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STANDING COMMITTEE ON THE LAW OF PATENTS

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PROPOSALS BY THE DELEGATIONS OF THE DOMINICAN REPUBLIC AND BRAZIL CONCERNING ARTICLES 2, 13 AND 14 OF THE DRAFT SUBSTANTIVE PATENT LAW TREATY

Document prepared by the International Bureau

I. INTRODUCTION

1. At the seventh session of the Standing Committee on the Law of Patents (SCP), the Delegations of the Dominican Republic, on behalf of the Delegations of Chili, Colombia, Cuba, Ecuador, Honduras, Nicaragua, Peru, Venezuela and its own country, and Brazil submitted proposals relating to Articles 2, 13 and 14 of the draft Substantive Patent Law Treaty (SPLT). These proposals, which are reproduced in Annex I (Dominican Republic) and Annex II (Brazil), relate to issues such as the protection of public health, the environment and other areas considered to be of vital importance, as well as the protection of genetic resources and traditional knowledge. The Chair summarized the debate of the SCP on these issues in the context of draft SPLT Articles 2 and 13 as follows (see document SCP/7/8 Prov.2, paragraphs 31 and 203):

> "A proposal to amend paragraph (2) [of Article 2] was made jointly by nine delegations, and was supported by some other delegations. One delegation, supported by several other delegations, proposed the inclusion of a new paragraph (3). One delegation suggested that these proposals be included in the draft Treaty, within square brackets, for further discussion. Several delegations, however, did not support these proposals, and questioned their relevance for the SPLT."

"The discussion on this provision [Article 13] was a logical follow-up of the discussion on draft Article 2. In view of the divergent opinions, the International Bureau would further reflect on those issues."

2. The debate in the SCP demonstrates the importance of the matters contained in the mentioned proposals, as well as the need for further reflection on the issues they raise. This document aims to contribute to that reflection, and to promote both a better understanding of the relationship between the proposals contained in Annexes I and II of this document and the work undertaken by the SCP on patent harmonization, and a discussion about the future direction the SCP might wish to take on these issues.

II. DRAFT SUBSTANTIVE PATENT LAW TREATY (SPLT)

3. At earlier sessions of the SCP, as well as during the Diplomatic Conference on the Adoption of the Patent Law Treaty (PLT) held from May 11 to June 2, 2000, a considerable number of delegations and representatives expressed their wish to consider issues related to further harmonization of substantive requirements of patent law after the conclusion of the PLT. In addition, the Revised Draft Program and Budget for 2002-2003 includes, under Sub-Program 05.1, "Law of Patents," the following activities, *inter alia* (see document WO/PBC/4/2, page 51):

"Convening of four meetings of the SCP (and any Working Group set up by this Committee), to consider current issues relating to the law of patents, including:

- continuation of discussions on further harmonizing patent law;

…"

4. At its fourth session in November 2000, the SCP started its work on substantive patent law harmonization, and mandated the International Bureau to establish first draft provisions for a future legal instrument. Since then, the SCP has been discussing provisions for the so-called draft Substantive Patent Law Treaty (SPLT), including draft Regulations and Practice Guidelines, at its fifth, sixth and seventh sessions held in May and November 2001 and in May 2002, respectively.

5. In respect of the coverage of the draft SPLT, the SCP decided that the provisions should address a number of issues relevant to the grant and validity of patents, such as the definitions of prior art, novelty, inventive step/non-obviousness and industrial applicability/utility, the issue of sufficiency of disclosure and the drafting and interpretation of claims (see report of the fourth session of the SCP, document SCP/4/6, paragraphs 47 to 49). In the course of its ongoing discussions, the SCP further made a clear distinction between issues related to the grant and validity of patents on the one hand, and the exercise of the patent rights on the other, and agreed that the latter should not be covered by the draft SPLT. In this context, the SCP also agreed that infringement issues should, as a general rule, not be covered by the SPLT.[1]

[1] One exception to this principle relates to the provisions on claim interpretation (including equivalents), which would apply to infringement procedures. One reason for that decision was the understanding that the drafting of claims depended on how the claims were interpreted at a later stage in infringement proceedings.

6. In sum, the SCP agreed to limit the scope of the draft SPLT to the deep harmonization of a number of issues relating to the grant of patent rights as well as the validity of patents. Thus the SPLT itself would not limit the freedom of Contracting Parties to regulate any matters which are not included in the scope of the SPLT as described, for example matters relating to the rights conferred by a patent or the enforcement of the patent rights. Examples of such matters include the types of exclusive rights conferred by the patent, the exceptions to such rights, the use of patented subject matter without the authorization of the right holder, exhaustion of patent rights, and judicial procedures and border measures against acts infringing the patent rights.

III. DEVELOPMENTS IN OTHER INTERNATIONAL FORA

7. In recent years, at the international level, intellectual property rights and public health, the environment, genetic resources and traditional knowledge have been discussed in various fora. In particular, within WIPO, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) already addresses certain of these issues. Outside of WIPO, the work undertaken in the framework of, in particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as well as of the Convention on Biological Diversity (CBD) is relevant to the issues under consideration.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

8. Before the Diplomatic Conference for the Adoption of the PLT, the Director General of WIPO conducted informal consultations concerning formalities in relation to the question of genetic resources. As the outcome of the consultations, it was decided that the issue of genetic resources would not be addressed in the PLT, but that a forum for discussing these issues would be established at WIPO. The following statement was agreed upon among the various regional groups and read out by the Director General during the Diplomatic Conference, the relevant part of which is as follows:

> "Member State discussions concerning genetic resources will continue at WIPO. The format of such discussions will be left to the Director General's discretion, in consultation with WIPO Member States."

9. Following the PLT Diplomatic Conference, consultations with Member States took place regarding the format and content of such discussions. As a result of the consultations, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established, to facilitate discussions on the relationship between intellectual property rights and genetic resources, traditional knowledge and folklore. In October 2000, the WIPO General Assembly approved the proposals contained in paragraphs 13, 16, 17 and 18 of document WO/GA/26/6. Paragraphs 13 to 18 of that document read as follows:

> "13. Following the recommendations of the regional consultations on folklore, the consensus achieved at the Meeting on Intellectual Property and Genetic Resources, the commitment reached in the context of the Diplomatic Conference for the Adoption of the Patent Law Treaty and subsequent consultations with Member States, the Member States might wish to consider the establishment of an Intergovernmental

Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore for the purpose of discussions on these subjects.

"14. The Intergovernmental Committee would constitute a forum in which discussions could proceed among Member States on the three primary themes which they identified during the consultations: intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore.

"15. Each one of these themes cuts across the conventional branches of intellectual property law and does therefore not fit into existing WIPO bodies, such as the SCP, the Standing Committee on Copyright and Related Rights (SCCR), the Standing Committee on Trademarks, Industrial Designs and Geographical Indications (SCT), and the Standing Committee on Information Technologies (SCIT). At the same time, the three themes are closely interrelated, and none can be addressed effectively without considering aspects of the others.

"16. It is proposed that the Intergovernmental Committee be open to all Member States of WIPO. In conformity with the budgetary allocations available under the Program and Budget and previous WIPO practice, WIPO would facilitate the participation of representatives of developing countries and of certain countries in Europe and Asia. As is usual in WIPO bodies, it is proposed that relevant intergovernmental organizations and accredited international and regional non-governmental organizations be invited to participate in an observer capacity. It is proposed that the Committee would hold its first session in the Spring of 2001 and that the next draft Program and Budget would provide for the Committee to meet twice a year in the 2002-2003 biennium. The Committee would report any recommendations for action that it might formulate to the WIPO General Assembly.

"17. At its first session, it is proposed that the Committee determine, within its sphere of competence, and in accordance with the Program and Budget, the agenda of items on which work should proceed. It would also determine the priority accorded to these various items. It is proposed that the draft agenda for the first session of the Committee include the items set out in the Annex to this document. It is also suggested that Member States be invited to submit proposals for issues to be considered at the first session of the Committee and documents to be prepared by the WIPO Secretariat for that first session. Section III, below, identifies issues that Member States may consider appropriate and which may form the basis for proposals for issues to be considered at the first session of the Committee.

"18. It is proposed not to establish separate rules of procedure for the Intergovernmental Committee, but rather that the general rules of procedure adopted for WIPO bodies, namely the WIPO General Rules of Procedure (publication No. 399 Rev.3) should apply, subject to any special rules of procedure that the Intergovernmental Committee may wish to adopt."

10. The IGC has held three sessions since its establishment, and has addressed a number of the issues mentioned in the preceding paragraphs. It does, however, not work in isolation, but rather in close cooperation with other fora concerned, in particular, the CBD. One relevant example in this context is that, on May 21, 2002, the Executive Secretary of the CBD

transmitted, at the request of the Conference of the Parties (COP) to the CBD, a letter inviting WIPO to prepare a technical study on, *inter alia*, questions relating to the disclosure of the origin of genetic resources in patent applications and prior informed consent. Following this invitation, the IGC mandated the Secretariat of WIPO to send a questionnaire concerning these issues to the members of the IGC, in order to gather information for the preparation of the said study. The questionnaire was prepared by the Secretariat of WIPO and mailed to the members of the IGC in August 2002.

11. The preceding paragraphs show that Member States of WIPO established the IGC specifically as the competent body within WIPO to discuss the relationship of access to genetic resources, protection of traditional knowledge and folklore with intellectual property. Further information on the ongoing work of the IGC is contained in the report of its third session which took place from June 13 to 21, 2002 (document WIPO/GRTKF/IC/3/17).

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

12. The TRIPS Agreement, administered by the World Trade Organization (WTO), covers all areas of intellectual property, including patents. It contains general principles, minimum standards of protection on intellectual property, provisions on enforcement of intellectual property rights and a mechanism for the settlement of disputes between or among the Members. The following aspects, in particular, are relevant to the issues addressed in the present document: (1) the conditions of, and the exceptions from, patentability; (2) the relationship between the TRIPS Agreement and the CBD; and (3) the TRIPS Agreement and public health.

13. The provisions of Article 27.2 and 3 of the TRIPS Agreement allow for certain exclusions from patentability as follows:

> “2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> “3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

14. These provisions relate to the possibility of excluding certain categories of inventions from patentability, but they do not address matters related to the exercise of the patent rights. For those matters, other provisions of the TRIPS Agreement, such as Articles 6 (Exhaustion), 30 (Exceptions to Rights Conferred) and 31 (Other Use Without Authorization of the Right Holder), are relevant. In addition, if a Member of the WTO does indeed exclude certain

inventions from patentability in accordance with Article 27.2 of the TRIPS Agreement, the commercial exploitation of the corresponding inventions would not be possible on its territory.

15. In respect of the relationship between the TRIPS Agreement and the CBD, Ministers of the WTO, in paragraph 19 of the Ministerial Declaration adopted at the fourth Ministerial Conference in Doha, Qatar, decided to examine the relationship between those two treaties:

> "19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

16. The review of the provisions of TRIPS Article 27.3(b), the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore are agenda items currently discussed at the Council for TRIPS. Issues raised and points made by delegations in the TRIPS Council in respect of these items are summarized in WTO documents IP/C/W/368 to 370.

17. At that Ministerial Conference in Doha, the Ministers of the WTO Members adopted the Declaration on the TRIPS Agreement and Public Health (see Annex III), which states that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" in paragraph 4. The Declaration explicitly mentions that "(e)ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (paragraph 5(b)), that "(e)ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency" (paragraph 5(c)), and that each Member is free to establish its exhaustion regime (paragraph 5(d)). The Declaration also explicitly recognizes certain flexibilities of the WTO Members under the TRIPS Agreement in the context of public health. The TRIPS Council, on the instruction of the Ministers of the WTO Members, is currently discussing the question concerning the difficulties that could be faced by WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under the TRIPS Agreement (paragraph 6 of the Declaration).

IV. THE CURRENT PROPOSALS

18. In view of the developments in the various fora mentioned above, the proposals set out in Annexes I and II raise three main issues for discussion.

19. The first issue is the forum that is appropriate for consideration of the questions raised in the proposals and the purpose of the proposed SPLT. The main objective of the SPLT, as indicated in Section II, above, is the harmonization of issues relating to the grant of patents. Harmonization is not, of course, an end in itself, but is sought in order to create the basic conditions for a more efficient sharing of the work load among patent offices in the context of a steadily increasing demand for patent rights which is placing strain upon the resources available to patent offices throughout the world. Are issues concerning the impact of the

exploitation of patents upon other areas of public policy appropriately dealt with in the context of an exercise seeking harmonization of conditions relating to the grant of patents? In particular, are the issues raised in the proposals set out in the Annexes more appropriately considered in the context of the discussions of harmonization of questions relating to the grant of patents or in the ongoing discussions taking place in the IGC, the TRIPS Council and the CBD?

20. A second issue that arises for discussion is the appropriate place, within patent law, to consider questions relating to the impact of the exploitation of patents on other areas of public policy. A distinction may be drawn between, on the one hand, the law relating to the grant of patents and, on the other hand, the law relating to the exercise of patent rights, once granted. It may be considered difficult to assess the social impact of the grant of a patent at the stage of grant, as opposed to making that assessment at the stage of the exercise of patent rights. An evaluation of the impact of a patent at the stage of grant may be problematic since many inventions will not have been commercially exploited at the time of the grant of the patent, so that the economic or social impact of the inventions may not be apparent. Furthermore, even if an invention has, both technically and commercially, reached a sufficient degree of maturity for its social and economic impact to be evaluated at the time of grant, the refusal of patent rights because of the importance of invention may lead to the paradox that the better the invention, the less likely it is to receive patent protection, with the consequence of a curious effect being produced on the patent incentive to innovate. In contrast, it may be more effective to evaluate the social and economic consequences of a patent on other areas of public policy at the stage of the exercise of patent rights. At this stage, appropriate measures may be taken to limit or control adverse consequences on other priority areas of public policy. This is the way in which considerations of competition law have always been accommodated in relation to the patent system.

21. A third issue that arises for discussion from the proposals contained in the Annexes concerns the drafting of the proposed exceptions to the grant of a patent or the grounds upon which a patent may be invalidated. In order to constitute workable exceptions in the context of an internationally harmonized approach to the grant of patent rights, the grounds upon which an exception may operate would usually need to be clearly defined in order to create sufficient certainty for a harmonized approach to be adopted.

22. The SCP is invited to take note of the contents of this document and to express views on possible ways to address the proposals contained in Annexes I and II.

[Annexes follow]

ANNEX I

PROPOSAL BY THE DELEGATION OF THE DOMINICAN REPUBLIC, ON BEHALF OF THE DELEGATIONS OF CHILI, COLOMBIA, CUBA, ECUADOR, HONDURAS, NICARAGUA, PERU, VENEZUELA AND ITS OWN COUNTRY, ON DRAFT SPLT ARTICLE 2(2)[1]

Article 2

General Principles

…

(2) [~~*Security*~~ *Exceptions*] Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests <u>or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment</u>.

…

Explanatory Note:

A growing number of countries recognize that the conservation and sustainable exploitation of their biological and genetic resources, and the respect and protection of traditional knowledge held by native or indigenous communities in their territories, are important for the overall development of those countries. In particular, the 1992 Convention on Biological Diversity (CBD) reflects that view, and a political will to recognize and implement certain principles linked to the protection of biodiversity and traditional knowledge.

Several provisions in the CBD are directly or indirectly relevant to intellectual property, in particular to the patent system. For example, it is worth noting the provisions that oblige Contracting Parties to respect and preserve traditional knowledge, innovations and practices, promote their application with the prior informed consent of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge (CBD, Article 8(j)).

The Convention on Biological Diversity recognizes the sovereignty of States over their natural resources, and that the authority to determine access to genetic resources rests with the governments and national legislation of those States. It also provides that access to genetic resources is subject to prior informed consent by the Contracting Party providing such resources, and that Contracting Parties must take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial use of genetic resources with the Contracting Party that has provided the resources (CBD, Article 15, paragraphs 1, 5 and 7).

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[1] Underlined text shows the proposed additions compared to the text as contained in document SCP/7/3.

With a view to their fulfillment of such international commitments and the implementation of national policies regarding the conservation and protection of traditional knowledge and genetic resources, a number of countries have adopted, or may wish to adopt, provisions to control access to traditional knowledge and genetic resources under their jurisdiction.

Every Contracting Party should remain free to exercise its jurisdiction and coercive power consistently in order to achieve its policy objectives and observance of its laws, including those whose purpose is the protection of traditional knowledge and genetic resources against unlawful appropriation and biopiracy. That right should be clearly recognized in the Substantive Patent Law Treaty.

[Annex II follows]

ANNEX II

PROPOSALS BY THE DELEGATION OF BRAZIL ON DRAFT SPLT ARTICLES 2(3), 13 AND 14[1]

Article 2

General Principles

(3) [*Public Interest Exceptions*] Nothing in this Treaty or Regulations shall limit the freedom of Contracting Parties to protect public health, nutrition and the environment or to take any action it deems necessary to promote the public interest in sectors of vital importance to its socio-economic, scientific and technological development.

Article 13

Grounds for Refusal of a Claimed Invention

(2) [*Compliance With Applicable Law on Other Matters*] A Contracting Party may also require compliance with the applicable law on public health, nutrition, ethics in scientific research, environment, access to genetic resources, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development.

…

[The Delegation of Brazil further indicated that its proposal made under draft Article 13 should also be taken into account in draft Article 14.]

[Annex III follows]

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[1] Underlined text shows the proposed additions compared to the text as contained in document SCP/7/3.

ANNEX III

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises,

including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

[End of Annex III and of document]