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**INTELLECTUAL PROPERTY RIGHTS AND TRANSFER OF TECHNOLOGIES
WHICH MAKE USE OF GENETIC RESOURCES**

Note by the Secretariat

I. INTRODUCTION

A. Item 5.4.2 and the Secretariat request

1. At its first meeting, the Conference of the Parties adopted a medium-term programme of work which called for its second meeting to consider a compilation of "information provided by Governments as well as relevant reports from appropriate international organizations regarding policy, legislative or administrative measures related to intellectual property rights as provided in Article 16 of the Convention and to access to and transfer of technology that makes use of genetic resources." (see, UNEP/CBD/COP/1/17, annex II, decision I/9, annex).
2. Accordingly, the Secretariat sent a letter to Governments requesting them to submit relevant national-level information to the Secretariat when registering at the second meeting of the Conference of the Parties in Jakarta, Indonesia. Information received from Governments will be made available as an information note for the second meeting of the Conference of the Parties, prior to the discussion of item 7.2 of the provisional agenda.
3. In addition, the Secretariat sent a letter to international organizations with relevant work programmes requesting information and reports or other publications of their organization related to this agenda item. Summaries of the work noted in the responses received by the Secretariat as at 2 October 1995 or found in available reports are included in section IV of the present Note. A bibliography of relevant reports and publications is contained as an annex to this Note. Information received after 2 October 1995 and prior to the second meeting of the Conference of the Parties will be circulated as an

addendum to the present Note. Copies of the reports received by the Secretariat will be available at the second meeting of the Conference of the Parties as reference material.

B. Background

4. The Convention defines genetic resources and genetic material in broad terms¹ reflecting the fact that a growing range of genetic resources are proving valuable for a range of scientific and technological applications. The Convention recognizes that access to genetic resources can lead to significant benefits - including access to and transfer of technologies which make use of genetic resources - thus creating a significant means through which the benefit-sharing component of its three-fold objective can be achieved.

5. Rather than putting the issue of intellectual property rights (IPRs) under the broader heading of "Technology Transfer" in its medium-term programme of work², the Conference of the Parties linked the issue of IPRs to transfer of technologies which make use of genetic resources and placed both under the overall heading of "Access to genetic resources." Article 15 sets the broad framework within which access to genetic resources is to take place. It recognizes that the authority to determine access to genetic resources rests with national Governments and is subject to national legislation. It also strategically places two paragraphs on benefit-sharing within its provisions, thus making very clear that access to genetic resources is a basis upon which benefit-sharing will be negotiated.³ Benefit-sharing may mean a variety of things, ranging from monetary compensation to training and involvement in research and development, to the transfer of technology. By linking IPRs to the transfer of technologies which make use of genetic resources and placing them under access to genetic resources, point 5.4.2 essentially takes a magnifying glass to arrangements for access to genetic resources and focuses on those components which involve the transfer of technologies which make use of genetic resources and the role of IPRs in that process.

6. During the elaboration of the Convention, the issues related to IPRs and, in particular, those related to IPRs and the transfer of biotechnology were complex and difficult. Article 2 defines biotechnology to mean "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." Hence, when the Convention or point 5.4.2 of the medium-term programme of work of the Conference of the Parties refer to technologies which make use of genetic resources, they are in essence concerned with biotechnology.

7. The Article 2 definition encompasses both conventional and new techniques.⁴ Nevertheless,

¹ Article 2 defines "genetic material" as any material of plant, animal, microbial or other origin containing the functional units of heredity. It defines "genetic resources" as genetic material of actual or potential value.

² Such a placement would have had direct implications for all the provisions of Article 16 dealing with IPRs rather than focusing on references to IPRs which relate to the transfer of technologies which make use of genetic resources. See, section III, B, below.

³ See, UNEP/CBD/COP/2/13, discussing Article 15 in detail.

⁴ Conventional techniques range from traditional selective breeding to the use of micro-organisms to make products such as bread or beer. The last 25 years have witnessed a "biotechnological revolution" with new techniques emerging - such as cell fusion, embryo transfer, recombinant DNA technology, tissue culture and new



when the reference connects these technologies with IPRs as it does in item 5.4.2 and Article 16 (3) of the Convention, the focus is on new technologies because it is these newer technologies and their products which are more likely to be currently protected by some form of IPRs.⁵

C. The structure of the Present Note

8. This Note first discusses the general features of IPR systems (section II). Section III examines point 5.4.2 in the context of the provisions of the Convention on Biological Diversity, in particular Articles 15 and 16. Section IV summarizes the work of international organizations of relevance to IPRs. Using the information from the responses from international organizations and a literature survey, section V briefly discusses what is known and what information is needed regarding intellectual property rights, the transfer of biotechnology and the possible benefit-sharing provisions of arrangements for access to genetic resources. The note concludes by presenting options for action which the Conference of the Parties may wish to consider in order to fill in the gaps in information and build relevant experience.

II. GENERAL FEATURES OF IPR SYSTEMS

9. There are two fundamental and interrelated roles for IPR systems, as an incentive for investment in creative activities and to facilitate access to and transfer of technology. The incentive role recognizes that the inventor assumes time and other costs associated with the creation process, so could never compete on equal terms with copiers whose costs, minus the creation process, are lower. The second, and less frequently discussed, role of IPRs, involves the ramifications for access to protected creations. The effects of IPRs on access are neither as clear nor as well documented as for investments.

10. Four forms of IPRs, are associated with technology development and transfer: patents, plant breeders' rights, (PBRs) trade secrets and trademarks. Patents - a form of legal property granted for an invention which gives to its owner the right to exclude others from any use or benefit of that invention without consent - are the type of IPRs, likely to be of most relevance to the transfer of biotechnology as part of access arrangements under Article 15. Those seeking access to genetic resources are likely also to seek patent protection over products developed using genetic resources in order to maximize the return on their investment in research and development.

11. Some new plant varieties may be seen as a form of biotechnological invention to which the original provider of genetic resources may wish to have access. The most common form of protection for new plant varieties is PBRs, which, in general, are intended to allow the commercial plant breeder a monopoly on the production of propagating material for the purposes of commercial marketing, its offer for sale and its marketing.

12. The other type of IPRs, likely to be relevant are trade secrets, which give the holder the right to prevent the acquisition and use of information. Biotechnology is knowledge-intensive. Access to

bioprocessing techniques - which enable biological resources to make greater contributions to human welfare. See, UNEP/Bio.Div.3/7, 23 May 1990.

⁵ Conventional technologies may either not fit IPR requirements or may have been in existence long enough so that the protection afforded by the IPR has expired.

information will therefore be an important aspect of meaningful access to and transfer of biotechnology. The use of trade secrets crystallizes the tension between the confidentiality requirements of some access seekers⁶ and the desire for open disclosure and the publication of results to stimulate use and further innovation.

A. Patents

13. Patents apply to a range of mechanical, chemical, electrical and biological products and processes including, where permitted, living organisms. Patents, like other forms of IPRs, operate as a balance between the inventor and society. Society grants a temporary, partial monopoly to the inventor. Temporary refers to the duration of protection, generally about 20 years; partial describes the scope of protection, the degree of difference required before a related development is not covered by the patent. Society receives in exchange more investment than would otherwise occur and the revealing (disclosure) of the invention. Disclosure not only permits competition soon after a patent lapses but also provides a storehouse of technical knowledge which would not otherwise exist. While IPRs and patent laws are national and, hence, differ from one country, to another, certain general requirements have emerged which are to a large extent uniform. These requirements apply to all industry, including the biotechnology industry, and include the need for the application to show novelty, non-obviousness and utility.

14. Innovation in biotechnology has raised many issues for patent law. There are four main kinds of biotechnological invention which may be subject to patent law: products, compositions, use and methods of use. Products are tangible new materials or entities including organisms themselves, parts of organisms (e.g. cell lines), substances produced from either of these and substances obtained or employed in recombinant DNA technologies. Compositions are mixtures of substances or organisms, the individual components of which may already be known, but which in combination can be shown to display a new property or exert a new effect. The typical patent application in classical biotechnology used micro-organisms or the cells of higher organisms to produce new products or to produce known products in a new or improved way. The only real problem these inventions presented from the patent perspective was how to provide a written description of the process which could be repeated by the skilled worker.⁷ The problem was addressed by the use of culture collections as depositories for "patent cultures."

15. As biotechnology and patent law evolved, microbiological inventions posed particular problems for disclosure in patent law.⁸ This is because, more often than not, repeatability cannot be ensured by written description alone. Patent legislation of an increasing number of countries has therefore developed to meet this problem and contains specific provisions for inventions involving micro-organisms. One international convention - the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures (1977)⁹ - deals entirely with micro-

⁶ Commercial researchers may seek to keep research results secret until they can obtain patent protection over the resulting invention.

⁷ This is the disclosure requirement noted in paragraph 13 above.

⁸ Microbiological processes, products produced by micro-organisms and micro-organisms are all considered patentable.

⁹ The Budapest Treaty entered into force in 1980.

organisms. The Budapest Treaty provides an internationally uniform system of deposit and lays down procedures which depositor and depository must follow. The Budapest Treaty also recognizes certain culture collections as "International Depositary Authorities" (IDAs) and a single deposit made in any one of the IDAs is acceptable by each country Party to the Treaty as meeting the deposit requirements of its own national laws.

16. Because the existence of IPRs, is linked with both the investment incentive and facility of access, a relevant issue is the geographic scope where protection is available. Over 100 countries have some form of patent legislation and are signatories to the International Convention on the Protection of Industrial Property (Paris Convention) of 1883, which is administered by the World Intellectual Property Organization (WIPO), a specialized agency of the United Nations. The purpose of the Paris Convention is to harmonize several aspects of IPRs, especially in the area of equal treatment. Equal treatment is known as national treatment which stipulates that foreigners must be granted the same rights as nationals.

17. Of the more than 100 signatory countries, as at 1988, 53 statutorily excluded plants and 54 excluded animals from protection.¹⁰ These include the members of the European Patent Convention (EPC) as well as a number of developing countries which adopted the WIPO Model Law for Developing Countries on Inventions: Volume I Patents. Both contain exclusions for patents for "plant or animal varieties and the essentially biological processes for the production of plants and animals". This language has proven ambiguous because the definitions of "varieties" and "essentially biological processes" have become unclear in the era of genetic engineering.

B. Plant breeders' rights

18. Plant breeders' rights (PBRs) are a specialized patent-like system for cultivated plants. PBRs were first systematized in 1961 under the International Union for the Protection of New Varieties of Plants (UPOV). In place of the novelty, non-obviousness and utility requirements of patent law, PBRs use distinctness, uniformity, and stability. Uniformity and stability are measures of true-to-form reproductiveness among specimens within a planting and intergenerationally. The principal test then is distinctness and for the variety to be "clearly distinguishable" from all known varieties.

19. PBRs are further distinguishable from patents by the allowance of so-called "farmers' privilege" and "research exemption", sometimes called "breeders' privilege". The farmers' privilege is the right to hold materials as a seed source for subsequent seasons (farmer-saved seed or bin competition). The research exemption refers to the right to use protected materials as the basis for developing a new variety or other research use.

20. Because of these differences, PBRs are generally considered to provide less protection than patents. They also apply to the whole plant or parts thereof. What they do not protect is the unique characteristic (the distinguishing characteristic) of the variety. For that reason, no real protection is provided for a variety with a bio-engineered gene which legally can be removed and used in another variety or with another distinguishing attribute added.

21. There are presently 27 members of UPOV, the international PBR convention, and all but Argentina, Uruguay and South Africa are developed countries. A number of additional countries have

¹⁰ World Intellectual Property Organization (WIPO), 1990. "Exclusions from Patent Protection". WIPO, HL/CM/INF/1 Rev., May.

national PBR laws, including Chile, Colombia and Kenya, among others. Details on the operation of those laws are limited.

C. Trade Secrets

22. Trade secrets assist in the maintenance of secrecy by imposing penalties (the recovery of costs) when information held as secret is improperly acquired or used. Examples of trade secrets include practices to improve the efficiency of a breeding process. Unlike patents and PBRs, no formal application procedure is needed for a trade secret; rather, the information must have commercial value and an effort must be made to keep it secret.

III. ARTICLES 15 AND 16: INTELLECTUAL PROPERTY RIGHTS AND THE TRANSFER OF BIOTECHNOLOGY

A. Article 15: Access to Genetic Resources

23. Article 15 sets the basic framework within which access to genetic resources is to take place and it provides a basis upon which the negotiation of the terms of benefit-sharing can take place.¹¹ Two paragraphs of Article 15 address the return of benefits derived from the subsequent use of genetic resources.¹² Most relevant to the issue of IPRs and the transfer of biotechnology is paragraph 7, which calls upon both developed and developing countries to take legislative, administrative or policy measures with the aim of ensuring that benefits arising from the results of research and development and from the commercial and other use of genetic resources are shared in a fair and equitable way with the Contracting Party providing the genetic resources. One aspect of benefit-sharing under this provision may be access to and transfer of biotechnology.

24. Article 15, paragraph 7, qualifies the obligation by stating that such sharing shall be on mutually agreed terms. The provision also calls upon the benefit-sharing to be carried out in accordance with Article 16, "Access to and Transfer of Technology."

B. Article 16: Access to and Transfer of Technology

25. Article 16 is the only article in the Convention which contains explicit reference to IPRs.¹³ Article 16 (3) directly addresses the relationship between intellectual property rights and access to and transfer of technology that makes use of genetic resources. It states:

¹¹ In brief, Article 15 recognizes that the authority to determine access to genetic resources rests with national Governments and is subject to national legislation. It calls for access on mutually agreed terms and with the prior informed consent (unless waived) of the source country Party. Conditions are to be created to facilitate access by other Parties for environmentally sound uses. Receiving Parties must share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other use of the provided genetic resources. They must also take steps to help providing Parties participate in research on their genetic resources.

¹² Article 15, paragraph 6, recognizes that one potential benefit is participation in the development and carrying out of scientific research.

¹³ Article 16, (2)(3) and (5) refer to IPRs.

"Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those genetic resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below."

26. Like Article 15 (7), Article 16 (3) places the obligation on both developed and developing Contracting Parties. Here each Contracting Party is to take measures with the aim of ensuring that all Contracting Parties which provide genetic resources, in particular developing country Parties, are provided access to and transfer of technology which makes use of those genetic resources, including those protected by patents and other intellectual property rights. Again, consistent with 15 (7), this provision calls for such arrangements to be on "mutually agreed terms."

27. Article 16 (3) states that its application must be consistent with paragraphs 4 and 5 of the same article. Paragraph 4 essentially calls upon each Contracting Party to take appropriate measures to encourage the private sector to jointly develop and transfer technologies.¹⁴ The reference to the private sector is particularly significant in the field of biotechnology, because the rapid development of biotechnology is largely the product of the private sector. Consequently, successful implementation of provisions calling for access to and transfer of these technologies will require its active involvement and cooperation.

28. Article 16 (5) calls upon the Contracting Parties to cooperate to ensure that IPRs are supportive of and do not run counter to the Convention's objectives. The provision recognizes that IPRs may have an influence on the Convention, but it does not state whether this influence is positive or negative.

29. In addition to the reference to paragraphs 4 and 5 of article 6, paragraph 3 is also qualified by stating it must be consistent with international law. This would include international law on IPRs. The most significant new development in this field is the conclusion of the Final Act of the Uruguay Round of Trade Negotiations, which includes as an annex the Agreement on the Trade Related Aspects of Intellectual Property Rights (the TRIPs Agreement).¹⁵ The TRIPs Agreement sets certain minimum standards for intellectual property rights, but also contains wide latitude as to the form and content Parties must adopt to fulfill their obligations. The TRIPs Agreement requires signatory States, including some 70 developing countries, to provide for the following protection within an extendable five- to ten-year period, depending on the level of development:¹⁶

(a) Contracting Parties shall provide for the protection of plant varieties by patents and/or by an effective sui generis system (Section 5, Article 27(3b)). Sui generis in this context means an individual law for the protection of a specific type of invention, such as PBRs for plants;

¹⁴ Article 16 (4) refers back to paragraph 1 and thereby covers technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

¹⁵ The Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, 15 December 1993, Multilateral Trade Negotiations (The Uruguay Round) Doc. MTN/FA, 33 I.L.M. 1 (1994), Annex 1C.

¹⁶ See, MTN/FA II-A1C.

(b) Patents may be prohibited to protect *ordre public* or morality, provided there is a justification exceeding the mere prohibition in domestic law (Section 5, Article 27(2)). That is, there must be an explanation/justification for the exclusion based on some national or cultural/religious priority;

(c) Plants and animals other than micro-organisms and "essentially biological processes for the production of plants and animals" may be excluded from protection (Section 5, Article 27(3b));

(d) Compulsory licenses may be issued in limited cases of due diligence to make a licensing agreement, of adequate remuneration, and subject to judicial review (Section 5, Articles 30 and 31). Compulsory licenses, where the Government overrides the inventor's right to prohibit use, are to be allowed but as a last resort only and then they must be fair to the inventor;

(e) Persons shall have the option of preventing others from using without permission information of commercial value so long as reasonable efforts have been made to keep it secret (Section 7, Article 39). What this says is that protected secrets cannot be taken and used.

30. The most immediate result of TRIPs is the number of countries presently involved in adopting legislation on PBRs through the route of joining UPOV. That group includes Chile and Colombia (membership pending) while other countries, including India, Pakistan, and the Philippines, could join by the end of 1995. Additional countries have established drafting committees for PBR legislation, but the completion dates are not known. Activities regarding patent law amendments and trade secret protection are not well documented.

IV. RELEVANT WORK OF INTERNATIONAL ORGANIZATIONS

Food and Agriculture Organization of the United Nations (FAO)

31. In 1983, the member countries of FAO established a permanent intergovernmental forum on plant genetic-resources - the Commission on Plant Genetic Resources (CPGR) - and a legal framework: the International Undertaking on Plant Genetic Resources. Since then the development of a Global System on Plant Genetic Resources for food and agriculture has been coordinated, overseen and monitored by the CPGR. The CPGR Code of Conduct on Biotechnology includes provisions on IPRs. Resolutions on PBRs and Farmers' Rights were adopted in 1989 by the FAO Conference.

32. Among matters under discussion within the Commission are IPRs concerning plant varieties, related technologies and farmers' germplasms; the impact of IPRs on the environment; and the revision of the International Undertaking on Plant Genetic Resources, to harmonize it with the Convention on Biological Diversity.

United Nations Conference on Trade and Development (UNCTAD)

33. IPRs are among the issues that have been discussed by the UNCTAD Ad hoc Working Group on the Interrelationship between Investment and Technology Transfer. One of the conclusions reached by the Group was that "in the post-Uruguay Round period, intellectual property rights protection is deemed to constitute an important component of an environment conducive to international transfer of technology, including FDI (Foreign Direct Investment). Further studies and technical assistance, in collaboration with the WTO, may be needed in order to elucidate the relationship between intellectual property rights and the transfer of technology, particularly for the implementation of the GATT

Agreement on TRIPs (Trade-Related Intellectual Property Rights), taking into account the characteristics of contemporary knowledge, inventions and ownerships".¹⁷

34. Supporting papers in the Supplement to the Trade and Development Report, 1994, complement the initial assessment of the outcome of the Uruguay Round. Chapter VIII of the Supplement is devoted to trade-related intellectual property rights (TRIPs). It analyses the key features of the Agreement and discusses its possible implications for the volume and costs of transfer and diffusion of technology in developing countries and for the costs associated with implementation and enforcement measures.

United Nations Development Programme (UNDP)

35. In 1994, UNDP commissioned a study from Rural Advancement Foundation International (RAFI) on indigenous knowledge and intellectual property rights. The study, "Conserving Indigenous Knowledge", attempts to raise the awareness of the value of traditional knowledge and to begin a dialogue with indigenous peoples and others on the ways to preserve this knowledge.

36. Three regional meetings have been held in Latin America, in Asia and in the Pacific region to start discussing the study.

37. Based on the outcome of these three meetings, a proposal for an Indigenous Knowledge Programme was prepared. The goal of the programme is to strengthen the capacity of indigenous peoples to defend and advocate their own interests in this area, and to prepare and implement activities that ensure the continuation of their innovation systems.

38. Among other outcomes, it is expected that at the end of this programme: (i) studies will have been conducted on the relation between biodiversity conservation and indigenous knowledge, bioprospecting agreements, IPRs and customary laws, and the relation between indigenous knowledge and the emancipation of indigenous people; and (ii) pilot projects will have been implemented in indigenous communities aimed at the revitalization/strengthening of indigenous knowledge systems.

United Nations Environment Programme (UNEP)

39. The creation of two centres in Japan, with the purpose of promoting the development and transfer of environmentally-sound technologies, was approved by UNEP's Governing Council in 1993. Among the objectives of these centres, particular emphasis is given to sustainable freshwater management technologies, as well as to other environment-related technologies. The centres will also work on developing modalities for financing endogenous capacity-building of scientific and technology centres, especially in developing countries and countries with economies in transition.

International Union for the Protection of New Varieties of Plants (UPOV)

40. Under UPOV, which administers the International Convention for the Protection of New Varieties of Plants, there are a considerable number of activities related to IPRs, PBRs and the use of genetic resources.

¹⁷ Final Report of the Ad hoc Working Group on the Interrelationship between Investment and Technology Transfer to the Trade and Development Board, United Nations, New York 1994 (TD/B/40(2)/17), paragraph 27.

41. UPOV gathers national laws on PBRs and prepares translations of these into English. It also develops guidelines for conducting tests for the "distinctness, homogeneity and stability" of plant varieties. Four Technical Working Parties are involved in this ongoing task, responsible, respectively, for testing guidelines for individual species for agricultural crops, for fruit crops, for ornamental crops and forest trees, and for vegetables. There are two special Working Parties: one studying the application and harmonization of biochemical and molecular techniques in the field of the protection of plant varieties; the other focusing on the possibility of automation and harmonization of computer programmes within UPOV, in order to promote and facilitate the harmonization of the methodologies used by member States for distinguishing between plant varieties.

42. UPOV has prepared a collection of the texts of the International Convention for the Protection of New varieties of Plants and all UPOV models, rules, guidelines and other important documents adopted or decisions taken by the Council of UPOV or its auxiliary bodies.

43. UPOV maintains contact with States and intergovernmental organizations interested in introducing systems of PBRs, and assists them, if so requested, in the preparation of laws on the protection of PBRs, in the implementation of these laws and in the amendment of existing laws to bring them into conformity with the Convention.

44. UPOV has created model legislation for Parties for the implementation of the 1978 revised Convention, and is in the process of creating similar models for the revised 1991 Convention, which are expected to be ready by the end of 1996.

45. A study on the effects of the TRIPs Agreement on the protection of plant varieties is under preparation.

World Intellectual Property Organization (WIPO)

46. One of the main tasks of WIPO consists of cooperating with developing countries in their efforts to develop intellectual property regimes. WIPO's cooperation consists mainly of: (i) advice, given by WIPO's staff and experts and through international meetings organized by WIPO; (ii) training, which may be individual (on-the-job) or collective (courses, seminars, workshops); and (iii) provision of documents and equipment.

47. The activities are, as much as possible, part of a "project" or plan of several years duration, designed in conjunction with individual developing country Governments or regional institutions.

48. Two types of assistance are of special interest in relation to IPRs and the environment: (i) the provision of advice and training to Governments, as well as to public and private sector organizations, on negotiations relating to the licensing of intellectual property and its management, where there is an impact on the environment; and (ii) the provision of free technological state-of-the-art reports covering various categories of technologies, including technologies relevant to the environment. Since the search service started, some eight thousand such reports have been provided.

49. In 1979, WIPO published the "Model Law for Developing Countries on Inventions. Volume I. "Patents" which is a revision of the text "Model Law for Developing Countries on Inventions," published in 1965.

50. A further contribution of WIPO to cooperation with developing countries is the WIPO Academy, created in 1993. Its objective is to conduct encounter sessions on current intellectual

property issues at the policy level, in order to enable the participants in the Academy, on return to their countries, better to formulate appropriate policies for their Governments. Activities with relation to assistance for developing countries, including assistance in relation to the implementation of the TRIPs agreement, are carried out by several WIPO development cooperation and external relation bureaus for different regions of the world.

World Bank

51. The World Bank has no specific policies or guidelines regarding IPRs. Nevertheless, IPRs are indirectly embodied in the forthcoming Operational Policy 4.11 "Cultural Property" that will supersede the Operational Policy Note 11.03 "Management of Cultural Property in Bank-Financed Projects", and in the Operational Directive 4.20 "Indigenous Peoples".

World Trade Organization (WTO)

52. The TRIPs Agreement, as part of the Marrakesh Final Act establishing the WTO, came into force on 1 January 1995. Much of the work of the TRIPs Council during the course of 1995 has been of a preparatory and procedural nature.

53. On the occasion of signing the Final Act, the Ministers adopted a decision on Trade and Environment establishing a WTO Committee on Trade and Environment and setting out a detailed programme of work for the Committee.

54. The Committee on Trade and Environment considered the issue of the relationship between the TRIPs Agreement and the environment at its meeting in June 1995. At the meeting WTO members put considerable emphasis on cooperation between the Secretariats of the WTO and of the Convention on Biological Diversity.

V. QUESTIONS RAISED ABOUT IPRS AND THE TRANSFER OF BIOTECHNOLOGY

55. As noted above, the relationship between IPRs and the Convention's provisions for access to and transfer of technology was a difficult issue in the negotiations for the Convention. The result is the compromise text of Article 16, an article filled with internal cross-references and, particularly in the case of 16 (5), open and inconclusive language. The difficulty was particularly intense with regard to IPRs and the transfer of technology which makes use of genetic resources. While a lot of information exists on the subject of IPRs and technology transfer, there is limited analysis of this information from the perspective of the Convention and its objectives. In addition, there is a lack of experience from which to draw conclusions on the effects of implementation.

A. What is known about IPRs and the transfer of biotechnology

56. It is known that:

- (a) Much of "modern" biotechnology is found in the private sector;¹⁸

¹⁸ Indeed, there are strong links between industry and universities causing a shift in focus from basic science (the results from which are traditionally freely available) to applied research (the results of which are often protected by IPRs, including trade secrets).

(b) While national systems vary in their scope and coverage, the general trend is towards an expansion of the scope of IPRs;

(c) The economic value of genetic resources has been increasingly recognized¹⁹, resulting from a combination of their perceived or potential scarcity, the advance of commercial biotechnology and the development of intellectual property systems to support that advance.

B. Issues on which more information is needed

57. As it relates to IPRs and the transfer of biotechnologies as part of access agreements, the Convention on Biological Diversity leaves a range of implementation policies available. The first step in determining the most productive way forward from the range of possibilities requires determining what questions are raised and hence what information and experience are necessary to make effective decisions. Some of the questions raised requiring more information and/or experience to answer include:

(a) What is the role of IPRs (in particular as compared to other factors) in facilitating or hindering the transfer of biotechnologies as part of benefit-sharing arrangements under access agreements?

(b) Of the biotechnologies of interest, what percentage are actually covered by IPRs? To answer this question Parties must first identify which biotechnologies are of interest. This involves determining biotechnology priorities and needs, including the capacity to absorb the technologies (see sub-paragraph (c) below). Certain techniques, such as many of the techniques involving tissue cultures, were developed in the past and never patented. It is unclear to what extent biotechnologies of particular relevance to developing country Parties are covered by IPRs because information about biotechnologies not covered by IPRs, is not gathered systematically.

(c) What are the limiting factors in acquiring biotechnologies? Many developing countries possess limited capacity to use and develop biotechnology. Because biotechnology is knowledge-intensive and does not involve the transfer of massive mechanical equipment, having access to information and training may be the most important means of acquiring biotechnology. The need to develop technological capacity may be the most serious limiting factor in access to and transfer of biotechnologies. Indeed, it may be that the capacity to use and develop biotechnology correlates with the capacity to pay the required royalties for transfer of biotechnology subject to intellectual property protection and the strength of the recipient country's intellectual property system. If this is the case, IPRs would not have a significant effect on transfer and it would make sense to focus on the other limiting factors, such as training and research development. The point is that Parties need to understand all the factors affecting these transactions in order to understand the role and effect of IPRs.

(d) What is the impact of transfer of biotechnology on the Convention's objectives and how do IPRs, among other factors, affect this impact? All the operative provisions of the Convention must take place within the overall context set by its three-fold objective of conservation, sustainable use and equitable benefit-sharing. If biotechnologies were to be transferred and thereby form part of an equitable benefit-sharing arrangement, it would still violate the provisions of the Convention if the transfer had a negative impact overall on the conservation and sustainable use of biological diversity.

¹⁹ Still, concern has been expressed regarding unrealistic expectations about the market potential of all genetic resources. See, UNEP/CBD/IC/2/14, 20 May 1994, paragraph 10 and footnote 12 citing Barton and Christensen.

In designing benefit-sharing arrangements, provision should be made to see that the benefits provide economic incentive to reinforce the conservation and sustainable use of biological diversity throughout the source country.

(e) How does the TRIPs agreement relate to the Convention on Biological Diversity? The TRIPs Agreement generally requires a strengthening of IPR regimes but, at the same time, provides considerable latitude in both the form and time-frame for implementation. In addition to resolving the larger questions of how these two instruments interrelate, Parties to the Convention on Biological Diversity which are also Parties to the TRIPs Agreement will need considerable information to assist them in identifying the most appropriate policies to meet their needs and obligations under both agreements.²⁰

VI. OPTIONS FOR ACTION

58. Much of the debate surrounding IPRs and transfer of biotechnologies arises from a lack of experience and an inadequate knowledge base concerning the role, effect and potential of IPRs on the transfer of biotechnologies that may be useful to source countries in negotiating agreements for access to their genetic resources. A framework for action adopted by the Conference of the Party could outline several ways in which Parties can move forward on implementation. It could also lay the groundwork for future elucidation and resolution of problem areas.

59. The framework for action should focus on gathering and filling gaps in information, involving the private sector as a critical component for successful implementation of biotechnology transfer provisions within access agreements and building practical experience with implementation.

A. Issues for study

60. Further study is needed on the impact of:

(a) IPRs on the transfer of biotechnologies to developing countries: As is clear from the bibliography annexed to the present Note, there is much published research on the impact of IPRs on technology transfer and development, but the issues have not often been considered from the perspective of the Convention. The information, however, is often quite relevant and has potential to add value to understanding the issue under the Convention. To move forward on the issues raised by point 5.4.2, the Conference of Parties may wish to analyse, based on available information, the impact of specific categories of IPRs at certain identified stages of the collection and use of genetic resources. Such a study would help Parties to place IPRs in context as one component of benefit-sharing arrangements which involve the transfer of biotechnology. A study of this nature would help to address the questions raised in paragraph 57 (a) and (b) above.

The study could also help explore the need for cooperation among Parties on standards for implementation. Such standards may be important to the private sector of industrialized countries wanting a known business environment and the assurance that no country's industry will be competitively disadvantaged. Standards may be important to the public and private sectors of developing countries wanting to ensure that they are not pressured into relaxing standards in competition for business.

²⁰ As noted in paragraph 29, the TRIPs Agreement sets certain minimum standards for IPRs, but also contains wide latitude as to the form and content Parties must adopt to fulfill their obligations.

(b) The TRIPs Agreement on the objectives of the Convention on Biological Diversity: If the Conference of the Parties decides to undertake an analysis of the relationship between these two agreements it would be most efficient to undertake one study which looks at the relationship in a holistic way. This task is, therefore, cast in broader terms than analysing the relationship of TRIPs to biotechnology transfer under the Convention on Biological Diversity. There is a large and growing overlap in Parties to the Convention on Biological Diversity and the TRIPs Agreement.²¹ The WTO Committee on Trade and Environment²² considered the issue of the relationship between the TRIPs Agreement and the environment at its meeting in June 1995 and will undoubtedly continue work in this area. The Conference of the Parties may wish to consider requesting an analysis which complements work going on in other institutions, but approached from the perspective of the Convention on Biological Diversity. An analysis of this nature would help address the question raised in paragraph 57 (e) above.

(c) The transfer of biotechnologies on the conservation and sustainable use of biological diversity and the role of IPRs and other factors in the process: As noted above, the provisions of the Convention are to be implemented as a whole so that they promote the three-fold objective of the Convention. Benefit-sharing can and should promote conservation and sustainable use. Biotechnologies are not to be transferred for the sake of their transfer, but to provide the basis upon which conservation, sustainable use and equitable benefit-sharing can be realized. Mechanisms that address the potential negative impacts of biotechnologies on biological diversity will need to be established. This is a subset of the broader need to determine what form or type of mechanism(s) needs to be in place so that the benefits returning to the source country support the conservation and sustainable use of biological diversity. Exploring possible mechanisms would help address the question raised in paragraph 57 (d) above.

61. In addition, detailed case studies of the role of IPRs in the transfer of biotechnologies from particular technology systems would yield valuable concrete information on the extent to which IPRs influence transfer in those systems.

B. Consultations with the private sector

62. As noted above, the private sector plays a central role in the biotechnology field. Consultations with industry are therefore key to achieving the Convention's technology transfer and benefit-sharing objectives.

63. Direct exposure to the perceptions of private industry, as the owners of many of the relevant biotechnologies, is critical. For many developing countries this is a new area of endeavour, and they therefore need to strengthen their links and experience with private industry. On the corporate side, the Convention and the opportunities it presents for partnerships are largely unknown and require a building of knowledge and experience. In addition, with the increasing privatization of economies there is a

²¹ As at 2 October 1995, there were 109 Parties to the Final Act of the Uruguay Round, 81 of whom are Parties to the Convention on Biological Diversity.

²² On the occasion of the signing of the Final Act embodying the results of the Uruguay Round of the Multilateral Trade Negotiation, the Ministers adopted a decision establishing a World Trade Organization Committee on Trade and the Environment. The tasks of the Committee as defined in the decision are the identification of the relationship between trade measures and environmental measures in order to assure sustainable development, and the provision of appropriate recommendations on whether any modification of the provisions of the multilateral trading system are required, compatible with the open, equitable and non-discriminatory nature of the system. MTN/TNC/45(MIN).

growing mutual dependence and hence a need for Parties to have better familiarity with their potential partners.

64. Discussions between corporate leaders of the biotechnology industry and policy officials and leaders of private industry in developing countries provide the opportunity to build trust by getting the groups together. The Conference of Parties may wish to consider how the clearing-house mechanism can assist in building trust between public and private institutions.²³

65. Finally, as indicated in section VI, C, below, cooperative exercises and agreements are a good way to build experience. It would be fruitful to get advice from those who will need to be part of any cooperative arrangements prior to their organization and conclusion. A first step would be open and frank consultations with the key members of the private sector.²⁴ The Conference of Parties may wish to consider asking the Secretariat to conduct such consultations perhaps in conjunction with the round table discussions suggested above. Consultations with the private sector would help address aspects of the questions raised.

C. Building practical experience

66. The best way to attract the private sector to the Convention is by encouraging it to cooperate. The Conference of the Parties may wish to consider how it can use the clearing-house mechanism to form bilateral pilot projects to attempt to build experience in cooperative arrangements which include as one component the transfer and development of biotechnologies. While the projects might be arranged between developed and developing country Parties, their aim should be to demonstrate how such arrangements can work with the private sector.²⁵ The projects should build on the experience that already exists in this area.²⁶ The Conference of Parties might wish to discuss determining how the Clearing-house mechanism might be used to see that the information on experience is effectively disseminated so as to be of use to all Parties.

67. These pilot projects would greatly enrich Parties' understanding of the practical realities of implementation. They would help focus attention on the realities of building capacity for technology research and development, designing equitable sharing of useful benefits, and developing and distributing appropriate technologies. Like the studies recommended in section VI, A, above, the projects would also help place the IPRs, issue in context by demonstrating in real situations that these rights are merely one component of the benefit-sharing process.

²³ See, UNEP/CBD/COP/2/6 which discusses the clearing-house mechanism in detail, including a proposal for a 2 year pilot phase.

²⁴ There are other actors, most notably indigenous and local communities, which were not actively involved in the negotiations, yet which are critical to the Convention's success. The Conference of the Parties may wish to consider if it is desirable to expand the Secretariat's consultations to include representatives of these communities and how this would relate to the preparation of item 6.5.1 of the medium-term programme of work on the implementation of Article 8 (j).

²⁵ Indeed, if the Conference of Parties chooses to endorse such pilot projects it may wish to expand the reach to show how these arrangements can include indigenous and local communities, another sector critical for the Convention's objectives, yet not actively involved in the negotiations.

²⁶ See, UNEP/CBD/COP/2/13 which discusses experience with access arrangements and issues to consider.

VII. CONCLUSION

68. The proposals for action contained in section VI above would enhance understanding of IPRs in the Convention and, in particular, of their effect on benefit-sharing arrangements involving genetic resources and biotechnology. Some, in particular the proposed bilateral pilot projects, require a longer time horizon than the annual²⁷ meetings of the Conference of the Parties. Actions requiring a longer time-frame will need to be planned realistically with the provision for progress reports to the Conference of the Parties.

69. In addition, the Conference of the Parties needs to consider how action in this area relates to other areas of its medium-term programme of work, in particular the establishment of the Clearing-house mechanism, the implementation of Article 8(j), its relationship with other international conventions and organizations, such as the WTO and the TRIPs Agreement, and its consideration of ways and means to promote and facilitate access to and transfer and development of technology. Indeed, on this last point, it might be most useful to have a comprehensive study analysing all the obstacles and opportunities for technology transfer, rather than focusing only on the role of IPRs. In addition, the Conference of Parties may wish to consider how the role of the financial mechanism established by Articles 20 and 21 can facilitate technology transfer of both protected intellectual property and technologies in the public domain.

70. For example, if bilateral pilot projects go forward, the Conference of the Parties may wish to request that information arising from the experience is available through the Clearing-house mechanism. Similarly, the projects may wish to consider how they will involve local communities to help create more information and experience of relevance to the implementation of Article 8(j).²⁸ This kind of coordination will ensure that the implementation of the work programme can move forward in an effective and coherent fashion.

71. As noted above, biotechnology is knowledge-intensive, making access to information and training an important means of acquiring biotechnology. Developing countries must therefore invest in training and create an environment that is conducive to access to information, especially to specialized databases. Article 18 establishes the Clearing-house mechanism and calls for cooperation to, inter alia: (a) develop and strengthen national capabilities by means of human resources development and institution-building; (b) encourage and develop methods of cooperation for the development and use of technologies; and (c) promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of the Convention. The Conference of the Parties should consider how the Clearing-house mechanism can be used to build capacity for meaningful access to biotechnology, including the handling of IPR-related issues.

72. The Conference of the Parties may also wish to note that the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) at its first meeting discussed the utility of including in patent applications using biological source materials information relating to country/countries of origin and common public knowledge of the use of those materials. The SBSTTA is looking to the Conference of the Parties for guidance with respect to the future work of the SBSTTA on the transfer of technology, in accordance with the provisions of Article 16 and other relevant provisions of the Convention.²⁹

²⁷ In accordance with the rules of procedure for meetings of the Conference of the Parties to the Convention on Biological Diversity, meetings will be on an annual basis, with a review of the periodicity taking place no later than at its fourth meeting (Rule 4).

²⁸ The Conference of Parties may wish to refer to UNEP/CBD/IC/2/14 (The rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the Convention on Biological Diversity).

²⁹ UNEP/CBD/COP/2/5, recommendation I/4, paragraph 2.

Annex I

List of documents and publications on intellectual property rights (IPRs) by relevant international organizations as at 2 October 1995

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United Nations (UN)

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United Nations Development Programme (UNDP)

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United Nations Environment Programme (UNEP)

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