

Geographical Indications and the Obligation to Disclose the Origin of Biological Materials: Is a Compromise Possible under TRIPS?

ICTSD Programme on IPRs and Sustainable Development

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Introduction

The proponents of the negotiations that led to the adoption of the TRIPS Agreement sought, and obtained, the establishment of a set of high minimum standards of protection in different areas of intellectual property. In response to the demands of its emerging biotechnology industry, the United States (US) was keen to ensure patent protection for inventions based on or related to biological materials.

While the TRIPS Agreement finally allowed Members to exclude plants and animals from patent protection, it obligated them to protect processes for the production of plants and animals to the extent they may be deemed not 'essentially biological',¹ as well as to grant patents over microorganisms (if they meet the patentability standards). The rationale for this artificial distinction between patentable and non-patentable subject matter is difficult to understand; it reflected perhaps developing countries' reluctance to accept an expansion of patent law in the area of living materials, but also the resistance by European countries to enter into obligations that would have required an amendment to the European Patent Convention (which does not allow patenting of plant varieties and animal races).

The mandated review of article 27.3(b) initiated in 1999 -but still pending- opened the door for requests by a number of developing countries to revise said article, *inter alia*, in order to make it compatible with the Convention on Biological Diversity (CBD). In fact, although the TRIPS Agreement was adopted in 1994, as part of the Final Act of the Uruguay Round, the negotiation of most of its clauses had already been concluded in 1991,² before the adoption of the CBD. During the 1990s, and in the light of the access and benefit sharing framework established by the CBD, a number of cases of misappropriation of genetic resources and associated traditional knowledge were reported, such as in relation to quinoa, ayahuasca, the neem tree, kava, barbasco, endod and turmeric.³ The recognition of the States' sovereign rights over the genetic resources under the CBD (article 3) put in a different perspective cases of misappropriation of genetic materials. 'Bio-piracy' became a growing

1 This concept, inspired in European law, has been narrowly defined by the European Patent Office (EPO), as illustrated by the Lubrizol case (decision T 320/87 of EPO, OJ. EPO, 1990). More recently, the EPO has granted patents on plants produced by conventional breeding methods. See, e.g., EP 1069819 on broccoli and EP 1211926 on tomatoes derived from conventional breeding (currently on appeal before the Enlarged Board of Appeal of the EPO).

2 After 1991, only two new provisions were introduced, in relation to compulsory licenses for semiconductors and non-violation cases. See Correa, Carlos (2007), *Trade Related Aspects of Intellectual Property Rights, A Commentary on the TRIPS Agreement*, Oxford University Press.

3 See, e.g., Mooney, Pat Roy (1998), "The Parts of Life. Agricultural Biodiversity, Indigenous Knowledge, and the Role of the Third System", *Development Dialogue*, Special Issue, Uppsala.



concern for developing countries, which impregnated the discussions about the review of article 27.3(b).

However, the effectiveness of developing countries in dealing with the issues of misappropriation of genetic resources has been limited by the proliferation of fora (WIPO, WTO, UNEP/CBD) in which intellectual property issues relevant to biological resources were addressed, and by the lack of coordination amongst developing countries. Abdel Latif has noted that

International deliberations on the relationship between IP, genetic resources and traditional knowledge provide a prominent example of the lack of coordination by developing countries in international IP standard-setting. In discussions on these issues at the CBD, the TRIPS Council, and WIPO, many developing countries have taken different positions with no other apparent justification than the lack of coordination between their respective delegations.⁴

Different reasons explain the absence of coherence in developing countries' positions on intellectual property as it relates to biological resources. They include limited staff in delegations, lack of resources to participate at a multiplicity of meetings in different international fora, and the fact that 'officials from the ministries of environment, which generally represent developing countries at CBD meetings, are often not fully informed of their countries' own proposals on genetic resources and traditional knowledge in other fora such as the WTO/TRIPS Council'.⁵ In some cases, the problem is that the view of the ministries involved in addressing a particular issue radically differ, and there are no mechanisms in place to formulate a unified national position.

The lack of coherence has reflected itself in the different positions taken by the same countries at the CBD, the TRIPS Council, and WIPO, for instance, on the appropriate forum (WTO/WIPO) to deal with issues of misappropriation of genetic resources, on the usefulness (strongly advocated by the US) of contractual agreements and databases in combating the misappropriation of genetic resources and traditional knowledge.⁶ Likewise, while several members of the Group of Like-Minded Megadiverse countries have proposed at the CBD the introduction of a mandatory

disclosure obligation for patent applications, the same countries did not support other members of this group with the same initiative at the TRIPS Council.⁷

Despite some signs of an increased coordination among developing countries in different fora, there are, in certain areas, diverging views on processes and substance. Notably, the proposal to enhance the protection of geographical indications (GIs) has been a particularly divisive issue amongst developing countries. India, Brazil, China, Ecuador, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and a number of African countries believe that GIs' enhanced protection will be to their benefit, whereas Argentina, Uruguay, Chile and other developing countries consider that such a proposal, if adopted, will bring disproportionate advantages to European producers.

The requirement to disclose the origin of genetic materials claimed in patent applications has gathered considerable support from developing countries. Among developed countries, Switzerland and the European Union (EU) have accepted the principle, but differ with regard to the nature of the requirement or the effects of non-compliance. In particular, they disagree about the possibility -pursued by developing countries- that a patent be revoked or otherwise limited in its effects if obtained in breach of a disclosure obligation regarding the origin of genetic resources or associated traditional knowledge.⁸

A proposal of 'draft TRIPS modalities' submitted by around 110 developed and developing countries at the WTO (see Annex), in 2008, attempts to link amendments to the TRIPS Agreement on three issues: creation of registry for GIs, establishment of a disclosure obligation, and extension of GIs protection.⁹ The proposal suggests the inclusion of these issues as part of the horizontal process in order to elaborate final draft legal texts with respect to each of these issues as part of the 'single undertaking'.

This policy brief examines, first, the elements under discussion in the 'draft TRIPS modalities, including a brief description of the origin of the proposals on the establishment of an international disclosure obligation. Second, it considers such modalities in the overall context of the Doha Work Programme and single undertaking. Finally, it presents some conclusions on the proposed modalities.

4 Abdel Latif, Ahmed (2005), *Developing Country Coordination in International Intellectual Property Standard - Setting*, 24 Working Paper, South Centre, 2005, p. 13, available at www.southcentre.org/index.php?option=com_docman.

5 Idem, p. 14.

6 Perhaps the most telling example of this situation was that of Peru, which was a vocal proponent of an anti-misappropriation regime in WTO and WIPO, but finally accepted a contractual approach in the Free Trade Agreement signed with the USA.

7 Idem, p. 29.

8 See, IP/C/W/369/Rev.1, 9 March 2006.

9 It should be noted that these three issues are not covered by the same negotiating mandate. Thus, at consultations held by WTO's Director General in October 2009, some Members questioned whether there was a mandate to negotiate a disclosure obligation. See Kanaga Raja, 'Lamy reports on GI extension, TRIPS/CBD consultations', *Third World Economics. Trends & Analysis, Issue No. 454, 1-15 August, p. 16*. See also See Frederick Abbott, *Post-mortem for the Geneva Mini-Ministerial: Where Does TRIPS Go From Here?*, Information Note Number 7, ICTSD, p. 1, available at ictsd.org/i/publications/16949/.

Elements in the ‘Draft TRIPS Modalities’

International registry for GIs

The EU was unable to obtain the establishment of an international registry for GIs during the Uruguay Round negotiations. The provision contained in article 23.4 of the Agreement stipulates that

In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

This provision established an obligation to negotiate (‘negotiations shall be undertaken’) but did not prejudge any particular outcome of the negotiations with regard to the modes and legal effects of notification and registration. The EU has not only been able to keep the issue on the negotiating agenda,¹⁰ but to expand it so as to cover not only wines but also ‘spirits’, which are not mentioned in article 23.4.

The ‘draft TRIPS modalities’ propose a system of registration that will give a strong legal effect to the registration of a GI, as it will create a presumption that it constitutes a protectable GI in accordance with the definition laid down in Article 22.1 of the TRIPS Agreement. Although this presumption would be rebuttable, the burden of proof would be shifted to the Member or the party applying for

the registration of a trademark or domestic GI.

In accordance with the proposal, allegations that a term has become, in common language, the common name of certain product will have to be substantiated. This means that the Member where registration of a GI has been sought or obtained would have to demonstrate ‘genericness’, either *ex officio* or upon request of a party.

Moreover, the international registry will have to be consulted not only for the registration of a GI but also of a trademark, thereby creating an obligation clearly beyond the TRIPS Agreement that would significantly strengthen foreign GIs vis-à-vis local trademarks.

Finally, the proposal suggests that the register be extended to all products, and not be limited to wines and spirits.

The ‘draft TRIPS modalities’ also contemplate ‘intensified’ ‘text-based’ negotiations in Special Sessions of the TRIPS Council. Recent discussions have shown, however, that deep differences on the subject still prevail at the Council for TRIPS.¹²

Disclosure obligation

The first proposals to introduce an obligation to disclose the origin of biological resources in patent applications were made in the context of the mandated but still pending review of article 27.3(b). Table 1 summarizes the first submissions to the Council for TRIPS on the subject.

Table 1: Disclosure obligation in the context of the review of article 27.3(b)

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|----------------------|---|
| India ¹³ | <ul style="list-style-type: none"> - Harmonise TRIPS with CBD either by requiring information on providers of genetic resources and countries of origin of biological material under TRIPS Art. 29, or by incorporating a provision that patents inconsistent with CBD Art. 15 must not be granted. - Exclude patents on all life forms. If this is not possible, then at least exclude patents based on traditional/indigenous knowledge and products and processes essentially derived from such knowledge. - There must be disclosure of the country of origin of the biological resource and associated knowledge, and proof of the provider’s consent, to ensure equitable sharing of benefits. - It should be left to national policy to decide what are patentable microorganisms, including in light of Art. 27.2 (morality or <i>ordre public</i>). - Developing countries like India cannot accept any further strengthening of the protection presently provided to life forms. |
| Brazil ¹⁴ | <ul style="list-style-type: none"> - Flexibility for members to exclude plants and animals should be retained. - Art. 27.3(b) should be amended to allow members to require further conditions for patentability, viz. (1) identification of source of genetic material; (2) traditional knowledge used to obtain that material; (3) evidence of fair and equitable benefit-sharing; and (4) evidence of prior informed consent for the exploitation of the patent. - Art. 27.3(b) should bear an interpretative note clarifying that discoveries or naturally occurring materials are not patentable. |

10 See paragraph 39 of the Hong Kong Ministerial Declaration, available at http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm.

11 See article 24.6 of the TRIPS Agreement.

12 See Third World Network (2009), ‘TRIPS Council takes up public health, TRIPS/CBD, drug seizure issues’, SUNS #6806 dated 3 November 2009, available at www.twinside.org.sg

13 IP/C/W/195 of 12 July 2000, WT/GC/W/255 of 16 July 1999, IP/C/W/196 of 12 July 2000, IP/C/W/161 of 3 November 1999 and WT/GC/W/294 of 5 August 1999.

14 IP/C/W/228 of 24 November 2000.

Table 1: *Continued*

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| Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe ¹⁵ | <p>- It should be clarified that the provisions on patenting of microorganisms only apply to genetically modified microorganisms.</p> <p>- Should provide that where a country grants patent protection to plant-based inventions, applicants are obliged to (a) declare the origin of materials and demonstrate prior consent of the country of origin and where relevant the indigenous or farming communities; and (b) pay compensation to the country or communities that had the material or the traditional knowledge used.</p> |
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Source: based on GRAIN, *Official country positions and proposals on TRIPS Article 27.3(b)*, http://www.grain.org/rights_files/trips-review-10-2004-en.pdf.

However, after considerable debate, the proponents of such an international obligation shifted from consideration of article 27.3(b) of the TRIPS Agreement to article 29. This change was logical, since article 29 deals with the general disclosure obligation imposed on patent applicants. Several submissions outlined the purposes and possible

scope of a disclosure obligation relating to patent claims on biological resources.¹⁶ A group of developing countries, later supported by the African, Caribbean and Pacific Group of States (ACP Group) and the Least developed Countries (LDC) Group, presented at the Council for TRIPS a proposal for a new article 29bis¹⁷ (see Box 1).

Box 1: Article 29bis. Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.
2. Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.
3. Members shall require applicants or patentees to supplement and to correct the information including evidence provided under paragraph 2 of this Article in light of new information of which they become aware.
4. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.
5. Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.

In parallel, the possible establishment of such a disclosure obligation was addressed by the CBD Panel of Experts on Access to Genetic Resources and Benefit Sharing,¹⁸ by the Ad Hoc Open-ended Working Group on

Access and Benefit-sharing,¹⁹ and by the 6th Conference of the Parties. Governments were invited to, encourage the disclosure of the country of origin of the genetic resources and traditional knowledge in applications for

¹⁵ JOB(99)/3169 and Add. 1.

¹⁶ See, e.g., “Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention”, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004.

¹⁷ Communication from Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania, Brazil, India and others – The Outstanding Implementation Issue on the Relationship between the TRIPS Agreement and the Convention on Biological Diversity – IP/C/W/474, Add.1, Add.2, Add.3, Add.4, Add.5, Add.6, Add.7, Add.8 and Add.9 Revision (Also circulated as WT/GC/W/564/Rev.2 and TN/C/W/41/Rev.2) 5 July 2006.

¹⁸ See Report of the Panel of Experts on Access and Benefit-sharing, document UNEP/CBD/COP/5/8, paragraph 127, 2 November 1999.

¹⁹ See Recommendations adopted by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, document UNEP/CBD/COP/6/6, Annex (31 October 2001).

intellectual property rights, where the subject matter of the applications concerns or makes use of genetic resources or such knowledge in its development, as a possible contribution to tracking compliance with prior informed consent (PIC) and the mutually agreed terms on which access to those resources and knowledge was granted.²⁰ COP 6 and 7 invited WIPO to prepare technical studies on the subject.²¹ The draft text on an ‘international regime on access to genetic resources and benefit-sharing’ prepared by Ad Hoc Open-ended Working Group on Access and Benefit-sharing²² includes a heavily bracketed provision on an obligation to disclose the origin of biological materials in patent and product approval applications (see Box 2).

This draft text²³ presents many common elements with that submitted to the Council for TRIPS but also some noticeable differences. Some of them are the result of divergences between the developing countries and the EU. While the latter generally supports the introduction of a disclosure obligation, it does consider that non-compliance should not be sanctioned with the revocation or non-enforceability of the granted patent. In addition, at least one of the (bracketed) proposals extends the obligation to other intellectual property rights, and there is text suggesting the creation of ‘a certificate of compliance with national legislation and requirements on access and benefit-sharing, issued by the country of origin’.

Box 2: Disclosure Obligation in the International Regime on Access to Genetic Resources and Benefit-sharing

- [1. [Patent] [Intellectual property rights] applications [and product approval applications] whose subject matter concerns, is [directly based on][derived from or makes use of] [genetic resources][biological resources][, their derivatives][and products] and[/or] associated traditional knowledge [shall][should][may] disclose the country [providing [genetic resources][biological resources][, their derivatives][and products]] [of origin] [and/or the country providing the resource] [in accordance with the Convention] [or source of such] [genetic resources] [biological resources], [their derivatives] [and products,] and [/or] associated traditional knowledge[.],[, as well as [information on prior informed consent and] evidence that provisions regarding prior informed consent, mutually agreed terms and benefit-sharing have been complied with, in accordance with the national legislation[, regulations and/or requirements] of the country providing the resources [in accordance with the Convention].]]
- [2. Each Party [shall][should][may] put in place effective enforcement procedures so as to ensure compliance with the obligations set out in the above paragraph. In particular, each Party [shall][should] establish administrative[, civil] and/or criminal measures for non-disclosure of the relevant information and the dissemination of false information to the national authorities, and [shall][should] ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application and to revoke or render unenforceable an intellectual property right or a product approval when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in the above paragraph or provided false or fraudulent information.]
- [3. [Compliance with national legislation and requirements in user countries [shall][should] be promoted][The obligations above-mentioned in paragraph 1 [may][shall][should] be met] by the presentation of a certificate of compliance with national legislation and requirements on access and benefit-sharing, issued by the country of origin in accordance with {...}.]

20 See Report of the Sixth COP, UNEP/CBD/COP/6/20, page 274 (27 May 2002).

21 The following studies were submitted by WIPO: *Technical Study on Disclosure of Origin Requirements in Patent Systems Related to Genetic Resources and TK*, UNEP/CBD/COP/7/INF/17 (2004), available at http://www.wipo.int/export/sites/www/tk/en/publications/technical_study.pdf; and *Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications* WIPO/IP/GR/05/3 (2005), available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=44610.

22 The Ad Hoc Open-ended Working Group on Access and Benefit-sharing (established by the COP in 2000) was mandated to develop guidelines and other approaches to assist Parties with the implementation of the access and benefit-sharing provisions of the CBD. The World Summit on Sustainable Development held in Johannesburg, in September 2002, called for action to “negotiate within the framework of the Convention on Biological Diversity... an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”. At the seventh meeting of the referred to Ad Hoc Open-ended Working Group (Paris, 1 - 8 April 2009), a first text for further negotiations on an ‘international regime on access to genetic resources and benefit-sharing’ was drafted.

23 A draft text submitted by the co-Chairs to the Ninth meeting of the Ad-Hoc Open-ended Working Group (Cali, Colombia, 22-28 March, 2010) provides for the establishment of several check points and disclosure requirements including at ‘[I]ntellectual property examination offices’, and the issuance of a permit or certificate as evidence of compliance (article 13) (UNEP/CBD/WG-ABS/9/3 26 April 2010).

The 'draft TRIPS modalities', seem to partially satisfy the developing countries' demands as articulated at the WTO and the CBD. Their proponents have apparently agreed to include a *mandatory* requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge in patent applications. This means that the TRIPS Agreement, if amended, would include an obligation applicable to all WTO Members not to process patent applications when this disclosure requirement has not been met.

However, the 'draft TRIPS modalities' leave many important issues open for further discussion. First, a definition of 'traditional knowledge' is yet to be agreed upon. This may be a very difficult task, as there is no generally admitted concept of traditional knowledge. Illustrative of this difficulty is that such a concept has not emerged after almost ten years of discussion at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Second, 'the nature and extent' of a reference to Prior Informed Consent and Access and Benefit Sharing are qualified as 'additional elements' and are still to be defined. Third, the only agreed consequence of non-compliance with the disclosure requirement is so far the possibility of suspending the processing of a patent application. No agreement is suggested about the possibility of imposing 'post grant sanctions' demanded by developing countries,²⁴ such as revoking a patent or declaring it non-enforceable when it were found that false or incomplete information was provided by the patent applicant.²⁵ It is also relevant to note that, in response to concerns of the biotechnology industry, the US has strongly opposed to the negotiation of a disclosure obligation relating to biological resources.²⁶

Finally, the disclosure obligation was also addressed at the WIPO IGC,²⁷ at the Standing Committee on the Law of Patents (SCP)²⁸ and in the context of the reform of the Patent Cooperation Treaty.²⁹ On October 1, 2009, the WIPO Assemblies adopted a decision establishing a new mandate for the said Committee. The two-year mandate states that the IGC will "without prejudice to the work pursued in other fora, continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions". The IGC was requested to submit to the 2011 WIPO General Assembly the text (or texts) of an international legal instrument (or instruments) that will ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions. WIPO General Assembly, the General Assembly will decide whether to convene a Diplomatic Conference to consider adoption of the proposed text (or texts).³⁰ The issue of the disclosure obligation referred to is likely to arise in the context of these deliberations unless an agreement is reached in the context of the WTO or of an 'international regime' of binding nature at the CBD.

Extension of GIs protection

A third component of the 'draft TRIPS modalities' is the extension of GI's protection provided for in article 23 of the TRIPS Agreement to all products. The application of the level of protection conferred under said article would essentially mean that right holders would have no need to demonstrate that the use of any designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other

24 See WT/GC/W/654, TN/C/W/41, IP/C/W474 of July 5, 2006.

25 The European Union has rejected so far the possibility of imposing sanctions that would affect the patent rights as such. An FTA signed between Colombia and the European Free Trade Association (EFTA) provides for civil, administrative or criminal sanctions in case of deliberate or unjustifiably false declaration on the origin or source. See David Vivas-Eugui, 'EL TLC entre la AELC y Colombia: un hito hacia la conservación de la biodiversidad, Puentes, vol. X, No. 4, September 2009: 8, <http://ictsd.net/i/news/puentes/56167/> (accessed October 10, 2009).

26 See e.g. WTO, *Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. Communication from the United States* (IP/C/W/469, 13 March 2006).

27 See, e.g., Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Seventh Session Geneva, November 1 to 5, 2004 *Patent disclosure requirements relating to genetic resources and traditional knowledge: update document prepared by the Secretariat*, WIPO/GRTKF/IC/7/10, October 15, 2004. See also European Community and its Member States, *Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications*. Proposal of the European Community and its Member States to WIPO, 16.12.2004 at: http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf.

28 See IP-Watch, *Disclosure Of Origin A Hot Topic In WIPO Patent Harmonisation Debate*, 11 April 2006, <http://www.ip-watch.org/weblog/2006/04/11/disclosure-of-origin-a-hot-topic-in-wipo-patent-harmonisation-debate/>.

29 Switzerland proposed an amendment to the regulations under the PCT to explicitly enable (without obliging) the national patent legislation of contracting parties to require the declaration of the origin of genetic resources and traditional knowledge in PCT patent applications. See PCT/R/WG/7/9, available at www.wipo.int/edocs/mdocs/pct/en/pct_r.../pct_r_wg_7_9

30 See 'WIPO Committee Pursues Global Governance of Inventions Using Genetic Resources', October 21, 2009, available at http://www.globalgovernancewatch.org/on_the_issues/wipo-committee-pursues-global-governance-of-inventions-using-genetic-resources.

than the true place of origin, misleads the public as to the geographical origin of the good or constitutes an act of unfair competition. Such an amendment to the TRIPS Agreement, plus the proposed international registration for *all* GIs, would give a major advantage to countries rich in GIs; this is obviously the case of the European countries, which are in possession of a large number of GIs to be potentially protected and enforced globally.³¹

A number of developed and developing countries,³² as mentioned, do not support this extension. Their governments or particular industries in their jurisdictions³³ are concerned by its possible trade implications (particularly the displacement of local products from domestic and foreign markets), and

by the lack of capacity to enforce their domestic GIs internationally. They would probably find little relief in the applicability, *mutatis mutandi*, of the exceptions contained in article 24 and, in the case of developing countries and LDCs, of the proposed special and differential treatment. Such a treatment often materializes in transitional periods for implementing the treaty obligations and in technical assistance, which may not suffice to offset the possible costs of an enhanced protection. In particular, the registration of GIs in developing countries may not enhance their exports to developed countries markets if the covered products are subject to quotas, tariffs or other restrictions, as in the case of coffee, tobacco and rum produced in Central America.³⁴

The 'Draft TRIPS Modalities' in the Context of the Doha Work Programme

The Doha Round faces a number of controversial issues that have so far frustrated its successful conclusion. Although several issues are on the negotiating table, the future of the Round is crucially dependent on a satisfactory resolution of outstanding divergences with regard to industrial tariffs and agricultural trade. The EU and the US seek significant reductions in the former in order to accept additional limitation to protectionist measures in the field of agriculture. So far, a number of developing countries consider insufficient the proposed concessions in that field, which would enable the maintenance of trade restrictive measures and, reciprocally, developed countries want to increase access of their industrial products to developing countries' markets.

The 'draft TRIPS modalities' may contribute to a final agreement, but they are unlikely to be determinant in generating the required consensus. There are various reasons for their possible limited impact on the Round as a whole:

- Despite the large number of Members that seem to support the extension of GIs protection, there are many that deeply disagree and that are likely to block a possible agreement on the subject. As noted by a

Report of the WTO Director General, such countries also oppose to work on the basis of the draft TRIPS modalities. The report points out that

a number of Members...believe that the case has not been made for such extension and that even basic objectives are far apart. In their view, the issue of GI extension should not be addressed in the context of the modalities decision and the suggested draft modalities text presented by the *demandeurs* would prejudice an outcome. Some of these Members are willing to continue fact-based discussions under the present process of work as agreed in paragraph 39 of the Hong Kong Ministerial Declaration but without prejudice to the outcome and the positions of Members and provided that there is a readiness to engage meaningfully on technical matters.³⁵

- For some of the dissenting Members (such as the US), all the three components of the 'draft TRIPS modalities' are probably unacceptable.³⁶
- The proposal presents a number of unsettled issues, such as the effects of non-compliance with access

31 For instance, between 2001 and 2005, 574 new applications of GIs were presented only in Spain. See Julio Paz Cafferata y Carlos Pomareda (2009), *Indicaciones geográficas y denominaciones de origen en Centroamérica: situación y perspectivas*, ICTSD, Geneva. The authors note that the possible advantages to be derived from local GIs are not automatic, and the use of GIs does not guarantee market access or commercial success (p. 12).

32 They include Australia, New Zealand, US, Canada, Mexico, Chile, Chinese Taipei and South Korea.

33 Cafferata and Pomareda report that, in Central America, for example, while coffee producers has sought to develop an GI with international recognition, milk producers rejects the expansion of GIs protection for cheese and, particularly, the use of the expression 'like' for products elaborated in the region. *Idem*, p. 7.

34 See, e.g., Carolina Belmar and Andrés Guggiana (2009), *Indicaciones geográficas en la política comercial de la Unión Europea y sus negociaciones con los países en desarrollo*, Policy Brief No. 4, ICTSD, Geneva, p.8.

35 *Issues related to the extension of the protection of geographical indications provided for in article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity*, Report by the Director-General, WT/GC/W/591, TN/C/W/50, 9 June 2008.

36 It has been noted, however, that the US might accept 'soft' versions of the disclosure obligation and of an international registry of GIs. See Frederick Abbott, *op. cit.*

legislation and the consequences of wrongdoing by the applicant, which would require further negotiation, even among its proponents.

- While issues relating to GIs are exclusively discussed in the context of the TRIPS Agreement, developing countries have introduced the disclosure obligation into the WIPO and CBD agendas. This may create the expectation of obtaining the recognition of an international obligation without ‘payment’ at the WTO. However, the content and legal nature of new possible international instruments are still undefined. Further, an amendment to said Agreement would allow a Member to trigger the mechanism of dispute settlement in cases where the obligation was not implemented.
- The proposed disclosure obligation, if adopted, would be one important element but would not provide the only solution sought for the problem of misappropriation of such materials.³⁷
- Although some developing countries have considerable expectations about the use of GIs to encourage high value added exports,³⁸ the overall economic impact of protection by GIs may be low³⁹ and substantial investments may be necessary for quality controls, certification of compliance with norms, marketing

Conclusion

The relationship between the TRIPS Agreement and the CBD has become an issue of major concern for developing countries. As noted, however, there has been insufficient coordination amongst developing countries’ to deal with this issue in different fora. The broad support received by a proposal to the Council for TRIPS for the establishment of an international obligation to disclose the origin of biological materials claimed in patent applications, suggests some progress in coordination and in the definition of a common strategy on the subject. Arguably, the establishment of a disclosure obligation would contribute to a more transparent and equitable patent

and, notably, for the enforcement of GIs rights in foreign jurisdictions.

The linkage made in the ‘draft TRIPS modalities’ between the adoption of a disclosure obligation, an international registry and an increased protection for GIs, may be seen, in sum, as a useful tactical movement to obtain support to the proposed obligation from the EU, whose interest in enhancing the international protection of GIs is notorious. This deal may be suitable to those developing countries that consider that increased GIs protection may benefit their trade interests. As noted, however, this may not be acceptable for a number of countries that have systematically opposed such an enhancement and which, in conjunction with other developed countries, may block a possible consensus on the subject.

While increased GIs protection and their international registration may create significant trade gains in the short term for European producers, it is uncertain how they may impact developing countries’ internal markets and exports.⁴⁰ The adoption of the disclosure obligation may generate economic benefits in the long term, provided that the mechanisms for monitoring patent applications and ensuring benefit sharing are in place. Hence, a more comprehensive and definitive solution to the problem of ‘bio-piracy’ would still need to be discussed in the context of the pending review of article 27.3(b) of the TRIPS Agreement.

system and to the fulfillment of the objectives of the CBD. It would also be instrumental to the achievement of some of the objectives of the recently adopted United Nations Declaration on the Rights of Indigenous Peoples.⁴¹

The incorporation of the disclosure obligation into the TRIPS Agreement would allow a Member to trigger the application of the WTO dispute settlement system in case of non-compliance. This would constitute a distinct achievement, provided that the scope and effects of the adopted obligation are properly defined so as to attain its purpose. Although negotiations in the context of the ‘international regime’ or at the IGC in WIPO would

37 *South Face*, ‘Disclosure of Origin at the CBD, WIPO and the WTO: Conflict, Coherence or Complementarity?’ Innovation and Access to Knowledge Programme, 24 January 2008, Palais Des Nations, Geneva, available at www.southcentre.org/southface/index.html.

38 See, e.g., Kasturi Das (2007), *Protection of Geographical Indications: An Overview of Select Issues with Particular Reference to India*, Working paper 8, CENTAD, New Delhi. This document notes that around 30 GIs of Indian origin have already been registered with the GI Registry in India, including Darjeeling (tea), Pochampalli, Ikat (textiles), Chanderi (sarees), Kancheepuram silk (textiles), Kashmir Pashmina (shawls), Kondapalli (toys), and Mysore (agarbattis). See also Fleur Claessens (2008), ‘GI rules: potential for African countries’, *Trade negotiations insights*, vol 7, No. 2, available at ictsd.net/downloads/tni/tni_en_7-2.pdf

39 See Ilbert, Helene and Petit, Michel (2009), ‘Are geographical indications a valid property right? Trends and challenges’, *Development Policy Review*, vol. 27, No. 5, p. 521.

40 Id. p. 521-522 (noting an increase in the registration of GIs in several developing countries and the strategy of combining GIs with trademarks to win export markets).

41 See, in particular, article 31 of the Declaration.

leave some room to operationalize such an obligation, their outcome is uncertain, including the mechanisms that may be available in cases of non-compliance and whether developed countries will adhere to any new

instruments.⁴² The adoption of an effective disclosure obligation in the context of the TRIPS Agreement, hence, should continue to be the priority for developing countries.

ANNEX

Draft modalities for TRIPS-related issues (17 July 2008)

JOB(08)/80

17 July 2008

DRAFT MODALITIES FOR TRIPS-RELATED ISSUES

Communication from Albania, Brazil, China, Ecuador, the European Communities, India, Indonesia, the Kyrgyz Republic, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group

The following communication, dated 17 July 2008, is being circulated at the request of the Delegations of Brazil, the European Communities, India and Switzerland.

Proponents of the TRIPS-related issues under the Doha Work Programme (GI Register, TRIPS disclosure requirement and GI Extension) agree to include these issues as part of the horizontal process in order to have modality texts that reflect Ministerial agreement on the key parameters for negotiating final draft legal texts with respect to each of these issues as part of the single undertaking. The central objective of the proponents remains the adoption of a procedural decision that would open up the way for negotiations on the three issues.

We therefore submit draft modalities for consideration by Ministers for TRIPS-related issues.

DRAFT MODALITIES FOR TRIPS-RELATED ISSUES

GI Register: draft Modality text

1. Members agree to establish a register open to geographical indications for wines and spirits protected by any of the WTO Members as per TRIPS. Following receipt of a notification of a geographical indication, the WTO Secretariat shall register the notified geographical indication on the register. The elements of the notification will be agreed.
2. Each WTO Member shall provide that domestic authorities will consult the Register and take its information into account when making decisions regarding registration and protection of trademarks

and geographical indications in accordance with its domestic procedures. In the framework of these procedures, and in the absence of proof to the contrary in the course of these, the Register shall be considered as prima facie evidence that, in that Member, the registered geographical indication meets the definition of “geographical indication” laid down in TRIPS Article 22.1. In the framework of these procedures, domestic authorities shall consider assertions on the genericness exception laid down in TRIPS Article 24.6 only if these are substantiated.

3. Text-based negotiations shall be intensified, in Special Sessions of the TRIPS Council and as an integral part of the Single Undertaking, to amend the TRIPS Agreement in order to establish the Register accordingly.

TRIPS/CBD disclosure: draft Modality text

4. Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent applications. Patent applications will not be processed without completion of the disclosure requirement.
5. Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.
6. Text-based negotiations shall be undertaken, in Special Sessions of the TRIPS Council and as an integral part of the Single Undertaking, to implement the above. Additional elements contained in Members’ proposals, such as PIC and ABS as an integral part of the disclosure requirement and post grant sanctions, may also be raised and shall be considered in these negotiations.

GI Extension: draft Modality text

7. Members agree to the extension of the protection of Article 23 of the TRIPS Agreement to geographical indications for all products, including the extension of the Register.

⁴² The US has not ratified yet the CBD, and very few developed countries have adopted legislation that may partially support its implementation in a way that protects the interests of developing countries supplying genetic resources.

8. Text-based negotiations shall be undertaken, in Special Sessions of the TRIPS Council and as an integral part of the Single Undertaking, to amend the TRIPS Agreement in order to extend the protection of Article 23 of the TRIPS Agreement to geographical indications for all products as well as to apply to the exceptions provided in Article 24 of the TRIPS Agreement *mutatis mutandis*.
9. Special and Differential treatment shall be an integral part of negotiations in the three areas above, as well as special measures in favour of developing countries and in particular least developed countries.

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The views expressed in this Policy Brief are those of the author, and do not necessarily represent the views of the International Centre for Trade and Sustainable Development (ICTSD) or any institution with which the author might be affiliated.

ICTSD welcomes feedback and comments on this document. These can be sent to Ahmed Abdel Latif at aabdellatif@ictsd.ch

ICTSD has been active in the field of intellectual property since 1997, in particular through its Programme on Intellectual Property Rights (IPRs) and Sustainable Development. One central objective of the programme has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries that includes decision-makers and negotiators, as well as representatives from the private sector and civil society, who will be able to define their own sustainable human development objectives in the field of IPRs and advance these effectively at the national and international level.

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