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Assessing the Development Impacts of Intellectual Property Negotiations, Proposals, Reforms and Agreements:

A concept note

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The Challenge and the Need

Historical evidence shows that well designed IP systems can benefit national economies just as poorly designed ones can harm them. But how does one go about designing an appropriate IP system or fine-tuning an existing one? The economic and social impact of IP reform is very hard to predict reliably, especially in the long-term, and particularly in the case of developing countries. This is a real handicap in the present situation where countries are pressured to negotiate and implement new multilateral trade rules, bilateral or regional free trade or investment agreements, and to respond to powerful stakeholder groups – often foreign ones – demanding changes to national regimes that may not serve the interests of their citizens and other domestic stakeholders. Such difficulties in measuring impacts make it difficult for governments and their representatives to know what negotiating position to adopt on IP, how best to handle complex trade issue-linkage bargains, and how far they should accommodate the demands of international business interests clamouring for change to domestic IP rules.

As with other areas of business regulation, IP policymaking is, or at least should be, a matter for *national* decision-making involving the collaboration of all *national* stakeholders, including owners, users and the public. Foreign interests should not be ignored but government business regulation is about what is good for the national economy and the country's citizens. Good policymaking cannot be based solely on the implementation of obligations accepted in multilateral treaties or regional or bilateral trade agreements. Unfortunately, policymaking often seems to be done in this way, which is to say that *polycytaking* is the norm rather than *policymaking*. What we have here are both technical and political challenges. Development Impact Assessment (DIA) processes, as suggested below, can help to solve the technical challenge. They may also contribute to overcoming the political challenge too.

The Development Impact Assessment idea is definitely one whose time has come. Thus, the Friends of Development suggested at the first session of the Inter-sessional Intergovernmental Meeting on a Development agenda for WIPO that implementing pro-development principles and guidelines in WIPO might involve:

*...undertaking independent, evidence-based “Development Impact Assessment” (DIA) to consider the possible implications of each norm-setting initiative for core sustainable development indicators such as innovation, access by the public to knowledge and products, job creation, poverty alleviation, equity, respect for cultural diversity, protection of biodiversity, health, and education, particularly in developing and least developed countries.*¹

Similarly, Sisule Musungu has suggested:

*... that independent evidence-based development impact assessments (DIA) should be undertaken to evaluate the possible implications of proposed norm-setting activities for key indicators such as the contribution to innovation, access to knowledge and education.*²

And most recently, Chile made the following proposal to the WIPO Provisional Committee on Proposals Related to a WIPO Development Agenda:

*We propose the preparation of a study to assess what the appropriate levels of intellectual property are, taking into account the particular situation in each country, specifically its degree of development and institutional capacity.*³

At the same meeting, the Friends of Development suggested that WIPO’s norm-setting activities should ensure, *inter alia*, that:

*before commencing norm-setting activities potential impacts, especially development impacts are analysed and the potential costs, especially for developing countries, are evaluated by means of strengthened member-driven evaluation, study and research mechanisms.*⁴

Moreover, according to the Friends of Development, a key question to be considered is that of:

What member-driven mechanisms, procedures or rules are necessary to enable WIPO to undertake independent and objective research and studies as well as evaluation, *including evaluation of development impacts* of intellectual property rules?

This concept note provides a preliminary exploration of the DIA. It is hoped that, if not this author, others may feel inspired to take the idea further so that it may be given a practical expression.

¹ WIPO doc. IIM/1/4, 2005.

² Musungu, SF “Rethinking innovation, development and intellectual property in the UN: WIPO and beyond”. Quaker International Affairs Programme, 2005

³ WIPO doc. PCDA/1/2, 2006.

⁴ WIPO doc. PCDA/1/5, 2006.

Potential and Limitations of Development Impact Assessments

The DIA concept does not seek to turn the economic-socio-environmental – that is to say, sustainable development-related – analysis of IP reform into an exact science. We are a long way from being able to perform such a feat. But promoting and operationalising it may have some positive strategic and practical results.

First, making DIAs a requirement places a heavy burden of proof on those demanding strengthened IP protection to produce more convincing evidence of its necessity than they customarily offer.

Second, related multi-disciplinary approaches like *Environmental Impact Assessment* and *Sustainability Impact Assessment* are well-established. In fact, impact assessments exist in various flavours. In the UK, the National Institute for Health and Clinical Excellence defines *Health Impact Assessment* as “a developing process that uses a range of methods and approaches to help identify and consider the potential – or actual – health and equity impacts of a proposal on a given population.” The Institute for Development Policy and Management at University of Manchester, UK, and the Stockholm Environment Institute have produced Sustainability Impact Assessments of proposed WTO multilateral negotiations for the European Commission. In 2001, the UNEP produced a *Reference Manual for the Integrated Assessment of Trade-related Policies*. Some of the methodologies, procedures and experiences employed in designing and carrying out these other types of impact assessment may be transferable. This is likely especially to be the case for assessments of trade negotiations and trade-related policies.

Third, if conceived holistically, DIA broadens assessment of the effects of IP reform far beyond narrow conceptions of economic efficiency such as Pareto optimality⁵ or Kaldor-Hicks efficiency,⁶ important as these may be, towards wider and deeper notions of development that incorporate human welfare and environmental sustainability. Consequently it can be an extremely valuable and appropriate analytical and decision-making tool for development.

Fourth, a catchy concept attracts attention and, one would hope, the interest of individuals who may devote their efforts to elaborating its meaning further.

⁵ “If an economic system is Pareto efficient, then it is the case that no individual can be made better off without another being made worse off. It is commonly accepted that outcomes that are not Pareto efficient are to be avoided, and therefore Pareto efficiency is an important criterion for evaluating economic systems and political policies.” http://en.wikipedia.org/wiki/Pareto_efficiency, visited 23 February 2006.

⁶ “Using Kaldor-Hicks efficiency, a more efficient outcome can leave some people worse off. Thus, an outcome is more efficient if those that are made better off could *in theory* compensate those that are made worse off ...” http://en.wikipedia.org/wiki/Kaldor-Hicks_efficiency, visited 16 February 2006.

Basic Elements of DIAs

Most impact assessments consist of at least two elements. The first is the assessment itself. The second is the on-going consultation process involving stakeholders and independent experts.

The assessment

The assessment would comprise determination of the *timing* of the DIA, its *objectives*, its *scope*, the *development indicators* to be selected, and of what *data* to be generated for measuring performance levels and monitoring trends in respect of the indicators. The assessment would lay out the *benefits*, *costs* and *risks*, but would not be just descriptive and analytical. It would of necessity be prescriptive; it must feed into policymaking, otherwise it is pointless.

The timing of the DIA is very important. It could take place at the start of negotiations or during the drafting stages of a given proposal, reform or agreement. But *ex post* DIAs may also generate useful results, for example, in terms of taking advantage of the interpretative flexibilities in adopted agreements and of designing “damage limitation” responses and counterproposals.

The scale and scope of the DIA could be very broad or reasonably narrow and would be determined by the following factors:

- *The scale of the assessment*
One could envisage an ambitious DIA whose scale is sustainable development in all its aspects. But in many cases, this would be infeasible and unnecessary. Or it could deal with a specific development objective like one of the Millennium Development Goals or Targets. Alternatively, one could focus the DIA on a particular issue of current concern to developing countries, such as the extent to which *access to knowledge*, *technology transfer* or the achievement of *food security* would be, or are being, facilitated or hindered.
- *The scope of the negotiation, proposal, reform or agreement*
The breadth could cover a whole agreement. This would be a huge task, especially with a complex and wide-ranging agreement like TRIPS and if a broad range of development indicators were being considered. It could, on the other hand, be more modest in its aims, such as assessing an FTA, provisions being considered for a WTO Ministerial Declaration or trade round, or a specific legal reform or rule change such as disclosure of origin, extension of copyright term, or introduction of 5 years’ pharmaceutical test data protection.
- *The number of development indicators*
A small number of indicators could be used, such as ones relating to the achievement of food security, or to universal access to medicines. On the other hand, one could select a range of indicators to cover a broader development issue

(or issues), such as those that may be gleaned from the UNDP Human Development Reports. Clearly, the number of indicators selected would largely depend on whether the focus of the DIA is development in its broadest sense or a specific development-related issue, or a development objective.

- *The geographical or economic breadth to be covered*
The DIA could have a global scope or it could be confined to a national economy. Alternatively, it may be limited to a specific economic activity, business sector or type of product.
- *The extent of accuracy desired*
One could envisage a thorough in-depth assessment. This may in some cases be expensive and time consuming. On the other hand, “quick and dirty” DIAs may still be worthwhile.

The consultation process

The consultation process should be multi-stakeholder and democratic, ensuring that all groups with an interest and expertise to offer including consumers and the poor have the opportunity to design, influence, monitor and review the process. If not, there is a real danger that the DIA could lack all legitimacy and be perceived as “rubber stamping” decisions already made. Also, without such an inclusive and open process, it will be much more difficult for governments to determine where exactly the national interest does lie in respect of IP law and policymaking.

The Next Step: Identifying a DIA Case Study

This note suggests that to better understand the potential and possible pitfalls of DIAs, it might be worthwhile to outline how an assessment could be carried out on the basis of a matter of current concern. A number of possibilities spring to mind. For example, one could plan DIAs on the food security implications of the various possible ways developing countries could implement TRIPS Article 27.3(b). Given that developing countries are accepting provisions relating to the protection of innovations in plant breeding and biotechnology in FTAs, the choice of food security is timely and may be quite revealing. Another topical focus of a DIA would be the development impacts of new rules requiring patent applicants to disclose the origin of genetic material used in an invention. Equally timely would be a DIA on the effects on public health of data exclusivity measures in free trade agreements.