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PATENT-RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK AND THEIR LEGISLATIVE IMPLEMENTATION AT THE NATIONAL AND REGIONAL LEVELS - PART II

Document prepared by the Secretariat

1. In the context of the discussions on Development Agenda recommendation 14, Member States, at the sixth session of the Committee on Development and Intellectual Property (CDIP) held from November 22 to 26, 2010, in Geneva, requested the International Bureau of the World Intellectual Property Organization (WIPO) to extend document CDIP/5/4 to cover five new flexibilities.

2. Document CDIP/7/3 on Patent-Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part II was presented at the seventh session of the CDIP. As this session was suspended on May 6, 2011, the document was considered when the session was resumed on November 14, 2011, and the Committee decided to set a deadline on February 6, 2012, for submission of comments by Member States. The CDIP further agreed that the document would continue to be considered at CDIP/9, together with the comments received from Member States by the above date.

3. Comments received by the Secretariat from the Delegations of Brazil, Netherlands and the United States of America are contained in the Annex to this document.

4. *The CDIP is invited to take note of the contents of this document and its Annex.*

[Annex follows]

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COMMENTS ON DOCUMENT CDIP/7/3: PATENT-RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK AND THEIR LEGISLATIVE IMPLEMENTATION AT THE NATIONAL AND REGIONAL LEVELS

BRAZIL

Following the decisions taken by the Committee on Development and Intellectual Property (CDIP) during the 7th session, the Brazilian delegation would like to present comments on the following chapters of document CDIP/7/3 (Patent-Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels):

- Chapter III: Patentability of substances existing in nature;
- Chapter IV: Disclosure-related flexibilities;
- Chapter V: Substantive examination.

The following comments were already provided, during the 7th session of the Committee, as oral statements.

Chapter III - PATENTABILITY OF SUBSTANCES EXISTING IN NATURE

With respect to patentability of substances existing in nature, the Brazilian delegation would like to point out the risk of granting patents on naturally occurring materials, isolated from their natural environment, produced by means of a technical process, or in purified or altered form. Risks involve the granting of patents with a low level of inventiveness or no inventive step at all, sometimes simply as a policy to reward investment or the so-called “sweat of the brow”. This makes all the more relevant the development of a system for protection of traditional knowledge, as well as effective rules on a mandatory disclosure for inventions which use genetic resources.

In paragraph 46, for the sake of a balanced argument, there should be a mention to experts who argue that granting patents to mere discoveries is not compatible with the TRIPS Agreement. Moreover, one also notes that the lack of definition of what an invention is constitutes one of the most important flexibilities in the TRIPS Agreement. A discussion on that flexibility was not further developed by document CDIP/7/3. Each Member State has the flexibility to design their patent systems in accordance with their own legal system and practice.

Chapter IV: DISCLOSURE-RELATED FLEXIBILITIES

Regarding disclosure-related flexibilities, descriptive sufficiency is a very important matter that should be further developed by document CDIP/7/3. It is a matter covered by recommendations of the Development Agenda and lies at the core of a balanced and efficient intellectual property system. Sufficiency of disclosure is also a tool to improve legal certainty, since more clarity of description contributes to define the boundaries of the patents. The Brazilian delegation suggests that a revised version of document CDIP/7/3 includes a section dedicated to that issue.

The Brazilian delegation is of the view that the approach adopted by document CDIP/7/3 concerning the best mode disclosure requirement should also be revised. Best mode requirement does bring a layer of complexity to the patent granting process, but one should bear in mind that the granting of a patent leads to a temporary monopoly, which is a derogation of free competition (one of the most important pillars of market economy). Best mode requirement contributes to the achievement of the basic trade-off which underlies the patent system: the granting of exclusive rights in return for access to knowledge and technology. Best

mode requirement is particularly important for developing and least developed countries, since it facilitates technology transfer.

In what regards disclosure of the origin of genetic resources, this delegation believes that Member States of WTO and WIPO should find a common solution for this matter as soon as possible. We need to find a multilateral solution in order to make the IP system supportive of the provisions of the Nagoya Protocol as well as to guarantee that the IP system will not grant erroneous patents based on the misappropriation of genetic resources and traditional knowledge. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has a clear mandate to find a common ground in what regards the protection of genetic resources and traditional knowledge. The Brazilian delegation considers that a mandatory disclosure requirement is the best way for strengthening, as far as intellectual property is concerned, the Nagoya Protocol and for ensuring that countries will not grant erroneous patents. Member States should fight against theft and misappropriation of biological material and associated traditional knowledge with the same impetus they fight against other IP violations, due to the negative impacts over traditional communities and biodiversity at a broader level.

Chapter V: SUBSTANTIVE EXAMINATION

In what concerns substantive examination, the Brazilian delegation has reservations about paragraph 83, which states that conducting search and substantive examination for all applications may not be the best approach for all patent offices (with a clear reference to developing and least developed countries). WIPO should support Member States in developing national capacities to fully develop their national IP systems, rather than suggest that having a complete patent system should be something restricted to a few countries only. Document CDIP/7/3 should mention that the first option available for all countries is to develop a national system of full substantive examination.

In fact, document CDIP/7/3 implies that some member States should only revalidate patents granted abroad without taking into account the quality of these patents. It also suggests that, while revalidating those patents, those countries should also assume that those patents fully comply with disclosure requirements and that the criteria for patentability were applied to these patents accurately.

Chapter V of document CDIP/7/3 should, in consequence, be revised in order to be in line with the Development Agenda Recommendations. The Development Agenda foresees that IP system should be inclusive, allowing developing and least developed countries to benefiting from it. An adequate approach to this issue is accessing how cooperation may foster national capabilities. In this sense, member States would be more prepared to develop their national system of full substantive examination, should this be a an domestic policy objective. Adopting other options should be a matter for national decision. Hence, WIPO could help its Members to fully implement their international commitments, while taking into account their different socioeconomic realities and legal systems.

THE NETHERLANDS

With regard to formal examination in the Netherlands, it is important to highlight that the patent will be granted, regardless of the outcome of the examination. This could be highlighted in a footnote, which would read: "Regardless of the outcome of the examination, the patent will be granted."

UNITED STATES OF AMERICA

The United States takes note of the study on "Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels – Part II" (CDIP/7/3) and expresses its appreciation to the Secretariat for preparing the study. Without endorsing the study's findings and conclusions, we offer the following comments on the discussion of "Disclosure-Related Flexibilities" (Part IV), "Substantive Examination" (Part V), and "*Ex Officio* IP Office Control of Anti-Competitive Clauses in Patent Licensing Agreements" (Part VI). Our comments are offered in the hope that they will bring a broader perspective and context to these discussions and thereby improve the quality and usefulness of the document. We recommend that Member State comments be appended to the study.

Comments on Part IV

1. With respect to the Parts on "Disclosure-Related Flexibilities" and "Substantive Examination" (pages 20-35), we noticed a few references to practices at the U.S. Patent and Trademark Office that appear to be incomplete. We discussed these issues with the Secretariat on the margins of the Seventh Session of the Committee on Development and Intellectual Property and understand that the Secretariat has made a note of our proposed edits.

2. With respect to the "Indication of the origin of biological material" section of the study (pp. 27-29, paragraphs 74-80), the document discusses WIPO and TRIPS Council submissions containing proposals for new disclosure requirements in the patent laws as one type of "patent-related flexibility," but it does not sufficiently acknowledge that the so-called "patent disclosure requirement" is not universally accepted as a flexibility permitted by TRIPS. Furthermore, the document does not consider submissions that identify the limitations and harmful effects of such proposals. The United States has produced several such submissions (see, for example, IP/C/W/209, IP/W/C/434, IP/C/W/449, IP/C/W/469). We suggest that document CDIP/7/3 also reflect submissions containing counterpoints to proposals for new disclosure requirements.

3. Although paragraphs 72 and 73 set forth the commonly accepted criteria for patentability, *i.e.*, novelty, inventive step and industrial application, the origin of biological material has not been shown to be material to patentability. No linkage has been made between source and these patentability requirements. Instead, proponents have suggested that by knowing the origin of a biological material, an examiner would be inclined to perform a deeper search of known uses in that origin. No evidence has been shown that such a search would be productive, instead of leading the examiner away from a more comprehensive search of prior art. Furthermore, the description of biological material in the context of patent applications treats inventions as being clearly related to a single biological material instead of tens, hundreds or more biological materials. We suggest that document CDIP/7/3 reflect the complexity of determining when an invention relates to a biological material, what biological material has been claimed, and when the source of a biological material would need to be disclosed.

4. A new patent disclosure requirement will not guarantee that the relevant parties obtain prior informed consent, and will not ensure that benefits will be shared equitably with the providers of genetic resources. Rather, it would add uncertainties to the patent system; produce additional burdens for both patent applicants to comply with and national patent offices to administer; and have a chilling effect on the innovation process.

5. Additionally, we note that a well-functioning patent system includes various features that help prevent the erroneous issuance of patents. We take this opportunity to provide a representative list of features of the U.S. patent system that are particularly relevant:

(a) U.S. patent law provides that a patent applicant must furnish the examiner with "information material to patentability."[1] If particular genetic resource constituted such material information, there would be a requirement to disclose that genetic resource. Moreover, if access to a genetic resource is material to being able to make and use the invention, then the applicant is required to disclose the source where the applicant obtained the genetic resource (if the material continues to be available there), or to deposit the biological material, in accordance with the Budapest Convention (if the material cannot be guaranteed to be available at the source).

(b) U.S patent practice requires examiners to conduct extensive searches of publications, patent literature, and other materials, to determine whether the claimed invention is entitled to a patent. The sources to which examiners look include specialized databases that feature information about genetic resources.

(c) Most patent applications are made available for public inspection before they are granted, and the current U.S. practice allows the public to submit information regarding those published applications, for the examiner's consideration.

(d) Under U.S patent practice, it is possible to correct a patent, after it is granted, to cancel or amend claims to subject matter that the inventor was not entitled to claim.

(e) A U.S patent application may include search information from many sources. For example, an application filed via the Patent Cooperation Treaty ("PCT") may include an international search report or a Supplementary International Search, which may encompass information from examiners from different parts of the world. Similarly, Patent Prosecution Highways (PPHs) also allow multiple patent offices to share search and examination results.

Comments on Part V

1. Part V provides a useful discussion of substantive examination, but may not sufficiently explain the time required to examine a patent application and thus underscore why it is useful for an examiner to be able to specialize in a certain area of technology, and why this need for specialization is important. Specialization allows examiners to efficiently examine a patent application, which in turn allows the cost of patent examination and the fee paid for a patent application to be examined to be reduced. Regional patent offices can offer a suitable economy of scale to allow sufficient specialization. Part V should be expanded to provide more guidance to describe the factors that Members should analyze in deciding what substantive examination formalities to select, and better understand the benefits of worksharing and regional patent offices.

Comments on Part VI

1. We appreciate that the mandate from the Committee on Development and Intellectual Property to the Secretariat was to conduct a study on the narrow topic of anti-competitive clauses in patent licensing agreements and the role of IP offices in reviewing such clauses. We nonetheless believe the study's treatment of that topic could benefit from its placement within a broader context that recognizes the generally pro-competitive nature of patent licensing.[2]

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[1] See Title 37, Code of Federal Regulations, Section 1.56; Manual of Patent Examining Procedure, Chapter 2000.

[2] *See* U.S. Dept. of Justice and Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property (April 6, 2005), § 2.0, *available at* www.justice.gov/atr/public/guidelines/0558.htm. The same policy was adopted in the Federal Trade Commission and U.S. Dept. of Justice's 2007 Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, *available at* www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf.

2. Patent licensing is generally procompetitive because it permits patent owners to maximize the usefulness of their inventions by giving them the opportunity to combine their intellectual property rights with other parts of the production process, such as manufacturing facilities, channels of distribution, and workers. Patent licensing promotes more research and development by expanding opportunities to benefit from patent rights beyond selling the patent right, increasing incentives to pursue new inventions. Patent licensing facilitates technology transfer and permits companies to engage in open innovation, acquiring access to use the best inventions that fit their business model, even if they originate in other companies' research and development efforts. Cross-licensing frequently resolves blocking patent scenarios that can prevent companies from using their own technologies, thus enhancing innovation and competition. As a result of patent licensing, consumers benefit from the introduction of new products and reduced costs of production.

3. In particular, grantback clauses — agreements to grant patent rights from licensees back to the original licensor — may provide procompetitive benefits. Grantbacks can promote innovation and the subsequent licensing of inventions by protecting the ability of first innovators to practice improvements to their inventions after having enabled this follow-on invention by others. Grantbacks that are limited in scope to the licensed technology and are non-exclusive are unlikely to harm competition.

4. Another element of a broader context that should inform the study is that competition policies vary widely among countries and regions. IP offices in many jurisdictions, such as the United States, do not register licensing agreements in a registry, nor do they examine the competitive impact of IP licensing agreements. Rather, competent antitrust agencies, or courts hearing antitrust claims, perform this complex and nuanced analysis as needed, on a case-by-case basis. Moreover, jurisdictions like the United States analyze the vast majority of all licensing agreements under the rule of reason, looking closely at the economic effects of the agreement on the relevant market(s) to determine whether any harm to competition outweighs the procompetitive benefits of the agreement. IP offices generally are not set up or qualified to examine the nuances of IP-related competition issues in this manner.

[End of Annex and of document]