Including the Requirement of indicating in Patent Application the Source of Genetic Resource and related Traditional Knowledge as One of the Topics to be Discussed within SCP

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I. General comments on the direction of SCP's future work

After the adoption of PLT at the Diplomatic Conference held in 2000, WIPO started its work on concluding a Substantive Patent Law Treaty (SPLT) at the 4th session of the WIPO Standing Committee on the Law of Patents (SCP) in April, 2001. Up to now, the SCP has held seven sessions in this regard.

At the beginning, the drafting SPLT was aimed to harmonize all of the substantive requirements concerning the grant of patent right in patent laws worldwide. However, the harmonization work did not proceed so well as expected. On the one hand, with respect to some issues, such as the scope of patentable subject matters and practical app1icability, the opinions of different member states diverged severely. Consensuses can not be reached thereon. On the other hand, alone with the proceeding of the discussion, developing countries paid more and more attentions on the draft SPLT and presented a quite number of new suggestions so as to safeguard the interests of developing countries, which raised more divergence.

For the two reasons mentioned above, the drafting work of SPLT is difficult to go ahead. At the present time, there are mainly two different opinions on how to continue the work of the SCP.

According to one opinion, SCP should concentrate its efforts on the *consistent examination standards throughout the world, improved patent quality, and a reduction in the duplication of work performed by patent offices* (see Document WO/GA/31/10). More concretely, it suggests to focus the discussion on four topics, namely definition of prior art, grace period, novelty and non-obviousness/inventive step.

According to another opinion, the establishment of SPLT should pay more attention to the interests and the demands of developing countries (see Document WO/GA/31/11). As some member states mentioned in

document *PROPOSAL BY ARGENTINA AND BRAZIL FOR THE ESTABLISHMENT OF A DEVELOPMENT AGENDA FOR WIPO* (Document WO/GA/31/11)，*a vision that promotes the absolute benefits of intellectual property protection without acknowledging public policy concerns undermines the very credibility of the IP system.*

There is no doubt that patent system promotes the progress of science and technology through the legal protection provided for technological innovation. The improvement of patent system, however, should not focus only on the aspects such as enhancing patent quality and reducing the duplication of work performed by various patent offices, it should be endowed with more important and more essential goal, that is, patent system shall "*contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations* (Article 7 of TRIPS). When we discuss how to harmonize the substantive requirements on the grant of patent right in different countries, we should follow the fundamental objectives ascertained in the TRIPS and consider seriously the different developing stages of different countries and their different demands raised thereby.

The substantive condition on the grant of patent right is one of the most important aspects of patent law, which produces essential impacts to the economy and society of each country. As a developing country, China believes that the selected topics to be discussed within SCP should include the issue of development, which is concerned by all developing countries. SCP has to respect the different demands of all member states.

II. Proposal for topics to be discussed in SCP

Considering the difficulties of the drafting work of SPLT we are now confronted and in order to raise efficiency and improve the work, it seems to us sensible to limit properly the scope of the future discussion. However, based on the general consideration mentioned above, China believe that the limited topics should include al least some of the issues concerned by most developing countries.

Taking into account the importance of the reliable protection of

genetic resource (GR) and traditional knowledge(TK), China proposes to include the issue of indicating in patent application the source of genetic resource and related traditional knowledge as one of the topics to be discussed in SCP with the top priority.

The reasons are as follows:

1. The legal protection of GR and related TK has great importance and significance

It is well known that CBD has established THREE PRINCIPLES on GR, namely the national sovereignty with respect to its GR， the right of being prior informed and consented by the sovereign state with respect to the utilization of its GR, and the right of the sovereign state to share the benefits produced from the utilization. Those principles have been recognized and accepted broadly by international society. In this connection, to establish the necessary rules through the international harmonization of patent laws and to ensure the disclosure of the source of GR and related TK in patent application will be of great significance for the realization the principles of CBD.

We have to recognize that mere preservation and maintenance of the existing GR themselves will not bring the sovereign state of the resource with actual economic benefits. To produce real economic value, scientific researches and relevant exploitation have to be carried out on the basis of the existing GR. Along with the rapid development of biological and genetic technology, inventions and creations based on GR, particularly in the technical fields of biology, pharmacy and agriculture, new inventions have been increasingly developed in the recent 20 years. This progress has brought great advantages to the whole human society and shall be encouraged fully.

In modern society, the progress of bio-technology can not achieved without the effective legal protection provided by patent system. However, when a patent right is applied and granted for an invention based on GR and related TK form one sovereign state, if the patent system does not offer a mechanism to guarantee the disclosure of the source of the GR and TK in the patent application, it will be not only difficulty for the sovereign state to exercise its sovereignty and to share the economic benefits derived from the invention, but also unable to

make use of the invention due to the monopoly incorporated by the granted patent. We have to say this result really runs counter to the principles of CBD.

In recent years, there have been some well known cases concerning GR/TK and patent right, such as the case of ayahuasca, the case of neem and the case of turmeric. These cases make people more aware of the close relationship between the protection of GR and protection of patent right, more deeply taste the disadvantages of the lack of effective mechanism in the existing patent system to prevent the so called “bad patent”.

In recent years, many countries called strongly for the introduction of the requirement of disclosing source of GR into patent system on various international fora in order to promote the protection of GR. It worth notice that India, Brazil and some other countries have explained how the introduction of obligation to disclose source of GR and TK will improve examination of patent application and prevent the generation of “bad patent” in their proposals submitted to WIPO (such as IP/C/W/429/Rev.1). The proposal submitted by Switzerland to the Working Group on PCT Reform (PCT/R/WG/5/11) as well as the proposal from European Commission to IGC (WIPO/GRTKF/IC/8/11) also indicate the essentiality of disclosing source of GR in patent application. It is proper to say this issue has already become one of the hot topics in the ongoing international discussion on patent system.

As the specialized organization in charge of international IP affairs under the UN system, WIPO should take the responsibility to promote actively the discussion on this topic in the forum of SCP and to facilitate the earlier establishment of the necessary international norm in the harmonized patent law.

It should be emphasized that the establishment of an international norm on the disclosure of GR and related TK in patent application will not only safeguard the interests of developing countries, but also the interests of developed countries. As an important measure which will improve the existing patent system so as to make it more favorable for international society in general, we hope that it will be accepted and supported by all member states.

2. The topic already has sufficient study and discussion basis

At the early stage of the discussion of the Patent Law Treaty (PLT), some developing countries, such as Colombia, proposed to adopt the requirement of disclosing origin/source of GR in patent law. Later, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resource/origin, Traditional Knowledge and Folklore(IGC) for the discussion on the topics of protection of GR, TK and so on in October, 2000. Conference of Parties of CBD, the Working Group on PCT Reform and the TRIPS Council of WTO also put the topic into their agendas for consideration successively

The Decision VI/24 (UNEP/CBD/COP/6/20) of the 6th Conference of Parties of the Convention on Biological Diversity in 2002, inter alia, indicates that：

Invites Parties and Governments to encourage the disclosure of the country of origin of genetic resource/origin in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resource/origin in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resource/origin was granted;

Also invites Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development;

WIPO has also made great efforts on the work in this field. At the invitation from CBD-COP, WIPO prepared *Draft Technical Study on Disclosure Requirements Related to Genetic Resource/origin and Traditional Knowledge* (see WO/GA/30/7Add.1 ANNEX) and *Draft Examination of Issues regarding the Interrelation of Access to Genetic Resource/origin and Disclosure Requirements in Intellectual Property Rights Applications* (see WO/GA/32/8 ANNEX). Those documents make a systemic research on the disclosure requirement in patent application relating to GR and TK.

In the mean time, there has been many legislation and practices at the regional and state level, such as the Andean Community Decision 391 on a Common Regime on Access to Genetic Resource/origin (adopted at July 2, 1996), the Andean Community Decision 486 on a Common Industrial Property Regime(adopted at September 14, 2000)， the Draft Central America Protocol on Access to Genetic and Biochemical Resource/origin and Associated Traditional Knowledge, the European Directive 98/44 on the Legal Protection of Biotechnological Inventions, the Patents Act(amendment) 2002 of India, the Provisional Measure No. 2.186-16 of Brazil (adopted at August 23, 2001), the Bio-diversity Law (No.7788) of Costa Rica (adopted at April 23,1998), the Regulation on Protection of Plant Varieties of Peru (adopted at May 6,1999), the Law on Biological Diversity of Venezuela (Law No. 4,780 of 2000) and the Patent Act (Amendment) of Norway(taken effect in May, 2004), etc. All these researches and practicing legislation have made good basis for the international harmonization.

From our perspective, once the issue of disclosure of GR and related TK in patent application is included into the SCP agenda, there will be two key problems to be discussed.

Firstly, in what situations patent applicants should be required to disclose the source of GR and related TK, including the definition of GR and related TK and what kind of invention should be considered directly based on GR and related TK.

Secondly, what kind of legal consequence would arise for applicant's failure of fulfilling the requirement to disclose the source of GR and related TK in patent application.

It is important for us to make sure that the established mechanism on disclosure of the source of GR and related TK in patent application, on one side, will promote the realization of the principles of CBD and, on the other side, will not bring unnecessary burden and unreasonable limitation to patent applicants.

III. Conclusion

It is widely recognized that the patent system worldwide should be harmonized while taking into account the development of society and economy as well as paying more attention to the public benefit and

striking the balance between right and obligation. When selecting the topics for the future work of SCP, we have to make sure each of them embody the need of development, be mutual supportive with other international rules such as CBD, and balance the different demands of developed and developing countries.

Based on the above consideration, China would like to propose to include the topic of disclosure of the source of GR and related TK in patent application into the SCP future work agenda and to add relevant provisions in the draft of SPLT.