Brazil
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Brazil's position on the principles and methodology of work that should be employed in the preparation of the response by WIPO

The Conference of the Parties to the Convention on Biological Diversity (CBD) has invited WIPO and other international organizations to examine, and where appropriate address, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications.

A number of different fora, both within and outside WIPO, are currently engaged in discussions on the issue of the interaction between access to genetic resources and disclosure requirements in IP applications, particularly patent applications. Alternative proposals and views have been expressed on how to approach the issue.

The response to be prepared by WIPO to the CBD should be fully mindful of all such discussions in all relevant fora, including those within WIPO itself (Standing Committee on the Law of Patents and Working Group on Reform of the PCT), and should be inclusive of all positions. The best way to fulfil the principle of inclusiveness is to ensure that WIPO's response clearly and comprehensively sets out and reflects all proposals and views regarding patent disclosure requirements and genetic resources that may have been presented by WIPO Member States in different fora. Only in this way could WIPO make a useful contribution to the current discussions of the CBD on access and benefit sharing.

In this regard, the simplest and most realistic way to proceed may be for WIPO to elaborate a table of comparison that would list in some detail the different aspects of the various proposals. Given the current state of play of discussions in different fora, within and outside of WIPO, it would not be advisable for WIPO to pass judgment on the different options and to seek to advocate specific approaches to the detriment of others, as such a course of action could be prejudicial to the positions of its Member States.

These considerations should be borne in mind, in particular, with respect to the invitation to examine "options for model provisions on proposed disclosure requirements". The elaboration of any options for model provisions that would in any way leave out aspects of proposals tabled by Brazil and other developing countries in different fora, as described below, would be unacceptable.

In preparing its response, WIPO should also be guided by the terms of the invitation of the CBD, all of which were carefully negotiated at the 7th Conference of the Parties. The CBD invitation, in particular, notes that WIPO should address certain issues "*where appropriate*", and that this should be done in a manner that is "supportive of and does not run counter to the objectives of the CBD".

As a mega-diverse developing country, Brazil takes a great interest in discussions on the interaction between intellectual property and access to genetic resources and strongly

supports the establishment of effective global measures to address the grave international problem of "bio-piracy". In this regard, Brazil is among the proponents of measures designed to ensure a harmonious and mutually supportive relationship between the patent system and the CBD. In the World Trade Organization (WTO), Brazil's contribution to the discussions on this issue have taken the form of a proposal to amend the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which it has tabled together with other developing countries in the context of the current Doha Development Round. The views and positions of Brazil on this matter are reflected in the following WTO documents: IP/C/W/356, IP/C/W/403, IP/C/W/420, IP/C/W/429Rev.1 and IP/C/W/438. It is expected that these documents will be supplemented by new submissions to the WTO TRIPS Council in the near future.

The substantive views regarding disclosure of origin reflected in the proposal tabled by Brazil and other developing countries in respect of the WTO TRIPS Agreement are relevant to other international instruments in the field of patent law, such as those administered by WIPO, as well as other instruments under negotiation. They are directly relevant to the general discussion on the interaction between access to genetic resources and disclosure requirements in intellectual property applications, as well as the negotiations in the CBD on the international regime on access and benefit sharing. Brazil insists, therefore, that the substance of its proposals should be properly reflected in the response of WIPO to the invitation of the 7th COP of the CBD.

<u>Position of Brazil on patent disclosure requirements and genetic resources</u>:

Brazil is of the view that patent applicants for inventions relating to biological materials and/or associated traditional knowledge, under the existing relevant international treaties, should be required, as a condition for acquiring patent rights, to disclose (i) the source and country of origin of the biological resources and associated traditional knowledge used in the invention, (ii) evidence of compliance with prior informed consent under the relevant national regime, and (iii) evidence of compliance with fair and equitable benefit sharing under the relevant national regime.

The following is a summary of the main aspects of the position of Brazil on this issue, as expressed, *inter alia*, in the WTO TRIPS Council and relevant WIPO bodies (Standing Committee on the Law of Patents and Working Group on Reform of the PCT), as they may relate to different parts of the invitation of the CBD:

(a) Options for model provisions on proposed disclosure requirements;

Disclosure of origin, prior informed consent and fair and equitable benefit sharing (henceforward, "disclosure of origin") should be a mandatory requirement, to be imposed on patent applicants in all jurisdictions, preferably through an amendment to relevant international intellectual property treaties, such as the WTO TRIPS Agreement.

(b) Practical options for intellectual property rights applications procedures with regard to the triggers of disclosure requirements;

-- Functions of the requirement:
It is envisaged that the establishment of a mandatory, universal disclosure of origin requirement will contribute to the attainment of the following objectives:

(1) Improve the substantive examination of patent applications, by (i) helping to ensure that all relevant prior art information is available to the patent examiner; (ii) helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under, for example, Article 27, paragraphs 2 and 3, of the TRIPS Agreement, as well as related provisions of other international agreements; (iii) helping to systematize available information on biological resources and associated traditional knowledge that will continuously build the prior art information available to patent examiners and the general public.

(2) It is foreseen, furthermore, that the disclosure requirement will also be relevant to the determination of inventorship or entitlement to the claimed invention, and would be useful in cases relating to challenges to patent grants, including disputes on inventorship or entitlement, as well as infringement cases.

(3) In some cases, disclosure of origin may also facilitate or permit the actual execution of the invention, such as where a biological material is endemic to a specific location;

(4) Disclosure of origin would, moreover, constitute a necessary and effective incentive measure for patent applicants to comply with the access and benefit sharing legislation of countries of origin of the biological resources, in a manner that would contribute to the realization of the principles and objectives enshrined in provisions of international IP treaties, such as Articles 7 and 8 of the TRIPS Agreement. More generally, it would constitute an important realization of the principle of *equity*.

(5) As a transparency measure, disclosure of origin would help keep track of the commercial exploitation of biological materials for the purposes of benefit sharing.

-- Triggers of disclosure requirements:
The disclosure requirement would have both substantive and formal implications. Any use of biological resources and associated traditional knowledge, the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention, would be sufficient to trigger the disclosure obligation. Even where the use was only incidental, it would be sufficient to trigger the obligation, if the disclosure were relevant for prior art, inventorship or entitlement determinations, the scope of the claim and/or for understanding or carrying out the invention. Among others, the uses that would be relevant for prior art, inventorship or entitlement determinations, the determination of the scope of the claims and/or for understanding or carrying out the invention could include, among others, where the biological resources and/or traditional knowledge is used:

(a) to form part of the claimed invention;

(b) during the process of developing the claimed invention;
(c) as a necessary prerequisite for the development of the invention;
(d) to facilitate the development of the invention; and
(e) as necessary background material for the development of the invention.

While there will be administrative implications and there may be cost implications for applicants as they are expected to at least employ all reasonable measures to determine the country of origin and source of the material to meet this obligation, it is not foreseen that administrative procedures and costs related to meeting the obligation would be in any way burdensome.

-- Nature of the requirement:
A patent application will be deemed to comply with a disclosure of origin requirement if it contains a declaration, in a prescribed form, indicating the source and country of origin of the biological resources and/or associated traditional knowledge used in an invention, as well as a declaration that prior informed consent and fair and equitable benefit sharing have been complied with under the relevant national regime. These declarations should be accompanied, where relevant, by the actual evidence of prior informed consent and benefit sharing, for example, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin.

(c) Options for incentive measures for applicants;

-- Legal effects of non-compliance with the requirement:

As already noted, the proposed disclosure of origin requirement will have both formal and substantive components and implications. The nature of the legal effect of insufficient, wrongful or no disclosure of origin, and of evidence of prior informed consent and fair and equitable benefit sharing, will depend on whether one is dealing with a formal or substantive component of the disclosure and whether it is at the level of pre or post-grant.

In this context, where the insufficient, wrongful or no disclosure is discovered before the examination or grant of a patent, the legal effect could be that the application would not be processed any further until the submission of the necessary disclosure declarations and evidence. This could be accompanied with penalties and time limits within which the proper disclosure declarations and evidence should be provided, otherwise the application could be deemed withdrawn. In essence, the insufficient, wrongful or no disclosure of the source and country of origin of the biological resources and/or traditional knowledge, as well as failure to provide evidence of prior informed consent and fair and equitable benefit sharing, should justify the non-processing of the application.

Where the insufficient, wrongful or lack of disclosure of source and country of origin is discovered after the grant of a patent, the legal effect could include:

-- Revocation of the patent where it is determined that the proper disclosure would have led to the refusal to grant the patent either on the grounds of lack of novelty due to the existence of prior art or on grounds of *ordre public* or morality and where there is fraudulent intention for the insufficient, wrongful or lack of disclosure. In addition to revocation, criminal and/or administrative sanctions may also be imposed, for example, where the insufficient, wrongful or lack of disclosure amounts to a false representation;
-- Full or partial transfer of the rights to the invention where full disclosure would have shown that another person or community or governmental agency is the inventor or part inventor or would otherwise be entitled to all or part of the claimed invention; and,
-- Narrowing the scope of the claims where parts of the claims are affected due to lack of novelty or fraudulent intention or where full disclosure would have led to refusal to admit those parts of the claims.

Similarly, where the failure to provide evidence of prior informed consent is discovered after the grant of a patent, the legal effect could include:

-- Revocation of the patent. In addition to revocation, criminal and/or administrative sanctions may also follow, outside the patent system, in particular, to ensure adequate compensation where it is eventually determined that no prior informed consent was obtained;

-- Criminal and/or civil sanctions, including the possibility of punitive damages, could follow, again outside the patent system, where it is determined that the patent holder in fact obtained prior informed but did not provide the evidence in the application.

Additionally, sanctions should also apply in cases of failure to provide evidence of fair and equitable benefit sharing. These shall be elaborated upon at a later time.

While a certain level of leeway may be given here on the exact legal effect for each infraction, every State should nevertheless have an obligation to ensure that the effect of insufficient, wrongful or lack of disclosure, and/or of failure to provide evidence of prior informed consent and fair and equitable benefit sharing, is effective in terms of its deterrent, compensatory and equity value.

(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;

The proposals for a mandatory, universal, disclosure of origin requirement may have implications for WIPO-administered treaties, as well as treaties under negotiation. Many of these implications have not yet been fully discussed by WIPO Member States. Discussions, nevertheless, have taken place on the matter in the context of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and the draft Substantive Patent Law Treaty (SPLT). Brazil has made specific proposals with respect to the draft SPLT in the Standing Committee on the Law of Patents and has, moreover, expressed itself on the issue of disclosure of origin, in the context of the PCT, in past sessions of the Working Group on Reform of the PCT, as well as in the WIPO General Assembly.

(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

Discussions on certificates of origin/source/legal provenance are still ongoing in other fora. Brazil would approach this matter in the context of the positions expressed with respect to items (a), (b) and (c) above.