guatemala, where the data protection regime had changed several times over a short period of time.

11. In this context, participants discussed the expansion of data exclusivity via free trade agreements (FTAs). The free trade agreements in this respect contain TRIPS-plus provisions, such as the prohibition of reliance on prior test data of both patented and off-patent products by marketing approval authorities; the requirement of local/national novelty of "new" chemical entities (as opposed to universal novelty); the requirement to extend exclusive protection for 5 years to data that has been *disclosed* through the grant of marketing approval (as opposed to the limitation of protection to *undisclosed* data under TRIPS); and the extension of data protection beyond the expiry of the corresponding patent.
12. Participants expressed concern about a number of implications generated by FTAs in terms of early working, compulsory licensing, the Doha Declaration, as well as ethical considerations. With respect to early working, it was observed that a number of FTAs did not authorize "Bolar"-type exceptions in the area of data exclusivity. In this context, reference was made to the distinction under new EU legislation between data and marketing exclusivity. The requirement in many FTAs that marketing approval during the patent term shall depend on the consent or acquiescence of the patent owner threatens the effectiveness of compulsory licensing as a tool to promote access to medicines, including the Decision for the implementation of paragraph 6 of the Doha Ministerial Declaration.
13. Participants agreed on the characterization of clinical trials (including the resulting test data) as public goods. The role of public institutions in carrying out clinical tests *vis-à-vis* the private sector was also discussed. In the IP system, the public domain used to be an important element of institutional settings, but the system has evolved. There has been a shifting of the public domain – as illustrated by the Bayh-Dole Act in the United States⁴ and laws concerning data exclusivity and protection of non-original databases.
14. On the other hand, participants pointed out that in certain sectors of industry, such as software, the protected subject matter tended to be so complex that even the disclosure of the invention did not effectively enable third parties to engage in follow-on innovation. As opposed to patent law, data exclusivity rules do not prevent third parties from providing similar clinical test data based on independent efforts (even though the economic barriers and risks for such exercise could be too high, for instance in the case of granting of voluntary licenses or price reductions by the patentee). In that respect, patents may be considered to limit the public domain to a greater extent than data protection rules.
15. The above changes and trends have particular effects in developing countries and in the area of science, where IP now covers information that was not protected before, and where rising costs of publication have been observed.
16. Participants agreed on the need to re-examine existing models for innovation and to consider new models, such as: an international R & D treaty; compensatory liability regimes as a cost sharing option (giving a right to use the data in exchange for an automatic right to compensation, thus avoiding access barriers to information); and, the treatment of clinical trials and

⁴ US legislation enacted in 1980 which grants the right to universities to patent federally funded inventions and provides incentives to them to license these technologies for commercialisation.

resulting data as public goods. In this respect, a further suggestion was made to produce this knowledge in internationally financed laboratories by placing it in the public domain (international public health research initiative).

17. Reference was also made to the importance of competition law for the control of abusive practices that diminish the public domain. It was noted that the TRIPS flexibilities in this respect (Articles 8.2 and 40) were not affected by current FTAs.
18. Annex I to this report lists the several ideas, research agendas and recommendations made on this segment of the deliberations.

(b) Fostering access to education, research, and dissemination of knowledge through copyright and challenges of open source models⁵

(i) General trends in copyright law: access to knowledge

19. In discussing a conceptual framework for copyright, participants expressed the view that there was a need for a paradigm shift. Instead of viewing public access to knowledge as a limitation or exception, access should be considered as a positive right to information. Some participants felt that current copyright law, instead of advancing intellectual creativity on a global scale, was mainly used to favour certain cultures, economies and corporate interests over others.
20. Participants expressed concern about increasing privatization of knowledge through copyright. In this context, the digital environment poses a two-fold challenge: a) the shift from print to electronic production means that less printed material is available in developing countries; b) the same shift results in easier control of access and dissemination by means of technology protection measures (TPMs) in combination with anti-circumvention provisions. Copyright was not conceived for the digital environment as is illustrated by the TRIPS copyrightability of software source and object codes; they constitute ideas, not mere expression. Thus, the traditional ideas/expression dichotomy is blurred in the digital area. The combination of technological protection with legal protection has led to over-protection. In this context, it was emphasized that the WIPO copyright treaties did not require domestic implementation comparable to the U.S. Digital Millennium Copyright Act (DMCA). Thus, developing countries should not simply import the DMCA, but rather the respective 1996 WIPO Copyright Treaty (WCT) provisions (allowing all exceptions consistent with law), as well as the Agreed Statements to the WCT.
21. Neither the Berne Convention nor the TRIPS Agreement contain specific access rights, as opposed to well-defined rights of protection. In this context, participants stressed the importance of the three-step-test under Article 13, TRIPS, which effectively limits the scope of limitations available to Members

⁵ The discussion was based on papers presented to the Dialogue by Ruth Okediji and Rishab Ghosh. The paper by Peter Jaszi, referred to above, was also relevant to this segment. The papers are available at http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004-2/bell4_documentation.htm

for the promotion of access and dissemination of copyrighted works.⁶ As opposed to Article 9(2) of the Berne Convention, the TRIPS Agreement extends the three-step test beyond the right of reproduction to apply to all the rights under the Berne Convention. It was observed that according to the WTO Panel in *United States - Section 110(5) of the U.S. Copyright Act*,⁷ payment of equitable compensation to the copyright holder would under certain circumstances be a means to pass the three-step test.

22. The right of distribution as incorporated in the WCT provides the copyright holder the right to control materials once they have been sold (on the Internet, posting and forwarding are considered to constitute distribution). This represents an exception to the exhaustion of copyright.

(ii) The Berne Appendix

23. The Berne Appendix for the compulsory licensing of copyrighted material was considered impracticable for developing countries, due to a number of reasons, such as:
- High transaction costs and problematic administrative procedures;
 - High risk, compared to low gain (the use was limited to teaching purposes, thus causing economies-of-scale problems);
 - The need for double licensing (one for translation, another for reproduction);
 - The broadcasting provisions were very limited (e.g., the broadcasting organization must be headquartered in the respective country);
 - Some USA-sponsored FTAs require abstention from the use of the Berne Appendix;
 - Most FTAs (USA and EU) require WCT and WPPT TRIPS-plus standards on limitations and exceptions. The EU approach requires respect of “highest international protection standards”. This emerging state practice is problematic;
 - The Appendix is rarely used. Attempts to use it have encountered threats of unilateral trade sanctions.
24. Participants observed that instead of the Berne Appendix, the general flexibilities of the TRIPS Agreement, particularly Articles 8 and 40, provided developing countries with space to adopt public policy measures according to their circumstances and needs. Discussing further alternatives to the Berne Appendix, the view was expressed that the value of the “fair-use” doctrine was vastly overrated. It has become the focus to address all limitations and exceptions, while actually it was very limited under U.S. jurisprudence. The more valuable avenue for the promotion of access to information is the idea/expression test. The latter is threatened by the U.S. DMCA, which renders illegal circumvention measures targeted at the idea itself, not the expression.

⁶ According to the three-step-test in Article 13 of the TRIPS Agreement, exceptions to exclusive copyrights 1. must be confined to certain special cases; 2. must not conflict with a normal exploitation of the work; and 3. must not unreasonably prejudice the legitimate interests of the right holder. Every copyright exception must satisfy these three cumulative requirements.

⁷ WT/DS160/R of 15 June 2000.

(iii) Free Open Source Software (FOSS)

25. Participants further discussed the development potential of Free Open Source Software (FOSS), with particular reference to the promotion of the ability to create and to add value. It was stressed that participation in FOSS, as opposed to proprietary software, promoted the development of certain skills such as programming, knowledge of copyright law and licensing practices, team work and team management. FOSS, from this perspective, may be qualified as a form of technology transfer (i.e. from those paying for formal training to those who do not have the means to do so). Finally, reference was made to the potential reduction of costs, considering the waiver under FOSS of licensing fees, as opposed to proprietary software. This was of particular importance in developing countries, where other expenses such as labour costs were relatively low.
26. As to the interaction of copyright and FOSS, it was clarified that under a FOSS license, copyright was used to preserve the open character of the software. The licensor waives his copyright to redistribute and modify the program on the condition that the licensee equally authorizes third parties to modify the program.
27. Participants further discussed means to translate the advantages of FOSS in practice. For instance, reference was made to the development of business models for developing country FOSS providers. Finally, participants were of the view that software patents may constitute a threat to FOSS, as they monopolize the ideas FOSS was supposed to build upon.
28. Annex II to this report lists the several ideas, research agendas and recommendations made by participants on this segment of the deliberations.

Annex I:

Recommendations: Policy Action and Research Gaps

Preserving Public Goods in Health⁸

(a) Advancing pro-development approaches to negotiations

Context: To advance a pro-development approach in various negotiation fora, the participants identified a host of framing issues and trends. The prevailing misconception that places “property over knowledge, where the exception is the public domain and access” demands response.

- Opportunities to reframe include the need: to replace “limitations and exceptions” with “user rights”; to re-conceptualise the notion of intellectual “property” and associated language like “theft”; to draw the line between IP protection of creative contributions and disguised protections of investments; and to decouple data exclusivity from the existing layer of IP protection;
- The TRIPS-plus process compromising the public domain and the production of public goods is not only happening in the South. The North is also concerned. Focus group-based research suggests that people in the USA resonate to notions of fairness, equity and distribution as well as invocations of corporate greed;
- Some have sought to advance intellectual property ownership as a human right in international agreements and covenants. If these efforts were to succeed, this would represent a major setback for those arguing that access to essential goods is the human right;
- Several normative trends were troubling:
 - Research institutions—from the North and now in the South—increasingly encourage appropriation of knowledge rather than research as a public good undertaking;
 - IP infringement has also become criminalized.

Recommendations/Research Leads:

- Undertake collective efforts to educate policymakers in developed and developing countries, including those in the judiciary;
- Formulate affirmative rights and strategies;
- Design strategies for differential IP regimes according to levels of development;
- Advocate differential pricing in the case of medicines, according to respective levels of development;

⁸ Carlos Correa and its rapporteur Anthony So chaired the Working Group that elaborated these recommendations, finally endorsed by the Dialogue.

- Build coalitions with Northern stakeholders (e.g. SMEs and consumer associations) and work with public opinion;
- Conduct further research to thwart efforts that seek to enshrine IP as a human right in various international agreements.⁹ Advancing competing rights of access to essential goods as human rights might play a role here.
- Draw out the distinction, through studies, of how IP should not serve as a means to protect investment as opposed to encourage invention and innovation;
- Define a comprehensive view as to what is meant by “rights to information”;
- In implementing trade secrets laws, based on Article 39.2, TRIPS, to consider translating in full the US Trade Secret Act, which provides for reverse engineering by honest means;
- There is a need for developing countries to define a positive agenda with short, medium and long-term objectives, comprising:
 - Opportunities of the development-oriented agenda in WIPO;
 - An example of a short-term defensive measure is to consider mitigating the impact of data exclusivity in terms of
 - Early working;
 - Compulsory licensing;
 - Exceptions;
 - Linkage with patent duration;
 - Waiting periods (to be defined);
 - Consideration of options in data exclusivity protection such as compensatory liability regimes that would include automatic rights and payments;
 - In the long term and with the view to improving transparency in the system and recognizing clinical trials as public goods, consideration of co-sharing solutions
 - Start consideration in less controversial areas such as neglected diseases and vaccines.

(b) Promoting new approaches to free trade agreements

Context: The Dialogue considered ways to use the free trade agreements (FTAs) as a means to avoid FTAs that are not in the interest of developing countries, and actions to mitigate the impact among those countries that had already accepted

⁹ The UN Committee on Economic, Social and Cultural Rights (CESCR) has engaged in drafting a General Comment on Article 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) concerning the right of everyone to benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author. In this context, concern has been expressed by civil society that the General Comment does not in sufficient clarity reflect the distinction between protecting the moral and material interests of authors on the one hand and the protection of intellectual property rights on the other hand. See Sisule F. Musungu , "The Right of Everyone to Benefit from the Protection of the Moral and Material Interests from any Scientific, Literary or Artistic Production of which he is the Author. Preliminary Comments on Draft General Comment No. 18" (on file with UNCTAD-ICTSD).

such FTAs. By “not in the interest of developing countries,” the Dialogue considered TRIPS plus provisions.

- The discussion touched on a range of issues to consider: i) building a coalition among developing countries to resist TRIPS-plus FTAs; ii) more sharply targeting those to mobilize in response to such FTAs; iii) avoiding obligations that exceeded requirements under Article 39.3, with the fallback option of a compensation approach to data; iv) preventing restraints on the option of exercising compulsory licensing; and v) minimizing the impact of anti-circumvention measures on access to medical information;
- In trade negotiations, market access concessions may be ephemeral, especially when other developing countries seek and are offered the same concessions. Market access may be given, but market share is no guarantee. In contrast, IP concessions are lasting.

Recommendations/Research leads:

- Develop options for negotiating a pro-development, alternative free trade regime. Such a regime would not accept TRIPS-plus obligations and prevent data exclusivity from becoming another layer of protection beyond IP. Advocate the application of the Doha Declaration to the data exclusivity regime as it relates to undisclosed clinical trial data. Explore opportunities and strategies to develop counter-regime norms in public health, human rights, and other international fora;
- Explore sustainable (as compared to ad hoc) strategies to build broad-based coalitions among developing countries and between stakeholders in developed and developing countries. Recognizing the perceived incentives for striking an FTA with the United States, undertake research and education on the implications of FTAs on broader development policy (investment, services and government procurement) beyond IP may be necessary. Weigh the trade-offs between ephemeral market access concessions versus lasting IP concessions;
- Conduct supportive analyses, such as assessments of priority medicine needs (possibly drawing on PAHO methodology), impact of scenarios of rising levels of data exclusivity (as done for Turkey), transparency or disclosure of investments protected under proposed FTAs, and costs of implementation of FTA requirements in a country that has signed a TRIPS-plus agreement;
- Study strategic negotiation issues for FTA discussions. Identify potential conflicting obligations sought by the USA and EU in the FTAs. Identify exceptions and limitations in US and EC laws that are omitted from the FTAs and TRIPS. Outline TRIPS-compliant affirmative rights and affirmative access strategies (including open source strategies);
- Explore the meaning and implications of side letters and agreements in relation to the FTAs;
- Study in detail the impact of the MFN clause on FTAs;
- Analyze the consequences of FTA-based non-violation complaints in the IP area;

- Assist developing countries in WTO litigation;
- Consider means of collaboration with policymakers and pharmaceutical manufacturers to ensure generic drug competition in developing countries.

(c) Recognizing clinical trials as a public good and developing new models of innovation

Context: The group discussed how to improve pharmaceutical innovation, particularly for neglected diseases endemic to developing countries. Several different, potentially complementary approaches entered the discussions—public-private partnerships, a system of treating and funding clinical trials as a public good, and an international R&D treaty.

- For neglected diseases, where the commercial market potential is low, intellectual property might be held less strongly, and there may be opportunities for developing new models of R&D, as well as licensing IP. However, sometimes the same target molecules might have potential not only as treatments for neglected diseases, but also for common diseases with commercial markets. In such cases, one may need to negotiate for IP access as a public good;
- Klausner, et al., had written a paper on the HIV/AIDS vaccine enterprise.¹⁰ In this paper, they had proposed a grid approach, where those involved might collectively and systematically investigate various options and share all of their data. One solution path that scientists considered was a data warehouse with several levels of confidentiality protection, thereby enabling different levels of access and data sharing with the larger research community;
- Public-private partnership suggests arrangements where the private partner might own rights over the invention, but in fact, there is a greater range of IP ownership possibilities to explore. As pharmaceuticals have become much less vertically integrated in recent years (with acquisitions from biotech and academia as well as contract research organizations), one might consider an alternative pipeline with subcontracted services, less encumbered by exclusive rights. If such a model were to work for neglected diseases, perhaps it might serve as an exemplar for other areas of drug R&D;
- The treatment of clinical trials as a public good would require tying public financing to correspondingly lower drug prices. This could be done through strengthening the government's ability and willingness to act on patent abuse through the threat of regulatory tools like compulsory licensing;
- Through an international R&D treaty, one could shift the trade framework from one focused on property rights to one focused on R&D. Mass social movements have come from big ideas like this one;

¹⁰ See paper at [http://www.aidsscience.org/Science/Science--Klausner_et_al_300\(5628\)2036.htm](http://www.aidsscience.org/Science/Science--Klausner_et_al_300(5628)2036.htm)

- Beyond IP, one also must consider other incentives among scientists to share their results, as in the Human Genome Project, or not to collaborate, such as the competition to discover and publish first;
- Define the role of dependent patents and their implications for R & D.

Recommendation/Research leads:

- Explore further the ideas of treating clinical trials as a public good and of pursuing an international R&D treaty. Consider whether alternative models of innovation might be developed, particularly where there is no commercial market, such as for neglected diseases;
- Promote a better understanding of liability regimes in the context of developing countries;
- Consider how to align incentives of investigators and institutional stakeholders for placing research into the public domain. How can one overcome the secrecy encouraged by competition among scientists and foster the collaboration seen in efforts like the Human Genome Project?; Put forward promising ideas for alternative approaches to supporting innovation to the WHO Commission on Innovation, Intellectual Property and Public Health.

(d) Exploring new models of pharmaceutical research, development and production

Under this overall theme, the dialogue discussed various sub-issues, such as

- Redefining approaches to technology transfer and commercialisation;
- Considering the new role of Least Developed Countries in pharmaceutical supply;
- Promoting the potential of patent pools; and
- Exploring regional collective action for pharmaceuticals.

Redefining approaches to technology transfer and commercialisation

Context: Much of the discussion focused on the Bayh-Dole Act in the United States and on whether it might serve as model or misstep as an approach to emulate in developing countries.

- Elements of the approach, taken under the Bayh-Dole Act, have spread to Japan and Europe, thereby prompting questions of whether the model was appropriate or not to countries at different stages of economic development;
- The potentially positive effects of subsidies on the promotion of innovation and R&D are widely recognized. On the one hand, the Bayh-Dole Act might help to leaven the knowledge generated in the university setting. Federally funded innovation, picked up by the private sector, depends on patenting and licensing encouraged by the Act for commercialisation;

- On the other hand, supporting innovation by awarding patents was described as inappropriate, applying only to the developed country context. From a developing country context, patenting university inventions might boomerang by creating costly exchange norms or cost barriers to research tools among these institutions;
- University technology transfer offices often face incentives to generate revenues for their institutions from the licensing of intellectual property. The costs of staffing these offices and patenting promising university inventions put pressure on these offices to recoup this sunken investment and more;
- In encouraging the commercialisation of federally funded research, the Bayh-Dole Act favoured U.S. small businesses, and reportedly this may affect the willingness of U.S. universities to partner or collaborate with developing country institutions on R&D.

Recommendations/Research leads:

- Re-define a research agenda for science and technology for developing countries. Explore the public domain of science and the sharing of available data with developing countries;
- Develop models for commercialising knowledge that optimally preserve public goods for health;
- Create an alternative metric—separate from the licensing revenue generated—for assessing the success of universities and their technology transfer offices in meeting the double bottom line of contributing to the knowledge or research commons;
- Conduct a study of the Bayh-Dole Act’s impact on international scientific collaboration with developing countries;
- Redefine the concept of transfer of technology as a better bargaining tool against over-protection trends.

Considering the new role of Least Developed Countries in pharmaceutical supply

Context: In many least developed countries, the status of patent protection on pharmaceuticals is not clearly known. Some may have product patent protection for drugs in place. This concern has been voiced for Bangladesh, a potential site for scaled-up pharmaceutical production among the ranks of least developed countries.

Recommendations/Research leads:

- Provide legal assistance to study the issues of existing pharmaceutical patent protection in least developed countries, particularly where pharmaceutical production might be scaled up till TRIPS obligations come into effect in 2016. Where there are obstacles to local production, consider options for reversing these impediments in country-level IP laws. Consider ways in which TRIPS obligations for technology transfer from developed to developing countries (Article 66, Paragraph 2) might be met;

- Assess the status of the generic pharmaceutical industry in different developing countries and where they stand with respect to the free trade agreements. Consider investment strategies that would be required to establish pharmaceutical suppliers among least developed countries. Assess this potential through the development of competitive indicators for establishing local generic drug manufacture. Conduct a study of what will happen to pharmaceutical production and supply in developing countries post-2005, especially as India and China fall under the curtain of TRIPS compliance;
- Explore the place of developing countries innovators in the incipient system of transnational innovation in the post-TRIPS era with the risk of facing marginalisation;
- With focus on preserving public goods on health, examine world data on patent protection. Park and Ginarte have an index that runs from 1960 through 1990. It was felt by some participants that there was bias in the construction of this index.

Promoting the potential of patent pools

Context: The pooling of intellectual property may have value upstream and downstream in the pharmaceutical value chain of production. Different patent holders may hold building blocks for vaccines, such as the malaria antigen MSP-1, and drugs in fixed-dose combinations, and assembling these components may be held up by high transaction costs or patent holdouts. Upstream, groups like the Malaria Vaccine Initiative seek to pool components necessary for R&D of a vaccine. Downstream, drawing upon the example of the aircraft manufacturers' patent pool, an essential drug patent pool might be proposed. Such a patent pool would seek voluntary licenses for essential drugs from drug manufacturers, but failing that it would seek compulsory licenses assigned by country governments.

Recommendations/Research leads:

- Study further the potential for upstream and downstream pooling of IP for pharmaceutical products. In particular, consider the creation of a patent pool on essential medicines, beginning with those needed to treat AIDS. Examine antitrust and other issues involved in implementation of a patent pool.

Exploring regional collective action for pharmaceuticals

Context: Developing countries may benefit from pooled procurement efforts for pharmaceuticals. The dialogue discussed how there might be synergy and cost savings in pooling these functions as part of a regional group of countries, sharing a similar endemicity and burden of disease.

- Better market intelligence on drug pricing and supply might strengthen their use of monopsony power against monopoly power;

- While some countries might register drugs by reference to another country with a well-established drug regulatory scheme, others require separate testing efforts. The costs of registering a pharmaceutical product for small developing country markets are sometimes prohibitive. And the costs of repeating bioequivalence studies and meeting other regulatory requirements specific to each and every country can be a barrier to generic drug entry;
- Harmonizing drug registration standards; increasing transparency of formulary selection, the prequalification of pharmaceutical suppliers, and tender processes; and ensuring guaranteed and timely payments for pharmaceutical procurement might be facilitated through regional, collective action;
- Collaboration on these different facets of procuring pharmaceuticals can occur at several different levels from joint procurement to coordinated purchases. Where the functions of national drug regulatory agencies are ceded to a regional authority, there will still remain many local activities to staff, such as post-marketing surveillance, and plans to build local and regional capacity for drug regulation should go hand in hand;
- In harmonizing drug registration at the regional level, one must beware of efforts that seek to set advanced technical standards in excess of any clinical or cost-effectiveness justification in developing country settings. Some have raised such concerns over the International Conference on Harmonization's efforts, which largely centre around industrialized countries;
- With drug registration occurring both at the EU country level and through the European Medicines Agency (EMA), there might be insights in the European experience for such a regional model.

Recommendations/Research leads:

- Support planning efforts to develop the business plan for regional collective action and pooled procurement of pharmaceuticals in the developing world.

Annex II:

Recommendations: Policy Action and Research Gaps

Fostering access to education, research, and dissemination of knowledge through copyright and challenges of open source models¹¹

(a) Reframing the debate

For too long, advocates of high levels of legal protection for intellectual productions have (literally) controlled the terms of the debate. Casting the case for protection in terms of “intellectual property” has influenced policy makers to conclude that any constraints on such protection are suspect and should be criminalized. In fact, however, one of the most important characteristics of any form of property (personal, real or intellectual) is its susceptibility to regulation: property rights derive from the state and are subject (with the broad framework of constitutional norms) to modification and revision in the public interest.

Although the vocabulary of intellectual property may be unavoidable, we must not fall into another terminological trap: that of characterizing public interest regulations of this form of property as “limitations and exceptions.” Although this is conventional usage, it carries with it an unfortunate and inappropriate implication that protection is the natural and normal state of things. The Dialogue was strongly of the view that, in future, the discourse of public interest regulations of intellectual property should be carried forward using an alternative vocabulary, such as “*public access rights to information*.”

(b) Resisting the re-regulation of the global economy

Context: The trend of expanding IPR regimes (in particular, TRIPS plus provisions in FTAs/RTAs) results in a re-regulation of the global economy. This trend produces tensions between the IPR regimes on the one hand and free trade provisions under the WTO on the other. In particular, it impermissibly constrains the sovereign power of the state to regulate property rights, stifles innovation, and restricts access to knowledge-based goods.

Recommendations/Research Leads:

- Research the appropriate level of competition necessary for the incipient transnational system of innovation to prosper. There is a need to determine how the rules should be formulated and who should be responsible for this formulation;

¹¹ Clemente Forero and rapporteur Vera Franz chaired the Working Group that elaborated these recommendations, finally endorsed by the Dialogue.

- Explore issues of compatibility between WTO free trade rules and the protectionist IPR provisions in FTAs/RTAs. Recent FTAs/RTAs have undermined free trade principles in IPR regulation and altered the balance of rights and obligations intrinsic to TRIPS. As a consequence, TRIPS' intended contribution to the promotion of technological innovation and transfer and dissemination of technology has been compromised;
- Call on the WTO Council for TRIPS to:
 - Consider and adopt the appropriate measures needed to prevent abuse of intellectual property rights by rights holders;
 - Consider and adopt the appropriate measures needed to prevent the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;
 - Undertake the review of implementation mandated under Article 71 of the Agreement in 2005 - when the transitional periods under Article 65 expire - with a view to examining the compatibility of emerging provisions under bilateral and regional agreements with TRIPS principles and provisions.

(c) Exploring opportunities for law and policy research and action promoting access to knowledge

Context: Sustainable access to knowledge is absolutely essential to the development enterprise of a country. There is a direct correlation between the availability of books and other literary and artistic works, and literacy levels in developing countries. Literacy is an indispensable aspect of development. Over 80 percent of educational materials used in developing countries come from developed countries. Likewise, progress in the health sector depends on ready access, on convenient and reasonable terms, to medical literature. Therefore, it is a matter of urgency for developing countries to develop mechanisms to facilitate access to locally relevant knowledge-based goods, especially educational and research materials. In particular, developing countries should be encouraged and supported in their efforts to reform the current international copyright regime, by introducing and promoting affirmative rights of access as well as maximum limits on copyright protection.

Recommendations/Research Leads:

- Catalogue and publicize the sources of public access rights permissible under the current international copyright regime, and the available models for articulating such rights. While there is no precise consensus about the exact scope of access rights provided for by international copyright law and permitted in national legislation, the Dialogue believes that there may be more opportunities here than generally are recognized, considering such sources of law and practice as the Berne Appendix; the three-step test of TRIPS Article 13; Articles 7, 8 and 40 of TRIPS; the preambles to the

1996 WIPO Conventions; and the “Agreed Statements” accompanying those conventions;¹²

- Develop a parallel list of access rights. This list should be made available to developed countries for their consideration, encouraging them to implement at the national level domestically relevant limitations and exceptions;
- Undertake an intensive six-month effort, in parallel with the research activities just described, to prepare a model law dealing with the implementation of “public access rights to information for culture, science, education and health” for consideration and possible adoption by developing countries. This effort should be undertaken in close cooperation with the governments of those countries, and be based on their assessment of development needs. The urgency of the recommendation derives from various sources, including the spread of FTAs/RTAs and the increasing prominence of “limitations and exceptions” in the agenda of WIPO. The proposed statutory language should cover both conventional copyright and “paracopyright” (i.e. anti-circumvention) legislation;¹³
- Encourage and support (in connection with the effort described in the preceding paragraph) the development of regional standards and approaches for access and dissemination. This could lead to the development of positive models of state practice for access rights;
- Draft model provisions on rights of access to information under anti-circumvention regimes, for inclusion in FTAs. In current FTA negotiations, the USA is pushing a version of anti-circumvention legislation offering space for only a few, narrowly defined exceptions and limitations. The permitted derogations reflect the interests of certain U.S. stakeholders, and are not tailored in any way to the needs of the countries with which these FTAs are being negotiated. Developing countries should develop (with help from NGO’s, experts and others) a consensus about a proposal for FTA language that would permit them to adopt appropriate solutions in their domestic implementing legislation;¹⁴ⁱ
- Propose a set of minimum mandatory limitations and exception and promote its codification in an international agreement, either as part of a

¹² In connection with the three-part test, this effort would deal (for example) with questions about to what extent national legislation could enable the distribution of educational and/or health-related materials on this basis without the authorization of the copyright owner, either without compensation or based on “equitable remuneration.” In addition, the effort would explore the possibility of enacting local legislation (based on Arts. 7, 8 and 40) that would create mechanisms for compulsory licensing of critical knowledge goods. And it would address the question of whether international agreements would permit local legislation to prohibit the enforcement of contractual restrictions that have the effect of overriding limitations on copyright provided for by statute.

¹³ The end product would be two-fold: a list of model provisions for possible adoption in national law and an accompanying explanatory memorandum.

¹⁴ The model FTA provisions representing this consensus could provide (for example) for education use exceptions for educational uses, library use exceptions, scientific use exceptions, etc. A more aggressive version of this approach might also include model language for so-called “encoding rules” in domestic implementing legislation, which would affirmatively prohibit the use of technological protection measures on digital information products of certain kinds (e.g. scientific data), insofar as they are made available within the territory of the country in question.

Treaty on Access to Knowledge or as a freestanding instrument. Research shall determine the areas to be included in such an instrument, including whether to limit its scope to knowledge-based goods traded across borders. With such an agreement in place, countries would be barred from negotiating access rights or mechanisms that are less than the minimum rights prescribed. Such a principle would prohibit the strategy of resorting to bilateral negotiations to pressure developing countries to narrow, waive, or relinquish flexibilities in existing copyright treaties;

- Research the reform and upgrade of the Berne Appendix for the digital age. There is a need for careful research and analysis to evaluate how the Appendix is supposed to function under the WCT, and what changes need to be made to ensure that access to digital works is enhanced, rather than impeded, by application of the Appendix. This research project could result in the development of a “model” Appendix that could form the basis for negotiations in WIPO in conjunction with the other efforts described above. This research could also provide new, innovative ideas for making the Appendix more user- friendly for developing countries such as the creation of on-line licenses, standardized forms to assist copyright offices in developing countries to process local requests for licenses, etc;
- Research and propose rules on IP exhaustion that would facilitate access through cross-border flows of trade (i.e., parallel imports). This would be an additional mechanism to promote access and competition in the market for knowledge-based goods;
- Develop a “Doomsday Scenario” detailing the impact of Technological Protection Measures (TPMs) on access to knowledge in developing countries;
- Investigate and test the latitude allowed by national legislation on information access rights (either now or in the future) for assembling compilations and other derivative works for use in developing country settings, particularly for the academic and non-profit sectors. In this connection, investigate how to make scientific data/materials and journals more accessible and relevant to researchers, faculty and students in these settings;
- Based on the analysis proposed in the previous paragraph, develop an 'open access' archive/mechanism across academic and non-profit institutions, where researchers and others might be encouraged by their institutions to deposit non-exclusive copies of their works in these repositories;
- Resist the proliferation of new *sui generis* forms of intellectual property that have the effect of withdrawing valuable information from the public domain; the primary risk here is that of protection for non-original databases, as practiced and advocated by the European Union.
- Promote strategies to prevent contractual agreements (especially in the form of “click-on” licenses), from being used to modify the default settings of intellectual property law in favour of restrictions on access.

(d) Advocating systems of knowledge production (open collaborative models) that inherently promote access to knowledge

Context: Open collaborative models (such as the Free Software and Open Source Software Movement/FOSS, Open Access Journals, the Human Genome Project, etc) have proven to be successful means for the production of knowledge-based public goods. Those models of production dramatically enhance the creation of and access to locally relevant knowledge in developing countries and should be exploited accordingly.¹⁵

The Dialogue discussions also highlighted the asymmetry of information between policymakers and those they regulate. Distribution, not just access, to such information was key in developing country settings.

Recommendations/Research Leads:

- Raise awareness in developing countries about the potential of FOSS and open collaborative models as effective competitive or ‘leapfrogging’ strategies;
- On the national level, promote through government procurement open standards and interoperability as means to successfully counter the software market’s tendencies towards natural monopolies. In particular, research the competitive nature of both public procurement regulation and practice and suggest ways in which tendering can be designed so as to offer a fair chance to multiple vendors and/or favour FOSS. Such research would need to recognize that public procurement in the software sector is frequently non-competitive by implicitly preferring specific proprietary software platforms supplied by a single vendor;¹⁶
- Develop and promote the adoption of a protocol enforcing the disclosure of patents in standard making processes, for both members and non-members of the standard making bodies (e.g. IETF, W3C). According to this protocol, patents covering technologies under consideration for adoption as a standard would have to be disclosed prior to their adoption as a standard. Undisclosed patents would be unenforceable. No conclusion has been reached as to the home of such a protocol. It could be part of the PCT or constitute a stand-alone instrument;
- Explore ways to alleviate the anti-competitive impact of contracts between major proprietary software companies and governments in developing countries;
- Develop a Doomsday Scenario (‘Risk Assessment’) on the effects of monopolies in large parts of the software market;
- Invite WIPO and other relevant organizations to undertake an assessment of anti-competitive practice in the software market;
- Encourage developing countries to explore opportunities to use Articles 8.2 and 40 of TRIPS to address the anti-competitive practices in the software market. Should developing country governments not be willing to

¹⁵ The following recommendations and research leads concern the benefits of FOSS as well as the interplay between FOSS and proprietary software markets in particular.

¹⁶ This recommendation relates not to the framework of international government procurement regulation, but rather to e.g. a national policy on ICT development.

consider this option, one should explore a strategy of collective action (individuals/NGOs) aiming at raising the issue of anti-competitive practices with the TRIPS Council;

- Study the difference and potential conflicts between patents and copyright for software. E.g., copyright regimes (as opposed to software patent regimes) do provide for the exception of reverse engineering;
- Compile a reader for developing country governments on the impact of copyright and patents on FOSS;
- Study the economic impact of software patents on both the development of proprietary and free and open source software;
- Explore in which areas other than software open collaborative models can be employed to produce knowledge-based public goods;
- Map the potential problem of asymmetry in information between the regulator and the regulated, between the public policymaker and private interests.
- Develop approaches — going beyond fair use — to ensure public policymakers' access to information at least tantamount to what those whom they regulate receive.
- Explore how open access journals and similar models might improve distribution as well as access to key information in developing countries.
