Disclosure Requirements:  
Incorporating the CBD Principles in the TRIPS Agreement  

On the Road to Hong Kong  

Dialogue Co-organized by CIEL, ICTSD, IDDRI, IUCN, and QUNO  
3-6pm in Room A at the WTO Public Symposium,  
Geneva, Switzerland, 21 April 2005  

Meeting Report  

1. Under Paragraph 19 of the Doha Ministerial Declaration, the TRIPS Council, in its review of Article 27.3 (b) and Article 71.1 of the TRIPS Agreement, is instructed to consider the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). This mandate is strengthened and broadened by Paragraph 12 and 31 of the Doha Ministerial Declaration, which call for addressing outstanding implementation issues and for mutual supportiveness between the trade and environment regimes respectively. Since then, work has focused particularly on whether and how patent applicants should be obliged to disclose the origin or source of the genetic resource and traditional knowledge used in an invention and provide evidence of prior informed consent and benefit sharing.  

2. Several proposals have been made by a number of countries, showing an emerging willingness to deal with the substantive and practical aspects of the issues. At the same time, academics and experts in the field have produced valuable research material with practical suggestions on moving this debate forward. Nevertheless, it has proved difficult to find the common ground needed to make appropriate use of the opportunity offered by the Doha Mandate. The aim of the dialogue was to support this process by highlighting and constructively discussing some of the potentially promising proposals made in the recent past.  

3. Ricardo Meléndez-Ortiz (ICTSD) and Martha Chouchena Rojas (IUCN) moderated the dialogue, welcoming participants and explaining the goals and format of the event and relevance of the issues addressed. Ms. Chouchena Rojas, for instance, noted the urgency of the need to identify ways to move negotiations forward, due not only to developments in the WTO but also because of the ongoing negotiations towards an international regime on access and benefit sharing at the CBD, in which the issues of disclosure requirements and prior informed consent are critical. Mr. Meléndez-Ortiz emphasized Hong Kong as an opportunity to advance mutual supportiveness through a practical and operational approach such as disclosure requirements.  

Addressing Misappropriation at the International Level – What is the Role of the TRIPS Agreement?
4. Panelists on the first topic were Begoña Venero from the Peruvian Patent Office and Felix Addor from the Swiss Patent Office. Ms. Aguirre Venero stressed that disclosure requirements were essential to make the patent system healthier, and provided examples from the Andean region – the cases of “uña de gato” and “maca” – that demonstrate the need to introduce these requirements (see also the policy note prepared by Ms. Aguirre Venero for the dialogue). She explained the importance of the TRIPS Agreement in this context due to the international nature of misappropriation: countries in the Andean region are taking measures at the national and regional levels, but those measures are useless for patents granted in other countries.

5. Though Ms. Aguirre Venero said that progress should be made in all fora currently analyzing the issue, she emphasized the TRIPS Council as the principal forum, in which all countries would be bound by a solution. Moreover, she stated that there is an overarching need to re-balance the TRIPS Agreement: it needs to be more equitable in order to be stronger. Suggestions for moving forward included providing further concrete proposals and specific examples of misappropriation. In Hong Kong, she stressed that the objective should be a mandate to modify the TRIPS Agreement.

6. Felix Addor also considered practical examples to be important, and affirmed that the objective of the Swiss proposal on disclosure requirements was precisely to overcome practical problems. However, Mr. Addor clarified that Switzerland, while willing to engage in discussions and wanting patents to be fair insofar as recognizing contributions of all involved, is not a demandeur. In particular, Mr. Addor explained that the proposal has four purposes: transparency; traceability of the use of resources; improving technical prior art; and increasing trust. Moreover, disclosure of source could increase mutual supportiveness between the intellectual property system and the CBD (details of the Swiss proposal can be found in the policy note Mr. Addor prepared for the dialogue). Mr. Addor pointed out four main advantages of the optional approach, including a) much faster progress can be expected; b) it provides the chance to gain experience; c) results will be identical as Switzerland and other European countries are planning to include these requirements and they form a critical mass; d) it would not oblige developing countries to change their laws.

7. In regards to prior informed consent and benefit sharing, he noted that it was difficult to ask patent offices to determine the truthfulness of documents and that the few relevant national systems with considerable differences would also pose problems. He pointed out the Swiss proposal would allow interested parties to verify these issues. Moreover, Mr. Addor explained that, as the TRIPS Agreement does not impede national disclosure requirements, it would similarly not be an obstacle to requirements for prior informed consent and benefit sharing, though the practical problems mentioned would still apply. Finally, he stressed that modifying the TRIPS Agreement would require much time – first getting the mandate and then resolving it – and that the result would be a burdensome requirement to change all legislations, even developing and least developed countries. Mr. Addor emphasized that those problems do not burden implementation of the Swiss proposal: it may not as “sexy,” but it is more feasible.

8. During the discussion, several questions referred to the Swiss proposal, including the difficulties of determining the source of traditional knowledge and the “contradiction” between Switzerland supporting a voluntary approach in regards to disclosure but insisting on a mandatory approach in regards to geographical indications. Mr. Addor responded that finding traditional knowledge was indeed important, which is why Switzerland suggested the use of databases. On voluntary vs. mandatory approaches, he stated that, since Switzerland implements disclosure of source, it does not care whether the international system is mandatory or voluntary, but would object to setting a mandatory system and then granting full exceptions to developing countries. Ms. Aguirre Venero responded to a question regarding the issue of disclosure in bilateral trade agreements, saying it was a crucial topic for Peru – not just for the government but also for the
private sector and non-governmental organizations – in ongoing negotiations with the United States. She stated that, while the outcome of the negotiations was still unclear, Peru would not accept rules that force it to change its current laws.

**How to Operationalize the Disclosure Requirement at the National level in a Manner Supportive of the TRIPS Agreement and the CBD?**

9. Panelists on the second topic were Michael Gollin from Venable LLP and David Vivas Eugui from ICTSD. Mr. Vivas focused on the national policy actions needed to complement disclosure requirements and on the intellectual property rules at the bilateral level that may impact disclosure requirements. He stated that disclosure would bring benefits for the intellectual property system, but that national systems of access and benefit sharing, for instance, were also crucial. Only sixteen countries have developed these systems, and only a handful includes user measures. Mr. Vivas considered that, if users are going to use legal paths, these must practicable. For Mr. Vivas, the benefits of disclosure for the patent system are less emphasized than those for the CBD system, but they are just as important. Besides increasing patent quality and improving prior art search, disclosure would give credibility to the patent system by recognizing one of the key requirements of development countries.

10. In bilateral trade agreements, Mr. Vivas stated that a number of provisions may impact disclosure requirements, in some cases creating more of a need for these requirements. He pointed out that provisions limiting causes for revocation, demanding ratification of UPOV 1991, and encouraging the patenting of plants, for example, make challenging patents more difficult and thus increase the need for disclosure requirements. Mr. Vivas also referred to the Andean proposal in the free trade negotiations with the United States, which includes provisions on traditional knowledge and benefit sharing currently being analyzed by the United States. He considered it to be an important precedent because it contains very concrete proposals, which are also needed at the multilateral level.

11. Michael Gollin focused on the kind of framework needed to evaluate the feasibility of disclosure requirements. He identified several relevant factors, including a) compatibility with existing treaties; b) compatibility with national laws; c) political viability (national and international); d) consistency with rules and customs of patent practices; e) consistency with other laws; and f) ease of implementation. In this context, Mr. Gollin expressed that direct approaches to disclosure – with sanctions within the patent system – could be more problematic than indirect approaches – those with sanctions outside of the patent system. Indirect approaches, on their part, could be more problematic than voluntary. He provided examples of strict and less strict versions of disclosure requirements.

12. Mr. Gollin noted that one of the main arguments against disclosure requirements, the inconsistency with international law, had been ruled out (more detail on this point can be found in the policy note Mr. Gollin contributed to the dialogue). Another, the inconsistency with national law, has still not proved an issue. Nevertheless, Mr. Gollin pointed out there could be some problems with disclosure requirements, including those relating to lack of capacity, negative domestic consequences, and the challenges to comply if there is no national access and benefit-sharing regime. In moving forward, Mr. Gollin highlighted the need to look at details, for example through analysis of existing legislation and drafting of model laws: many disagreements would dissolve if the discussion moved to a more concrete level.

13. Due to time constraints, discussion on these issues was postponed until after the third topic.

**The TRIPS World after Disclosure of Source and Evidence of Prior Informed Consent and Benefit Sharing**
14. On this issue, the panelists were Graham Dutfield from the Queen Mary Intellectual Property Research Institute and Atul Kaushik from the Indian Mission to the WTO. Mr. Dutfield began by saying he was not against disclosure requirements, though he was skeptical. From the perspective that disclosure of all the steps and elements of the invention was a necessary part of the bargain where a monopoly is granted in exchange for dissemination of information, he considered it was fully justified. If disclosure requirements are to become a part of international law, however, there will be a price tag, Mr. Dutfield warned. As a result, the challenges to be overcome before Hong Kong, in his view, include lack of clarity in the use of terms and determining whether disclosure would make a difference in practice (please see the policy note presented by Graham Dutfield to this dialogue for more information).

15. One concept Mr. Dutfield considers must be clarified is “biopiracy,” which the disclosure requirements are meant to address. While it has been a useful word, Mr. Dutfield considered it is not a sufficiently clear basis for a proposal to change international law. In many of the biopiracy cases, for instance, the patent should not have been granted in first place. In other cases, it is simply an instance of incremental knowledge – which is true of all knowledge. It is unclear why the contribution of indigenous people should be granted recognition that is denied to anyone else. Other unclear terms, in the opinion of Mr. Dutfield, are “origin” and the relationship between the invention and the genetic resource or traditional knowledge. Finally, Mr. Dutfield wondered what practical difference disclosure requirements would really make, as stopping biopiracy is not ambitious enough. For adding value to biodiversity and thus conserving it, it is an element. However, disclosure should go even beyond this and be tied to industrial policy, for instance. It should be about making things happen rather than stopping things from happening.

16. Atul Kaushik agreed that more work was needed on defining key terms related to disclosure. “Biopiracy,” however, could be understood to refer to two situations: 1) when patents are granted over genetic resources or associated traditional knowledge that should not have been; and 2) when the patents granted should, but do not, reward the tradition of conserving these resources. These principles have been recognized in the CBD context, and form the basis of what is now being discussed in intellectual property fora. As to the proposal by a group of developing countries, Mr. Kaushik affirmed its aims were beyond a “transparency exercise”, as Mr. Addor had characterized disclosure. He explained the three elements of the proposal, including disclosure of source and country of origin, evidence of prior informed consent, and evidence of benefit-sharing. Mr. Kaushik then addressed some of the alleged burdens that would result from incorporating these disclosure requirements in the TRIPS Agreement. For example, Mr. Kaushik said that identifying the country of origin would not inadequately hinder the patent applicant, because if he does not have the information, he would not be obliged to seek it out. Similarly, Mr. Kaushik argued against the idea that patent applicants ought only to be required to agree to benefit-sharing when they are certain there will be financial profit. He noted that benefit-sharing arrangements nearly always involve elements of capacity-building and non-monetary benefits, while financial benefits are uncertain and may come later. As a result, Mr. Kaushik affirmed that many of the concerns about the proposal are merely hypothetical and can be resolved. Moreover, he said the time had arrived to discuss the specific changes that the WTO requires in its agreements.

17. Questions posed to the panelists referred to several issues, including: a) the reaction of Swiss industry to disclosure requirements; b) the “price” developing countries would be willing to pay for disclosure requirements in the Doha Development Agenda; c) the definition of legal provenance; and d) the identification of national regimes on access and benefit-sharing. Mr. Dutfield stated that his preference for the term “legal provenance” was due to the fact it was simpler to define than, for example, “source.” Mr. Kaushik noted that having a database of existing access and benefit-sharing regulations would not be difficult, and pointed out a number
of precedents, including registers for geographical indications. Regarding the “price” of disclosure requirements, he affirmed it had already been paid when the Doha Development Agenda was established. As a result, as one of the outstanding implementation issues, its resolution was a pre-requisite for the conclusion of the Doha Round.

18. Mr. Gollin called attention to the fact a “price” is paid not only at the international level, but also at the national and individual levels. Laws, for example, will be implemented by intellectual property professionals and will need to be understood by patent applicants, universities, etc. Mr. Addor said that, while he could not speak for industry, in Switzerland businesses had had the opportunity to consider and evaluate a concrete proposal. In his view, the developing country proposal was not at this level, despite claims of ripeness by developing countries. For example, as long as questions regarding the goals of the system have not been answered clearly, it is impossible to determine the “price” developing countries will have to pay. Ms. Aguirre Venero affirmed that, while much still could be done at a national level, an adequate access and benefit-sharing system requires rules to be included at the international level: disclosure requirements are a critical piece of the puzzle. Finally, Mr. Vivas stated that disclosure requirements would not be as controversial if the discussion moved from a political to a technical debate, which is the step that needs to be taken in discussions at the Council for TRIPS.

Conclusion

19. Mr. Meléndez-Ortiz and Ms. Chouchena Rojas closed the dialogue with some concluding thoughts. Mr. Meléndez-Ortiz, for instance, highlighted the fact that the status quo is clearly not satisfactory: there is a recognition that the issue needs to be addressed. Moreover, he emphasized that disclosure requirements were a critical topic in the context of the development dimension of the Doha Round. Ms. Chouchena Rojas emphasized that, while there is still a need to discuss the different options, the issue of disclosure requirements is clearly on the table and it provides an opportunity to demonstrate how mutual supportiveness can be achieved. She affirmed that this mutual supportiveness would benefit not only the CBD, but also the international intellectual property system.