THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN TECHNOLOGY TRANSFER IN THE CONTEXT OF THE CONVENTION ON BIOLOGICAL DIVERSITY

A TECHNICAL STUDY

Final draft

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1. Introduction

1. At its seventh meeting, which took place in Kuala Lumpur, Malaysia, from 9 to 20 and 27 February 2004, the Conference of the Parties to the Convention on Biological Diversity ('the Convention' hereafter) adopted a programme of work on technology transfer and technological and scientific cooperation. The purpose of this programme of work is to develop meaningful and effective action to enhance the implementation of the pertinent provisions of the Convention. It spells out a number of strategic considerations to be taken into account in its implementation by the various actors. Grouped under four programme elements, it also spells out a number of operational targets and related activities required from Parties, other governments, international organizations and the Secretariat.

2. Element three of the programme of work, on creating enabling environments, seeks to "to identify and put in place institutional, administrative, legislative and policy frameworks conducive to private and public sector technology transfer and cooperation, taking also into account existing work of relevant international organizations and initiatives." Under this programme element, activity 3.1.1 calls for the preparation of technical studies that further explore and analyse the role of intellectual property rights in technology transfer in the context of the Convention on Biological Diversity and identify potential options to increase synergy and overcome barriers to technology transfer and cooperation, consistent with paragraph 44 of the Johannesburg Plan of Implementation. The benefits as well as the costs of intellectual property rights should be fully taken into account. The Secretariat of the Convention, WIPO, UNCTAD as well as other relevant organizations are identified as main actors to undertake this activity.

3. The present document responds to this request. Initiated by invitations that were sent by the Executive Secretary of the Convention on Biological Diversity to the executive heads of WIPO and UNCTAD in August 2004, it is the result of joint collaborative efforts by staff of the CBD, UNCTAD, and WIPO secretariats. Peer reviews provided by other competent organizations and individual experts, as well as by inhouse colleagues, are gratefully acknowledged.

4. The document is intended to make an in-depth, practical and substantive contribution to policy dialogue and consensus-building on the topic considered, and may by this nature contain observations and interpretations that are based on own understanding of the subject matter, in particular with regard to international intellectual property instruments. The document does not represent any official view of CBD, UNCTAD and WIPO; their secretariats; or their Member States.

5. Consistent with the request expressed in the programme of work of the Convention of Biological Diversity, the present document focuses on the role of intellectual property rights in technology transfer in the context of the Convention. Hence it does not claim that the exploration and analysis presented, as well the identified options to increase synergy and overcome barriers to technology transfer and cooperation, can simply be transferred to and applied in a more general context. While some of the insights presented may indeed also hold true in a more general context, others would be in need of amendment and/or qualification in order to do so, and still others may not be generally applicable at all.

6. The study is structured as follows. The first three chapters (grouped under section I) provide a more extensive introduction into the topic and serve to set the stage for the subsequent analytical chapters in the second section of the document. Chapter 2 provides a more detailed overview on the provisions and work on technology transfer under the Convention on Biological Diversity. Chapter 3 provides a more detailed explanation of the overall structure of the study. The role of intellectual property on technology transfer is multi-faceted and complex. Distinct effects of intellectual property rights can be identified within the different phases of transferring technology. Chapter 3 provides an overview of these different phases.

7. Section II of the study addresses the benefits and costs of intellectual property rights that may arise during the different phases of technology transfer: at the stage of technology development (chapter 5), when identifying transfer opportunities (chapter 6), during the actual transfer (chapter 7), and during the phase of adapting the transferred technology to local needs and conditions (chapter 8). Throughout the analysis, the concepts of "benefits" and "costs" will be interpreted in a broad sense and will not be restricted to the direct financial costs and benefits that are associated with commercial activities. Chapter 9 summarizes the main findings and provides tentative conclusions with a view to identifying potential options to increase synergy and overcome barriers to technology transfer and cooperation, as requested by the programme of work.

SECTION I: SETTING THE STAGE

2. Technology transfer under the Convention on Biological Diversity

8. The objectives of the CBD, which are to be pursued in accordance with its relevant provisions, are set out in Article 1 of the Convention: (i) the conservation of biological diversity, (ii) the sustainable use of its components, and (iii) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. It is noteworthy that this fundamental provision of the Convention already includes an explicit reference to technology transfer as a means to implement its third objective.

9. The programme of work on technology transfer and technological and scientific cooperation, adopted by the Conference of the Parties at its seventh meeting in 2004, identifies the provisions that are deemed relevant by the Conference of the Parties in addressing this subject-matter, by stating that "the purpose of this programme of work is to develop meaningful and effective action to enhance the implementation of Articles 16 to 19 as well as related provisions of the Convention." The remainder of this chapter will briefly review these Articles as well as the closely related Article 15 of the Convention, with a view to clarify the nature of relevant intellectual property mechanisms. This discussion is not intended in any way to interpret, limit, define or restrict the provisions covered; rather, it is intended to highlight in a non-exhaustive way the range of possible roles of intellectual property and intellectual property mechanisms that may be of potential relevance to these provisions, as a springboard for further discussion in subsequent chapters.

Article 16 (Access to and Transfer of Technology)

10. The basic obligation of all Parties regarding access to and transfer of technology is set out in paragraph 1 of Article 16 of the Convention. This paragraph recognizes that both access to and transfer of technology among contracting Parties are essential elements for the attainment of the objectives of the Convention. Mirroring the three objectives of the Convention, it then provides that each Contracting Party "undertakes...to provide and/or facilitate access for and transfer to other Contracting Parties of 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."

11. Article 16.1 also recognizes that technology includes biotechnology. Biotechnology is in turn defined in Article 2 of the Convention, on use of terms, as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.' This suggests that the present study should also consider any specific characteristics of the intellectual property system relating to this area of technology, rather than just considering access to and transfer of all technology transfer, and partly because there may be particular aspects of transfer of relevant technologies that pose specific policy, legal and practical questions. It may be necessary to focus on specific elements of national intellectual property law and practice relevant to such technologies, and the innovation structures and processes that apply in this domain. This includes, for instance, research in areas of technology that entail the use of genetic resources and microorganisms.

12. Paragraph 2 of Article 16 further stipulates that access to and transfer of technology to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed. Intellectual property may be one way of structuring or clarifying the nature of mutually agreed terms, or it may be one issue affecting access and transfer of technology that would have to be agreed upon as part of the concessional and preferential terms. For example, a technology may be licensed under intellectual property rights in a way that

specially favours developing countries, or humanitarian or non-profit purposes: this may be an option for public-interest licensing of technologies that assist in the conservation and sustainable use of biodiversity but that have other commercial applications which would effectively cross-subsidise their use in conservation and sustainable use.

13. The provisions of the Convention on technology transfer reflect the consensus of the international community, laid down in key international policy documents, that the development, transfer, adaptation and diffusion of technology and the building of related capacity is crucial for achieving sustainable development. For instance, principle 9 of the Rio Declaration on Environment and Development calls upon States to cooperate to strengthen capacity-building for sustainable development by technology transfer. Chapter 34 of Agenda 21 provides further important guidance on the transfer of environmentally sound technology, cooperation and capacity-building. Chapter 16 provides similar guidance on the environmentally sound management of biotechnology, including the establishment of mechanisms for the development and the environmentally sound application of biotechnology, of which technology transfer is an important component.

14. The Johannesburg Plan of Implementation of the World Summit on Sustainable Development (WSSD) reinforced this recognition by calling upon States to promote, facilitate and finance the development, transfer and diffusion of environmentally sound technologies and corresponding know-how in particular to developing countries and countries with economies in transition. In paragraph 44, world leaders recognized that a more efficient and coherent implementation of the three objectives of the Convention and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries. It would also include actions at all levels to, *inter alia*, promote concrete international support and partnership for the conservation and sustainable use of biodiversity in particular through the appropriate channeling of financial resources and technology to developing countries and countries based upon genetic resources, in accordance with articles 15 and 19 of the Convention, including through enhanced scientific and technical cooperation on biotechnology and biosafety, including the exchange of experts, training human resources and developing research-oriented institutional capacities.

15. Provisions on technology transfer are also included in other multilateral environmental agreements. For instance, the United Nations Framework Convention on Climate Change (UNFCCC) commits all Parties to promote and cooperate in the development, application and diffusion, including transfer, of technologies, practices and processes that control, reduce or prevent anthropogenic emissions of greenhouse gases not controlled by the Montreal Protocol in all relevant sectors, including the energy, transport, industry, agriculture, forestry and waste management sectors (Article 4 (1) (c)). Parties to the United Nations Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, undertake to promote, finance and/or facilitate the financing of the transfer, acquisition, adaptation and development of environmentally sound, economically viable and socially acceptable technologies relevant to combating desertification and/or mitigating the effects of drought, with a view to contributing to the achievement of sustainable development in affected areas (Article 18 (1)).

16. It is important to underline that the term "technology" as used in the Convention not only refers to technical machinery and equipment (the so-called "hard" technology), but also to the notion of "soft" technology, that is, technological information or know-how. $\underline{1}$ / This knowledge is brought about both

<u>1</u>/ Kranzberg, M., 1986: *The Technical Elements in International Technology Transfer: Historical Perspectives. In The Political Economy of International Technology Transfer.* J. R. McIntyre, D.S. Papp, (eds.), Quorum Books, New York, pp.31-46.

through research and innovation, that is, through moving ideas from invention to new products, processes and services in practical use, and through a complex and often costly process involving learning from others. 2/ Against this background, in the context of the Convention, relevant technologies include for instance techniques for *in-situ* conservation such as integrated pest management, as well as technologies for *ex-situ* conservation such as preservation and storage technologies used in gene banks. They also include technologies related to the sustainable management of biodiversity resources, for instance, sustainable forest management or integrated water management techniques. In addition, many monitoring technologies, such as remote sensing, are indispensable for the generation of updated and accurate biodiversity information, which is a crucial precondition to the design and implementation of policies for the conservation of biodiversity and the sustainable use of its components.

17. Technologies that make use of genetic resources include many examples of modern biotechnology. In a number of instances, the Convention provides for the transfer of such technologies as a means to implement its third main objective, that is, sharing the benefits arising out of the utilization of genetic resources in a fair and equitable manner – see paragraphs 26and 26 below for details.

18. Many of these technologies are of proprietary nature. Consequently, intellectual property rights, the legal regulation of intellectual property and the practical exercise and use of intellectual property rights and other intellectual property mechanisms each potentially have bearing on Article 16 and, consequently, on each of the objectives of the Convention.

- (i) For instance, technologies developed under the aegis of the intellectual property system and protected by it in some jurisdictions may be useful for the conservation of biological diversity (such as for instance, the above-mentioned remote sensing technologies for use in gathering and assessing information on biodiversity; or technologies for ex-situ conservation such as preservation and propagation technologies for ex-situ collections). On the other hand, some technologies may be seen as prejudicial to conservation of biodiversity, 3 and some national and regional patent laws provide for exclusions of technology that cause serious prejudice to the environment.
- (ii) Proprietary technologies may also contribute to the sustainable use of the components of biodiversity, such as for instance technologies for screening the active properties of genetic materials for possible therapeutic use or useful enzymatic activity.
- (iii) Intellectual property laws, as well as specific intellectual property rights and the way they are exercised, and mechanisms concerning patent disclosure, may help determine how benefits from the utilization of genetic resources are generated and shared and how the appropriate transfer of relevant technologies is undertaken. $\underline{4}$:

^{2/} The concept is also used in the note by the Executive Secretary on promoting and facilitating access to, and transfer and development of technology (UNEP/CBD/COP/3/21) prepared for the third meeting of the Conference of the Parties. For a discussion, see Lesser, W. (1997): *The Role of Intellectual Property Rights in Biotechnology Transfer under the Convention on Biological Diversity*. ISAAA Briefs No. 3. http://www.isaaa.org/publications/briefs/Brief_3.htm. For a discussion of different definitions of technology, see also IPCC (2001): *Methodological and Technological Issues in Technology Transfer*. Special Report of Working Group III of the Intergovernmental Panel on Climate Change, section 1.4 (http://www.grida.no/climate/ipcc/tectran/).

 $[\]underline{3}$ / In this regard, Article 19 (3) refers to living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity – the subject matter covered by the Cartagena Protocol on Biosafety under the Convention.

<u>4/</u> For example, the agreement between the Government of Samoa and the University of California concerning development of AIDS treatments from mamala bark provides for preferential access to resulting technologies for the benefit of developing countries.

Intellectual property rights may be among the 'rights over those resources and to technologies' referred to in the third objective of the Convention.

19. It is therefore no surprise that the role of intellectual property rights in technology transfer has been given particular attention when drafting the Convention, and has raised considerable and ongoing interest among Parties since then. Article 16 of the Convention establishes a number of further conditions regarding technology transfer which address or relate to intellectual property rights:

- Paragraph 2 of Article 16 states that, in the case of technology subject to patents and other intellectual property rights, access and transfer shall be provided on terms that recognize and are consistent with the adequate and effective protection of intellectual property rights. This provision suggests that the terms that govern the provision of access and transfer would need to consider the operation of relevant intellectual property rights. The role of intellectual property in relation to *access* may differ from its role in relation to *transfer*.
- Paragraph 3 of Article 16 requires Parties to take legislative, administrative or policy measures with the aim that Parties which provide genetic resources, in particular those that are developing countries, are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21and in accordance with international law.
- Paragraph 4 of Article 16 requires Parties to take legislative, administrative or policy measures with the aim that the private sector facilitates access to, joint development and transfer of technology for the benefit of both governmental institutions and the private sector of developing countries. Intellectual property laws and policies, including policies on management of publicly funded research and laws governing exceptions and licensing, as well as specific licensing, joint venture, research cooperation and other technology partnership arrangements that deal with intellectual property, are all potentially relevant elements of these measures, at least in some contexts.
- Lastly, paragraph 5 of Article 16 recognizes that patents and other intellectual property rights may have an influence on the implementation of the Convention, and stipulates that Parties should cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives. This requirement may point to the specific benefits of cooperation in relation to patents and other intellectual property rights as part of the overall framework of promotion of access to and transfer of CBD-related technologies.

Article 17 (Exchange of Information)

20. This provision requires Parties to facilitate "exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries." This information exchange shall include "results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1."

21. As it follows Article 16 and is distinct from it, this article suggests that a distinction can be drawn between the simple exchange of information as such, and the processes of access to and transfer of technology. Patent information systems are a key source of information, in the general sense of 'exchange of information' considered here. However, their practical availability and accessibility to widespread user groups have been transformed since the CBD was concluded. Patent information

systems also play an important role in the promotion of access to and transfer of technology, including in identifying useful or relevant technologies, determining the identity and patterns of ownership, ascertaining legal status and territorial reach of relevant patents and thus providing information on freedom to operate for those seeking to use this publicly disseminated technology.

Article 18 (Technical and Scientific Cooperation)

22. This Article requires Parties to promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity. Special attention is to be given to the development and strengthening of national capabilities, by means of human resources development and institution building (18.2). Cooperation is also required for "the development and use of technologies, including indigenous and traditional technologies" in pursuance of the CBD's objectives (18.4). Finally, contracting Parties are, subject to mutual agreement, to "promote the establishment of joint research programmes and joint ventures for the development of technologies" relevant to the CBD's objectives.

23. The form of cooperation envisaged in the Article is likely to raise practical and policy questions concerning intellectual property management, and appropriate ways of structuring cooperative research partnerships and technology development joint ventures. The overall policy guidance lent by the CBD may help to shape specific practical structures, partnerships and mechanisms to promote this form of cooperation.

Article 19 (Handling of Biotechnology and Distribution of its Benefits)

24. Article 19, on biotechnology, requires Parties to establish legislative, administrative or policy measures to provide for the effective participation in biotechnological research activities of Parties, especially developing countries, which provide genetic resources for such research; and to take practicable measures to promote and advance priority access by such Parties, on a fair and equitable basis, to the results and benefits arising from biotechnologies based upon the genetic resources provided. Such access shall be on mutually agreed terms.

25. In a manner similar to Articles 16 and 18, the provisions of this Article may require considering how intellectual property mechanisms are, and can be, used in structuring, managing and promoting these kinds of technology access and cooperative research arrangements.

Article 15 (Access to genetic resources)

26. Article 15 contains important elements regarding technology transfer in the context of access to genetic resources and benefit sharing. Paragraph 6 requires each Party to endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with full participation of, and where possible in, such Contracting Parties. Joint and in-country research is therefore considered an important avenue for the development of technological capabilities of Parties providing genetic resources. Paragraph 7 of Article 15 further requires each Party to take legislative, administrative or policy measures, as appropriate and in accordance with Articles 16 and 19, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from commercial and other utilization of genetic resources with the Contracting Party providing such resources. The transfer of technology has also been identified as a benefit-sharing option in Appendix 2 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization.

27. While it is not directly covered by the terms of this study, Article 15, in particular Article 15.6 and 15.7, would also relate to intellectual property rights.

Article 20 (Financial Resources

28. Finally, it is noteworthy that the Convention links the effective implementation of the Convention by developing country Parties to the transfer of technology by developed country Parties. Article 20 (4) of the Conventinoi states that the "extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties." 5

Outlook

29. As explained in the introduction above, the Conference of the Parties to the Convention recently adopted a programme of work on technology transfer and technological and scientific cooperation with a view to enhance the implementation of the pertinent provisions of the Convention. Activity 3.1.1 of the programme of work calls for the preparation of technical studies that further explore and analyse the role of intellectual property rights in technology transfer in the context of the Convention on Biological Diversity and identify potential options to increase synergy and overcome barriers to technology transfer and cooperation, while taking the benefits and costs of intellectual property rights fully into account. The inclusion of this activity in the programme of work of the Conference of the Parties mirrors the ongoing interest attached to the role of intellectual property in technology transfer under the Convention, and reflects the spirit of paragraph 5 of Article 16, that is, that Parties to the Convention should cooperate in regard to the influence of intellectual property rights on the implementation of the Convention in order to ensure that such rights are supportive of and do not run counter to its objectives.

^{5/} Similar provisions exist in other Conventions. See Article 4 (7) of the United Nations Framework Convention on Climate Change and Article 20 (7) of the United Nations Convention to Combat Desertification.

3. Phases of technology transfer

30. The process of transferring a technology can generally be separated into different phases. $\underline{6}$ / The impact of intellectual property rights may differ under each of these phases. This observation suggests to structure an analysis of the multi-faceted and complex role of intellectual property rights for technology transfer under the Convention in accordance with these phases:

(a) As a precondition for any transfer, technology needs to be developed. It is therefore important to include this development phase into the analysis even though it is not part of the actual transfer of technology;

(b) The identification of transfer needs and opportunities stands at the actual beginning of every transfer of technology. The transfer and exchange of information on the appropriate level is crucial at this stage;

(c) Arrangements for undertaking the actual transfer are taken in the next phase. For proprietary technology, the existence of an enabling legal environment is a key issue during this stage;

(d) The adaptation of transferred technology to local socio-economic and cultural conditions stands at the end of the procedure.

Technology development

31. As regards the *development of technologies*, incentives for innovation and technology generation are shaped, *inter alia*, by the legislative and regulatory conditions governing these technologies. The grant and effective protection of adequate intellectual property rights is typically assigned a key role in this regard, particularly in those sectors where fixed costs for research and development are high. <u>7</u>/. On the other hand, a number of recent contributions have highlighted constraints and limitations of real-world property right systems, which may actually generate obstacles that impede technology transfer in particular to developing countries. Examples include: the capacity and resource constraints of patent offices, in particular in prior art searches; the grant of overly broad patents; strategic incentives in applying for intellectual property protection for deterring research by rivals; the notion of patent thickets and the tragedy of the anti-commons, in conjunction with transaction costs on licensing markets. These issues will be addressed in more detail in chapter 5 below.

Identification of transfer opportunities

32. The *identification of transfer needs and opportunities*, through appropriate access to and exchange of information with regard to the existence of technologies and their potential for application, is an important initial step in the transfer process. In the case of technologies that are not easily copied, additional input of technical expertise and know-how may be needed from the initial developer with regard to the use of the technology and its adaptation to local circumstances. Existence and an adequate design of institutions for the gathering and dissemination of information, at national and international levels, may substantially lower search costs for potential technology providers and users. It will be argued in chapter 6 below that national and international patent databases can play a crucial role in this regard, and therefore constitute an important benefit of intellectual property right systems during this phase.

<u>6/</u> See section 1.6 of the IPCC special report *Methodological and Technological Issues in Technology Transfer*, referred to above, for a similar analysis distinguishing assessment (including identification of needs), agreement and implementation as well as evaluation, adjustment and replication as phases of technology transfer.

<u>7/</u> See Lesser, W. (1997), ibid, page 8; WTO (1996), ibid, pages 4-5.

The actual transfer of technology

33. Arrangements for undertaking the actual transfer are of particular importance for proprietary technologies, and especially for those technologies that are easily copied. For such technologies, the existence of an enabling legal and institutional environment for arranging the actual transfer is often underlined as a crucial precondition because of the nature of the mechanisms for such transfer and the desire by technology owners to secure adequate protection for their proprietary interests. Potential suppliers of technologies are arguably more willing to voluntarily transfer technology, especially technology that is easily copied, if the recipient country has an effective intellectual-property-rights regime in place. Moreover, as regards technologies that make use of genetic resources, several intellectual-property-rights-related mechanisms for the sharing of benefits may provide important avenues for the diffusion of biotechnologies, including on concessional or preferential terms where mutually agreed, in accordance with Article 16 (2) of the Convention. Examples include joint patents with stakeholders in countries of origin of genetic resources as well as joint research programmes with institutions in such countries. On the other hand, a number of real-world constraints, such as transaction costs in licensing markets or imperfect capital markets in particular in developing countries, are sometimes identified as limiting or even reversing the beneficial effects of intellectual property rights on technology transfer. These and related issues are addressed in greater detail in chapter 7 below.

Technology adaptation

34. The *adaptation of transferred technology to local needs and circumstances* is an important step and in many cases crucial for a successful transfer of technology. The identification of adaptation needs and of suitable tools for adaptation, through information-gathering and exchange, is an important element already when identifying transfer opportunities, and will also be important during the actual implementation and adaptation phase. With regard to proprietary technologies, the conditions underlying the transfer, for instance, the stipulations laid out in licensing agreements, may have an important impact on the adaptability of technologies, and will therefore often be decisive for the ultimate success or failure of the transfer. Furthermore, successful adaptation may require strengthening national capacities in research and development; again, conditions laid out in licensing agreements may play an important role. These issues will be addressed in chapter 8 below.

4. The forms and scope of relevant intellectual property rights

35. This chapter first provides an overview of general factors that may be relevant to the role of intellectual property mechanisms, and then considers how the intellectual property system is actually used and potentially can be used to further the objectives of the CBD in the course of implementing the specific provisions under consideration in this study. This provides the groundwork for discussion in the following section of the positive opportunities and the shortcomings of the intellectual property system in relation to transfer of technology in the context of the CBD, including a survey of advantages (or "benefits") and disadvantages (or "costs"), and a review of measures to maximise advantages and minimize disadvantages.

A. General considerations and objectives

36. The term 'intellectual property mechanisms' is used as a broader term than 'intellectual property rights' so as to cover intellectual property laws and systems that do not involve the grant or exercise of distinct 'rights' but are typically used in practical technology transfer processes – such as non-disclosure or confidentiality agreements, measures against unfair competition, and the use of public domain patent information (including technology that is subject to patent rights in some national jurisdictions but not in others). In addition, to some extent, it is the manner in which IP rights or mechanisms are deployed, and how they are used to structure and define technology partnerships, and not just the formal or theoretical legal scope of rights, that determine the form, direction and content of technology transfer. For instance, the same 'right' can be used in an exclusive manner to garner the necessary resources to bring a capital-intensive technology to the point of public dissemination; or to license technology non-exclusively to all potential users, possibly with preferential terms for developing countries or exceptions or waivers for public-interest purposes; $\underline{8}/$ or to construct a protected commons that ensures open access to derivative innovations. $\underline{9}/$

37. Since the current document specifically concerns the context of the CBD, and the impact of intellectual property on specific elements of that Convention, it does not attempt a comprehensive, general review and description of the intellectual property system and its more general role in transfer of technology: these broader questions are covered extensively in current literature $\underline{10}$ / and international debate. To assist in clarifying and defining the role of the intellectual property system and specific intellectual property mechanisms, a number of general factors can be identified and drawn on to guide the more detailed analysis.

38. It is important to note that intellectual property laws and mechanisms do not constitute a single, stand-alone form of knowledge management, necessarily to be adopted or rejected in their entirety, or to be used to the exclusion of other forms of knowledge management, innovation promotion and technology diffusion. They are a set of specific legal means, normally set by statute in the context of public policymaking, aimed at supporting the development and management of knowledge in the broader public interest or at suppressing unfair or misleading commercial practices.

39. Accordingly, most practical technology transfer mechanisms involving intellectual property will also touch on a combination of other non-IP elements, ranging from capacity development and training, to laws governing investment and legal remedies against abusive licensing practices. UNEP comments

<u>8/</u> See for example Amy Kapczynski, Samantha Chaifetz, Zachary Katz, and Yochai Benkler, Addressing Global Health Inequities: An Open Licensing Approach for University Innovations,20 Berkeley Tech. L.J. 1031 (2005)

<u>9/</u> See for example Biological Open Source License for Genetic Resources Indexing Technologies at http://www.bios.net/daisy/GRITLicense/750/1170.html

<u>10</u>/ See for example UNCTAD, Transfer of Technology, IIA Issues Paper Series, UNCTAD/ITE/IIT/28, 2001; Bernard M. Hoekman, Keith E. Maskus and Kamal Saggi, Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options, World Bank Policy Research Working Paper 2004.

that "environmentally sound technologies are not just individual technologies, but total systems which include know-how, procedures, goods and services, and equipment as well as organizational and managerial procedures. This implies that when discussing transfer of technologies, the human resource development and local capacity-building aspects of technology choices, including gender-relevant aspects, should also be addressed." $\underline{11}/$

40. Hence, the actual effect and operation of intellectual property in the context of access to and transfer of technology within the terms of the CBD will likely depend on the concrete choices made on a wide range of specific elements concerning: (i) decisions to take out or to forego intellectual property protection in each distinct jurisdiction concerned; (ii) choices concerning ownership and management of relevant intellectual property portfolios; and (iii) approaches to licensing and enforcement of intellectual property rights, including, possibly in the context of providing concessional or preferential terms as foreseen in Article 16 (2), degrees of exclusivity and non-exclusivity (such as for instance license arrangements that give non-exclusive access to interested parties), favourable terms for public-interest or non-commercial use, or for use in developing countries (e.g. licensing practices such as equitable access licenses for low and medium income countries).

41. In addition, options for technology transfer may be influenced by the approach taken in national patent laws on such issues as research exceptions, as well as regulatory measures, consistent with Article 40 of TRIPS, which deal with licensing practices or conditions which may impede the transfer and dissemination of technology. <u>12</u>

42. Another key potential role for intellectual property systems is clarifying and structuring the form of partnerships concerning knowledge development, deployment and dissemination – this may be one aspect of negotiation of mutually agreed terms as foreseen in Article 16 (3) of the CBD.

43. Consequently, the benefits or disadvantages of intellectual property in the context of access to and transfer of technology will not necessarily depend on binary questions of the presence or absence of intellectual property altogether, but the net effect of successive decisions and determinations, as well as the impact of broader regulatory questions such as safeguards against anti-competitive practices and abusive licensing practices.

44. In discussing the role of intellectual property rights in technology transfer, further scrutiny is needed of existing obstacles, such as a lack of legal expertise, foreign investor pressure, or lack of infrastructure, which are preventing developing country actors in fully exploiting the exemptions and safeguards within intellectual property regimes, such as the role of fair use/fair dealing, research exemptions, compulsory licensing, etc. Compulsory licenses would seem one area for identifying factors at play preventing access to certain forms of technology, especially those required in the public interest. One comment $\underline{13}$ suggested that it would be worthwhile to further examine the use of compulsory licenses, or the lack thereof, and that such examination could usefully be done by make use of the extensive literature thereon in the public health context.

45. The overwhelming bulk of intellectual property protection for claimed inventions, notably through the patent system, is concentrated in developed economies, with relatively few corresponding patents in the majority of developing countries. The principle of territoriality within the intellectual property system means that the bulk of this material is in the public domain in many developing countries.

<u>13/</u> Comment made by UNDP/GEF on the first draft of this study.

^{11/} United Nations Environment Program (UNEP), "Transfer of Environmentally Sound Technology, Cooperation and Capacity-Building," 34.4, at www.unep.org

<u>12</u>/ See for instance Chapter IX of the Intellectual Property Code of the Philippines, on Voluntary Licensing.

46. Practical access to technological knowledge contained in patent documentation has increased rapidly, but not necessarily with easy access to the legal information and advice that is required to determine freedom to operate with information that is located in this way.

47. Inappropriate patenting outcomes, where they occur, such as patenting of already disclosed traditional knowledge related to biodiversity, or patents that are invalid for other reasons, such as lack of novelty or inventive step, may constrain legitimate access to and use of technology. It is difficult, both in terms of time and money, for a concerned third party to obtain the revocation of patents that were erroneously granted. Specific legal requirements, such as those governing the recognition of prior art, will have an impact; moreover, irrespective of the particular legal design of the national patent and intellectual property system, the provision of adequate institutional capacity – in terms of staff and financial endowments for national authorities governing the intellectual property system and in particular the grant of patents – seems to be an important general precondition to minimize the number of erroneously granted patents.

B. Overview of intellectual property mechanisms relevant to transfer of technology under the CBD

48. This sub-section discusses key aspects of various elements of the intellectual property system that may be considered relevant to the transfer of CBD-related technology. It does not attempt an exhaustive account, but aims to provide a basis for discussion and further research. <u>14</u>/ It is recognized that there are ongoing discussions on substantive harmonization of international intellectual property law, bearing in mind that any such harmonization, if it were to be undertaken, would have to include strong in-build policy flexibilities for countries to customize their intellectual property frameworks to their specific policy objectives and their respective stages of the development. In light of the constant and dynamic evolution in this field, the present study does not attempt to provide a comprehensive comment on these discussions.

Patents

49. Patents are limited-term exclusivities over inventions that fall within a country's definition of patentable subject matter. They are limited to inventions that meet the core patentability criteria of novelty, inventive step (or non-obviousness), and utility or industrial application: these criteria are defined and determined in ways that differ between jurisdictions. This is especially the case in relation to certain biotechnology or genetic-resources-based inventions. Accordingly, inventions that are derived from access to genetic resources are likely to be patented in diverse ways in different countries, and may be eligible for patent protection in some countries and not in others. International rules provide for optional exceptions to patentable subject matter, including exceptions for technology that is injurious to the environment.

50. Patent rights are territorial: a patent granted in one country (or region) has no legal effect in other countries. Most inventions are patented in a small minority of countries around the world; they are free to be used in every country where no patent has been applied for or obtained. Patents confer rights on their holders to prevent, or to claim financial compensation for, the use of the covered technologies by third parties in the jurisdiction where the patents are in force. These rights are used as the basis for various forms of exploitation of the technology – through licensing, direct exploitation, or assignment of rights. Rights granted under a patent are also limited by a range of possible exceptions or limitations to patent rights, which vary between countries, but typically deal with matters such as use for research, use

^{14/} For instance, as rightly observed by the International Center for Trade and Sustainable Development (ICTSD) in commenting on the first draft of this study, plant breeders' rights under the Union for the Protection of New Plant Varieties Convention (UPOV) are not considered. See as further reference the statement on access to genetic resources and benefit-sharing as adopted by the UPOV Council at its thirty-seventh ordinary session in 2003.

for regulatory approval, use on vehicles in transit, government or 'crown' use, and compulsory licensing for use by third parties.

51. Patent applicants are required to disclose how to implement the claimed invention, and in some countries also have to disclose the best mode known of implementation. If a patent does not sufficiently disclose how to carry out the invention, so that a skilled person can put it into effect, it is invalid. Most of the content of patent documents comprises such technological teachings. This means that the patent system is a source of technological information: patent applications are published in most cases within 18 months of being filed, so they are close to state of the art, often being published before the final technology is put on the market – this is especially the case for inventions based on genetic resources, which may have long development times and may need to pass regulatory approval.

52. In the past, this information could be costly and difficult to access. But the application of recent developments in information technology means that this technological information is now more readily and inexpensively available to technology users worldwide. This information is therefore in the public domain of knowledge, in a legal and practical sense, although its use is constrained in the event that the patents are in force. Since patents are territorial and apply only to the jurisdiction in which they are granted, much of the technological information disclosed through the patent system is also in the public domain of use in many countries, particularly developing countries, in the sense that it is free to be used without authorization. Without limiting other options and obligations, using patent information systems to locate relevant technology, to track patterns of development, ownership and dissemination of relevant technology, and to locate potential technology partners, may be a useful practical element in implementing CBD objectives and provisions (especially those provisions concerning availability, exchange and transfer of technology under Articles 16, 17 and 18). The enhanced accessibility of patent data and the prospects for more systematic monitoring and synthesis of patent information provides opportunities for broader assessment of emerging patterns of innovation, research and industrial activity, clusters of ownership and control, and technological development, with potential use in illuminating the international environment of the implementation of these articles.

Technology transfer and the development, ownership and licensing of patents resulting from access to and use of genetic resources

53. Structuring the means of access to, transfer of and sharing of equitable benefits from technologies that make use of genetic resources may entail significant choices on the obtaining, assigning, licensing and exercising of patents on relevant technologies. This is one element of the appropriate and beneficial utilization of genetic resources, and of structuring mutually agreed terms and benefit-sharing arrangements. It can also have significant potential bearing on the transfer of technology and access to benefits from technologies derived from access to genetic resources. Commentators have questioned the appropriateness and suitability of a wholly bilateral approach, based exclusively on private contracts, to settling these issues, and stress the need for overarching principles and legal obligations that would provide a surer safeguard for the equity and legitimacy of specific arrangements and that would ensure that the intellectual property system is compatible with sui generis regimes on the access to genetic resources and the fair and equitable sharing of the benetifs arising out of their utilization. 15/ Such principles and obligations may also become important in light of potentially large differences in bargaining strength between the Parties to the contract, including expert knowledge and expertise, and associated bargaining skills. Even so, the arrangements made for defining each party's rights, interests and obligations regarding intellectual property, and for managing relevant patenting activity, can be one important aspect of ensuring that these agreements operate to generate new technologies and new

^{15/} On the international level, see for instance the discussions on whether and how to introduce a requirement to disclose the origin of genetic resources in patent applications.

benefits, shares those benefits equitably, and respects the interests and concerns of the resource providers.

54. More generally, when research is undertaken on genetic resources, this can result in inventions that can, at least in principle, be eligible for patents – although eligibility will vary according to different national laws. How such patents are owned, managed and exploited can influence how benefits are created and shared, and how widely and how effectively these new technologies are transferred, disseminated and made available on concessional or preferential terms. This includes settling in mutually agreed terms the threshold question of whether or not patents should be obtained at all on relevant technologies, and the kind of consultative and legal arrangements that may apply when potentially patentable inventions are developed or other milestones are reached, and agreement is needed on patenting questions. Accordingly, contractual agreements may contain provisions governing how intellectual property rights on research results are obtained and used, akin to the material transfer agreements that have commonly been used in academic research using genetic resources and other biological materials.

55. Issues dealt with in agreements include the entitlement to seek patents in inventions and other results of research using the resources, ownership and licensing of any such patents, responsibility for maintaining and exercising patents, the arrangements for distributing any financial or other benefits resulting from derivative patents, licensing back with additional technology transfer to the resource provider, and reserve or march-in rights that apply when the technology is not being developed or exercised in a way that meets the expectations of the resource provider: this may include targets for effective transfer of technology. Agreements can also require the recipient of the resource to report on any patents that are applied for, and similar developments. Some agreements make access conditional on not seeking intellectual property rights on the material received. How such intellectual property management issues are dealt with and the provisions governing the obtaining and exercising of patents can greatly influence the degree to which arrangements between the access provider and the resource recipient can achieve their goals and serve their mutual interests. <u>16</u>

56. A research project based on access to genetic resources may have, as its clear intention, the discovery of a patentable invention and the subsequent licensing and commercial development of that patent. Technology transfer arrangements may therefore be constructed so as to ensure that commercial benefits are balanced by guarantees of dissemination, technology transfer and distribution of benefits. Alternatively, an academic collaboration may inadvertently or unexpectedly result in a patentable invention; this may require additional arrangements to be settled to provide for appropriate technology transfer and distribution of benefits.

Undisclosed information (trade secrets)

57. Confidential information, undisclosed information, confidential know-how and trade secrets are overlapping concepts that define an area of law that is considered part of the general law of intellectual property. The range of laws and legal mechanisms differ considerably between national legal systems. International standards on undisclosed information are based on the suppression of unfair competition and in particular acts that are contrary to 'honest commercial practices' under the Paris Convention. The standards are elaborated in the WTO TRIPS Agreement, which explicitly requires the protection of undisclosed information, provided that it is secret, has commercial value because it is secret, and has been subject to reasonable steps to be kept secret. It is likely that significant amounts of such undisclosed technological information will be relevant to the effective implementation of Articles 16 to 19 of the CBD. In some cases, too, the providers of genetic resources may require certain information to

<u>16</u>/ See the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization, paragraph 43 (c) and (d) as well as Appendix I, sub-section B, paragraph 4. The Bonn Guidelines are available online at http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp .

be kept confidential – such as sacred traditional knowledge associated with genetic resources, or the exact location of potentially endangered species *in situ*.

58. Protection of undisclosed information can be contrasted with patents on several key points: (i) there is, by definition, no disclosure of the technology to the public or to third parties beyond the agreed access to the knowledge; (ii) there is thus no systematic teaching of the technology; (iii) the information does not enter the public domain generally; (iv) its protection depends to a significant extent on 'privity' between the provider and user of the information, so that its protection may be considered (in some legal systems at least) a formal legal relationship between information provider and information user, rather than protection of the information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices. These practices include breach of contract, breach of confidence and inducement to breach, and the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition. 17/

59. As noted, transfer of technology typically involves bundles of related elements, including patented project technology and background technology, as well as associated know-how that may partly be eligible for protection as confidential or undisclosed information, data relating to safety, efficacy or environmental impact, and other elements such as training and capacity building. Protection of undisclosed information may be particularly relevant to technology transfer relevant to the conservation of biological diversity in cases where disclosure of information about a rare or valuable resource may accelerate the extinction of the resource. For instance, the location of certain endangered species may be kept confidential, even while research proceeds on the basis of those species, to avoid overuse and uncontrolled harvesting of potentially valuable *in situ* biological resources that may contribute to species loss and undercut conservation efforts. <u>18</u>/

Traditional knowledge protection

60. Within the general field of intellectual property, it may be possible to include the protection of traditional knowledge (TK) through *sui generis* laws, although community expectations and legislative options for protection of TK generally go beyond the conventional scope of intellectual property law. This is illustrated by the work of the Ad Hoc Open-ended Working Group on Article 8(j) and related Provisions of the CBD. However, as a dynamic and emerging element of intellectual property law and practice which has a close relationship with the objectives and practical implementation of the CBD, this may be considered as one element of the broader intellectual property system relevant to the current document. A number of national laws for TK protection have a specific focus on biodiversity-related knowledge; others have a related, but distinct, focus, such as traditional medical knowledge. National laws 10/ deal with a wide range of objectives, including promoting the preservation, customary use and protection of TK, as well as its regulation, for instance, when used for medicinal purposes. The intellectual property aspect of such mechanisms is increasingly recognized as the process of clarifying or

 $[\]underline{17}$ / Article 39 (and footnote) of the WTO TRIPS Agreement.

¹⁸ For example, the use of confidentiality in relation to the conservation and dissemination of the Wollemi Pine (*Wollemia nobilis*), an ancient species (dated back over 150 million years, and widespread in the Cretaceous period, once assumed to be extinct): the location of the only known stand of the trees is kept confidential, as are the propagation processes, established to ensure that the species can be propagated and disseminated widely but without any negative impact on the *in situ* resource, while also creating reserves in the event that a natural disaster struck the in situ resource;

^{19/} Sophia Twarog and Promila Kapoor (Editors), Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions, UNCTAD,2004; Composite Study on the Protection of Traditional Knowledge, WIPO/GRTKF/IC/5/8; Consolidated Survey of Intellectual Property Protection of Traditional Knowledge, WIPO/GRTKF/IC/5/7

confirming the rules that define and suppress the misappropriation and misuse of TK. <u>20</u>/ Such protection of TK includes the recognition of positive rights in TK as such (positive protection), and mechanisms to prevent the grant of illegitimate patents or other forms of IP by others (defensive protection). In practice, a key issue is ensuring that during the documentation of traditional knowledge, and its subsequent dissemination, it should be protected against misappropriation and misuse. Technology partnerships, such as transfer of technology and access to benefits from biotechnology, may need to take full account of existing laws and emerging international standards governing the protection of traditional knowledge.

Copyright and database protection

61. The law of copyright and database protection may also be relevant to transfer of technology under the CBD, for example, with respect to the conservation of biodiversity, earth observation data and satellite images. Bioinformatics may be relevant to the utilization of genetic resources for the objectives of the CBD. Preparation, production, dissemination of and access to copyright materials, ranging from blueprints to training manuals and software, may be an important aspect of a complete technology transfer relationship. Copyright does not protect information as such, but rather the form of its expression; this means that facts as such cannot be protected by copyright, although the manner in which they are compiled and presented may be subject to protection, quite apart from the copyright status of facts or information in themselves. <u>21</u>/ *Sui generis* database protection, introduced in some countries (notably in the European Union) may have implications for access to information relevant to the nature, properties and use of genetic resources that is contained in databases. When databases are protected under *sui generis* systems, these may need to be considered in arrangements for transfer of technology.

C. Legal relationship between producer and user of technology

62. Apart from the specific features of intellectual property mechanisms, and the ways they are or should be used, assessment of the role and impact of intellectual property will also depend on the nature of the model of technology transfer that is considered:

- (i) where there is no legal relationship between the technology producer and the technology user
- (ii) where there is a specific, arms-length legal relationship a license, material transfer agreement or other agreement between the producer and user
- (iii) where there is a broader, structured legal relationship, such as a joint venture between the provider and user of the technology, or when the user is a subsidiary of the technology producer.

63. These distinctions are highly important for a number of reasons. The full package of technology involved in a transfer may often entail different elements of knowledge and capacity, rather than the subject matter of one specific property right. Components may include patented technology, unpatented know-how, associated designs, blueprints or software, training, background technology and manufacturing capacity that contribute to the efficient implementation of the technology, and access to necessary data and information. For example, concerning technology that makes use of genetic

^{20/} WIPO/GRTKF/IC/7/5, WIPO/GRTKF/IC/8/5, and WIPO/GRTKF/IC/8/6.

²¹ The WTO TRIPS Agreement provides that "Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself." Similarly, the WIPO Copyright Treaty provides that "compilations of data or other material, in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations, are protected as such. This protection does not extend to the data or the material itself and is without prejudice to any copyright subsisting in the data or material contained in the compilation. (Article 5, Compilations of Data (Databases); an agreed statement observed that this provision was "on a par with the relevant provisions of the TRIPS Agreement."

resources, broader regulatory issues may apply, including regulations governing genetically modified organisms, and regulations governing safety, environmental impact and efficacy. In these cases, access to data required to support regulatory approval may be key in effective transfer of the technology, so that a comprehensive technology transfer package may need to ensure appropriate access to such data, as well as other elements of know-how and capacity, to supplement the legal entitlement to use the technology under a patent license. Where technology transfer does not entail a legal relationship between the producer and user, it will typically not be possible to gain access to the full package of these components, as they may rely on some form of agreement between the parties. In these cases, other legal mechanisms may be necessary. In addition, as noted above, patent laws or related competition laws may govern the relationship between parties to a technology license, as a safeguard against abusive licensing practices. For example, some laws contain measures against some licensing practices that impede the transfer of technology.

64. In addition, the nature and degree of relationship may change during the technology transfer and adaptation process. For instance, new technology may be developed in the absence of any legal relationship, on the basis of background technology located through a patent search, making use either of a research exception under patent law or the fact that the patent is not in force in the jurisdiction where the research is undertaken. When the technology reaches a mature stage of development, this may lead to a cross-license or other form of legal relationship, where the adapted or improved technology is licensed to the producer of the original technology. The legal relationship may range from a simple license to a more complex research and development partnership involving background knowhow and licenses for background patented technology, benefit-sharing from improvement patents, and best endeavour clauses for the development and dissemination of new technologies (including public interest guarantees when this is required). The role, impact, costs and benefits of various intellectual property mechanisms will therefore differ depending on the nature of this relationship.

SECTION II: BENEFITS AND COSTS OF INTELLECTUAL PROPERTY RIGHTS

65. This section considers the advantages or "benefits" as well as disadvantages or "costs" of the various intellectual property mechanisms considered in the chapter above in relation to technology transfer under the CBD. The stages of technology transfer identified and described in chapter 3 of this report are:

- (a) Technology development as a precondition for its transfer;
- (b) The identification of transfer needs and opportunities, including through transfer and exchange of information;
- (c) Undertaking the actual transfer;
- (d) Adaptation of transferred technology to local socio-economic and cultural conditions.

66. The following chapters address the role of intellectual property mechanisms under each of these headings. A specific judgment on the costs or benefits of any specific intellectual property mechanism is likely to be difficult to establish, because of the variability in the manner of definition, administration, exercise and use of different forms of intellectual property rights, and the great diversity of practical technology transfer scenarios. The factors set out above illustrate some of the factors that may influence the beneficial effects, or otherwise, of intellectual property in the actual transfer of technology. To some extent, the actual costs or benefits experienced may depend on policy and legal settings, institutional capacity and the availability of resources and expertise, the broader regulation of technology (including, in the biotechnology domain, regulation of ethical, environmental, and human plant and animal health aspects of technology), and the regulation of business practices. In addition, the nature of the relationship between technology provider and technology user (and its evolution over time) may determine the effect of specific intellectual property mechanisms. It should be noted that even original research and the creation of technology inherently requires the use of existing technologies. Moreover, technology users frequently improve and adapt technologies, yielding new technologies that may be licensed back to the original technology provider. The role and impact of specific intellectual property mechanisms cannot, therefore, be limited to an analysis of technology providers as against technology users.

5. Technology development

A. General Remarks

67. Intellectual property mechanisms have a significant impact on the technology development stage. This impact is complex, and a wide range of options can be considered. In general, however, the impact, and the benefits and costs, of the use of intellectual property mechanisms at this stage will depend to a considerable extent on how these mechanisms are used in a dynamic sense. When used judiciously and effectively, these measures should enhance the benefits and reduce the costs, so the analysis may consider what manner of use or approaches to exercising these measures will optimize the intended benefits. Further, technology development cannot be considered in isolation from the broader context: any technology development process is also a technology use process. Background and enabling technology is typically one of the array of inputs required to generate new technologies, along with necessary financial, logistical and human resources. Equally, much technology development takes place through various forms of partnerships, research agreements, and institutional structures, which will determine how, and to what extent, IP mechanisms are used. As noted above, agreements governing the use of genetic resources may be counted as one such mechanism, as they may set conditions that determine if, and then how, IP titles should be obtained and exercised as part of the technological partnership set out in the agreement.

B. Key impacts of intellectual property mechanisms

Providing information on the state of the art of existing research and development, and identifying potential research partners or technology providers.

68. Effective use of patent information, for example, may provide an information platform for research and development aimed at developing new technologies. Several aspects of patent information may be considered relevant to the development of technology relevant to implementation of these elements of the CBD; these include: (i) access to information on 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; (ii) information on the legal status of patented technology required to make an assessment of freedom to operate and potential obstacles to research and development; (iii) information on broader trends in the development of such technologies, including information on the strengthening of national capacities and particular new research directions; and (iv) identification of potential research partners or technology providers through their patenting activity. Monitoring patent information has also provided access to information about claimed inventions that make use of genetic resources and biodiversity-related traditional knowledge, which are in tension with the objectives or legal provisions of the CBD.

69. Effective access to and use of such information requires a range of resources – information technology, access to data, and capacity in informatics and necessary analytical skills, as noted below.

Providing an incentive structure for capturing the necessary investment or deployment of resources for development of the technology.

70. The creation and development of new technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources may require the input of focused resources, from a range of sources. This may depend, too, on the approach taken for the garnering of resources and the means used to disseminate the technology. Some technologies relevant to the conservation of biological diversity may be intended essentially for use by public sector agencies or academic institutions quite separately from the commercial domain. Other technologies, including those that make use of genetic resources, may be developed and disseminated essentially through commercial

channels, through the intensive involvement of private sector entities. The core policy rationale of the patent system is to facilitate and to provide incentives for technology development, including both research and development, for technologies that require a degree of private sector input to bring them to fruition as workable products available in the public marketplace, although public sector innovation processes may also involve judicious use of the patent system (and other IP rights) to achieve their objectives as well. To the extent that private sector investment – in the form of capital, other resources, and risk exposure – is required for the creation and development of such technologies, the judicious deployment of intellectual property mechanisms helps in garnering and effectively focusing the necessary resources, as part of a broader incentive structure. To the extent that commercialization and commercial processes are relied upon for the dissemination and practical availability of the technologies in question, the clarity and predictability that is brought by a well functioning patent system may be considered a benefit, while any difficulties created by obscurity or uncertainty in the system, such as with regard to the assessment of novelty and non-obviousness in the context of prior art searches concerning tradition-based inventions, may be considered a cost.

Providing a means of structuring and defining specific roles, rights and responsibilities in research and development partnerships

71. Planning and structuring collaborative partnerships to undertake research and development of new technologies includes arrangements that define the respective roles and responsibilities of all those who bring resources and capacities to the innovation process. Agreement on an appropriate dispensation of IP mechanisms and how any resultant intellectual property should be owned, financed, administered and exercised is a key aspect of concluding such structures. Guarantees of technology transfer built in at this point can be highly determinative of actual technology dissemination and effective transfer once the technology has been developed to a functional level.

72. Where research and development partnerships entail use of genetic resources and associated traditional knowledge, issues of prior informed consent and equitable benefit sharing should also be considered from the earliest stages of research planning, to ensure compliance with the CBD provisions and national requirements in provider countries, as an integral component of the research and development partnership.

Leveraging access to background technology, research capacity and research tools

73. Planning and early implementation of research and development activities aimed at creating new technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources may require, or may be facilitated by, the strategic use of IP mechanisms to structure pathways to necessary inputs in the form of background or platform technology, access to research and development capacity, or specific research tools (access to which may be of particular concern in biotechnology research, either in the research phase itself, or in the subsequent development and commercialization of the outcomes of research).

C. Effective use of these mechanisms

Capacity constraints, including effective availability of patent information, and ability to undertake state of the art, technology landscape and freedom to operate analyses.

74. Depending on the purposes for which patent information is used, the costs and benefits of use of patent information will be influenced by a range of factors, For instance, patent information at the international level (the Patent Cooperation Treaty (PCT) system) and concerning patents in major economies is increasingly available over the Internet as a free resource. But information concerning specific patent activity in a particular country, and such details as the legal status of a patent or patent application, may not be that readily available.

Transaction costs of negotiating and establishing technology development partnerships and other research mechanisms, including financial and other costs of licensing in necessary technologies.

75. Developing any research partnership inevitably incurs costs, ranging from travel and logistical costs to engaging the specialized legal expertise that may be required to ensure the arrangements serve the interests of all parties. Some of these may be specifically attributable to intellectual property mechanisms (for instance, in undertaking background searches and other due diligence processes relating to intellectual property , and negotiating intellectual property issues such as warranties on the validity and non-infringement of intellectual property, and obligations concerning the management of project-related intellectual property and access to background intellectual property). From another aspect, intellectual property mechanisms may be used to lower transaction costs, for example in clarifying workable structures for ownership, access to and development of relevant technologies; IP mechanisms may be used, for instance, in clarifying rights and responsibilities, and determining the scope and boundaries of agreed entitlements and obligations.

Costs of patenting and of other IP mechanisms used to provide pathways for development and dissemination of technologies under development.

76. Where a research partnership or technology transfer arrangement entails the active protection of intellectual property, significant costs may be incurred, particularly if protection is to be obtained in multiple jurisdictions. These costs include professional charges and official fees. Some official fee reductions are available, for example for nationals of low-income countries within the PCT system. To the extent that any specific initiative does involve use of IP mechanisms, settling on arrangements for funding the obtaining and maintenance of IP can be a key issue.

Degree to which the research and innovation process depends on private investment, and the availability of background or enabling technologies held by other parties.

77. As a rule, intellectual property mechanisms are more likely to be relevant, and their costs and benefits more carefully weighed, in situations where the technology transfer scenario entails drawing on private sector resources or capacities, whether this involves private funding or investment, access to privately-held technology, or deployment of skills and drawing on other technology development capacities residing within private sector entities.

Condition of capital market, to the extent that the research process relies on the investment of private resources.

78. Technology development, and patterns of technology dissemination and transfer, can occur across a wide spectrum of private and public mechanisms. In some cases, private investment is a significant factor in establishing the necessary technology development and dissemination, potentially in a situation of considerable risk where a longer-term perspective is required. In such cases, the clarity and effectiveness of intellectual property mechanisms is likely to be a significant factor in attracting the necessary resources. However, poor access to capital due to an inadequate endowment in lending institutions and thin capital markets, may also impede long-term investments. On the other hand, where direct public funds apply and the public sector assumes the risk, different technology management, policy issues and incentive structures may apply. However, for some of the complex biotechnologies that are relevant to implementation of the elements of the CBD under consideration here, the full technology development process – ranging from the initial research to the development, regulatory approval and distribution of finished technologies – may entail the mixed participation of public and private players, and their respective resources and capacities.

Institutional policies and procedures for the management of IP arising from public-sector, institutional or philanthropic funding.

79. A diversity of policies and practices can apply to situations where technology development is largely undertaken by public sector bodies, and through the use of public-sector or philanthropic funds, and the cost and benefits of certain approaches to IP management and the choice of IP mechanisms is a subject of extended review and debate.²² The costs and benefits are typically assessed against an array of interests and issues: the need to engage sufficient resources and capacity to bring an unproven technology from the initial technical breakthrough stage to a functional and viable practical product; the strong expectations of the public that investment of public resources in research should result in technologies that are appropriately accessible; the need to clarify the objectives and mission of public institutions, and their appropriate engagement with the market sector in the furtherance of those objectives. Some form of exclusive right may be necessary to justify the needed investment and risk exposure required for the full technology development process, unless a fully open and non-exclusive innovation model is being pursued.

80. Such alternative modes of innovation are evolving in the marketplace – e.g., open source and open standards software – and are also proposed to be applied in the field of biotechnology. <u>23</u>/ Governments as well as international organizations are increasingly considering the merits of such options in their purchasing practices of relevant technology. Alongside contractual (licensing) arrangements, intellectual property rights retain an important role within these new innovation frameworks that requires more indepth analysis.

Clarity and scope of legal constraints on research and development, such as research exceptions to patent laws, exceptions for regulatory approval procedures, and the degree of legal presumption and de facto confidence in the validity of patents on relevant background technology.

81. Planning, developing and pursuing pathways to technology transfer may entail, even at the initial technology development stage, surveying the technological and legal background. The technological aspect entails making full use of available information resources to ensure understanding of the state of the art, the problems that have been addressed and resolved by other researchers, and the existing solutions that have been developed, as well as indicating gaps and opportunities, and alternative pathways that may be explored. The legal aspect entails a judgement as to the legal availability of technologies disclosed in patent documents; it is for this aspect that the factors cited here are most applicable: for instance, if there is a patent actually in force in the country where research will take place, it may be necessary to obtain guidance on the nature of research exceptions to patent rights, and other exceptions that facilitate product development processes (in particular taking steps towards regulatory approval). Specialist advice may be necessary to assess the actual scope of claims, as it is the claims, and not the general information disclosed in a patent document, that set the bounds of any exclusive rights conferred by a patent. In addition, the existence of a patent that is apparently in force does not guarantee that it would be found valid in the full scope it has been granted; a judgment as to freedom to operate during technology development may need to take into account the legal presumption as to the validity of any patent, and an experienced assessment as to the actual validity of any specific patent; a clearly invalid patent is unlikely to be successfully enforced, as an infringement action could be met by a counterclaim for invalidation or reduced scope of the patent in issue.

<u>22/</u> There is an extensive literature, See, for instance, Arti K. Rai and Rebecca S. Eisenberg, The Public and The Private in Biopharmaceutical Research; R. Kneller, Technology Transfer: A Review for Biomedical Researchers. (2001). Clin. Cancer Res. 7: 761-774.

^{23/} See the "Bio commons" proposal by CAMBIA. See as reference the UNCTAD/ICTSD document on CAMBIA Open Source Initiative at: <u>http://www.iprsonline.org/unctadictsd/dialogue/docs/Connett-Porceddu 2004-11-08.pdf</u>

Strategic incentives and incentives and deterrents to research

82. Linked to the above factors relating to freedom to operate is the question of ensuring appropriate incentives for technology development, both in the positive sense of creating incentives for the investment and appropriate application of the necessary resources and capacities, and the negative sense of avoiding perverse incentives that would deter researchers from pursuing desirable technology development pathways. The costs and benefits from the use of intellectual property mechanisms will in part depend on the way in which these incentives and deterrents are structured, and the manner in which they are exercised in practice.

Patterns of patent ownership and legal accessibility of technology

83. In particular, depending on the nature of technology under development, the jurisdiction where it is occurring, and the research and development methodology, charting a practicable pathway to technology development may depend on the patterns of patent ownership, particularly if there are applicable patents in force in that jurisdiction that cover core technologies, or if there is concentration of ownership of patents in a field of technology or complexity in patterns of ownership. Complex factual situations and patent claims over key technologies may create transaction costs in determining and negotiating freedom to operate and legal barriers have been cited as a potential obstacle to innovation; for instance, a clustering of patents on technologies that are necessary inputs to the desired technology development process. The 'patent thicket' has been defined as the 'problem caused by multiple upstream patents, where overlapping rights may impede the commercialisation of a product or process.'24 Patent thickets have to date been principally of concern and debate in relation to developed economies where there is a greater concentration of patenting activity and patent ownership, but may also be of concern in those developing countries where patent activity is intensifying in technologies relevant to use of genetic resources, or where the technology development process is focused on producing products for developed economies. By one analysis, multiple overlapping patents may lead to what is termed the 'tragedy of the anti-commons' - a situation where numerous right holders exercise rights to exclude one another, while no-one has a positive right to use the valuable technology covered by the rights. Patent pooling or a web of non-exclusive cross-licensing is one response proposed to this scenario. Debate and empirical analysis continues on the scope and extent of these problems, and the practical impact of such patterns of ownership. Costs and benefits may depend in part on licensing practices and the precision of claims granted concerning the relevant inventions. One scenario that has been widely debated concerns ownership of patents on genetic subject matter. In particular, it could be worthwhile to further explore how companies in developing countries deal with these problems. 25/

Breadth of patents and accessibility of public domain material

84. The patent system, by its foundational principles, is intended only to grant exclusive rights over material that is not in the public domain; that is to say technology that is already known or available to the public, or that is an obvious adaptation or application of known technologies. Patents that are drawn too broadly may encroach on the public domain and therefore may inhibit the use of public domain technology, even where a patent is considered to be invalid due to unreasonable breadth (since the costs of credibly and effectively challenging a doubtful or borderline patent may be beyond the reach of public

^{24/} Australia Law Reform Commission, Issue Paper 27, Gene Patenting and Human Health, glossary

^{25/} See OECD (2002): Genetic Inventions, Intellectual Property Rights and Licensing Practices. Evidence and Politics. OECD, Paris, and The Royal Society (2003): Keeping science open; the effects of intellectual property rights on the conduct of science. The OECD document concludes that, while the obstacles imposed by these mechanisms are sometimes substantial, actors such as firms, Governments and civil society in OECD countries are rapidly reorganizing their approaches to dealing with intellectual property rights protection, and often find pragmatic solutions to the problems associated with patent thickets. However, it appears to be less clear whether and to what extent this finding also applies to the relevant actors in the developing world, which typically operate under more severe constraints in terms of legal expertise and capacity.

sector or developing country institutions). The benefits of the system are enhanced by precise patent claims that focus wholly on genuine inventions and genuine new contributions to the technological base, while costs may arise from the deterrent effect of patents that cover public domain material, or obvious applications of known technology. The calculations of costs and benefits may differ considerably depending on the technological focus and economic status of one country or a sector within one country; some countries focus especially on investing their innovative resources in adapting and extending existing technologies, including making innovative use of technologies to meet needs ignored by other technological players; others may focus on fundamental breakthroughs and technological leadership in certain domains.

6. Identification of transfer opportunities

A. General observations

85. Intellectual property mechanisms have significant potential impact on identification of technology transfer opportunities. Patent information is of considerable potential benefit both (i) at the macro level, in determining the overall state of the art in a given area of technology and in monitoring trends, new directions, new players and changing geographical patterns,²⁶ in relevant technologies, and (ii) at the micro level, in determining who in particular (whether institutes, companies or individual inventors) is working on a specific technology, and who may be approached either to seek a license and further background technology and know-how, or to propose a more complex technology partnership (potentially involving cross-licensing or pooling complementary technologies, or arranging for licensing back of improvements or adaptations).

86. As discussed above, one of the principal aspects of the patent system is the transparency it confers to technology development processes. The practical benefits of this in-principle transparency depend, however, on the actual accessibility, cost and quality of the patent information, as well as capacity to make use of the information. Recent initiatives and technological developments, coincidentally since the time of the CBD's entry into force, have greatly enhanced the ready availability of patent information, including at the early stages of international filing.27/ As well as providing information about the technology itself, patent documentation provides details of inventor and applicant/patentee, which may be used in contacting potential technology transfer package. Patents may also be publicized by their owners or licensees as being available for access by others – this may be through official sources (such as the 'license of right' mechanism under some national patent laws), or through unofficial sources (private sector, <u>28</u>/ educational and research institutions, <u>29</u>/ or not-for-profit mechanisms <u>30</u>/).

87. A considerable proportion of patent information describes technologies that are in the public domain for one reason or another. Many patent applications do not go through to grant, and most patents lapse before their full term expires. Up to date information about the legal status of patents or patent applications in particular jurisdictions may therefore be helpful in determining what technology has passed into the public domain due to lapse or refusal of patent applications; and the lapse, expiry or invalidation of patents. Most technologies are patented only in a relatively small number of countries, typically with a concentration on developed economies. Since patent rights are territorial (and a patent granted in one country has no legal effect in other jurisdictions), the technology disclosed by a patent document may well be free to use in the majority of countries in the world, particularly for a developing country, since it is much less likely that a given technology will be protected by a patent in force in that jurisdiction. It is therefore important in determining technology transfer opportunities to obtain

²⁶ For example, to date in 2005, international patent applications for inventions classed as medicial substances derived from plants (IPC sub-classes A61K 35/78, 35/80, 35/82 and 35/84) were received from applicants in Australia, Belgium, Brazil, Bulgaria, Canada, China , the Czech Republic , Egypt, France, Germany, Hungary, Iceland, India, Israel, Italy, Japan, Madagascar, Mexico, the Netherlands, Norway, New Zealand, the Philippines, the Republic of Korea, Russia, Serbia, South Africa, Spain, Sweden, Switzerland, the UK and the USA.

^{27/} See for example PatentScope at http://www.wipo.int/patentscope/en/

<u>28/</u> See for example patent portfolio and licensing practices at:

http://www.ibm.com/ibm/licensing/patents/practices.shtml

<u>29/</u> See for example the environment sensing, environment remediation, screening, therapeutic and other technologies available at http://stanfordtech.stanford.edu/technology

<u>30</u>/ For instance, the BiOS Licensed Patents Inventory, which for example provides arrangements for licensing the patented GUSPlus gene and other technologies for use in molecular biology through the Plant Enabling Technologies BiOS License and the associated BiOS Technology Support Services Subscription Agreement (at

http://www.bioforge.org/forge/entry.jspa?externalID=41&categoryID=3., for is a new reporter gene).

information about whether a given patent located in one jurisdiction (for example, in Europe, Japan or the United States) has a corresponding patent in other countries where the technology transfer would actually take place (for example, if a certain technology was located in a Canadian patent document, and it transpired that there was no corresponding patent applied for or in force in Thailand, then the technology would be free to use in Thailand – provided no other rights separately constrained its use).

B. Effective use of mechanisms to identify and promote transfer opportunities

Ease of access, quality, comprehensiveness and timeliness of patent information, and capacity preconditions to make full use of patent information systems

88. As noted, the cost structures for access to and use of some patent data have been transformed in recent years, so that basic searches can be conducted for free over a regular internet connection. This enhanced access is particularly beneficial in gaining information about the state of the art of the relevant technology, and to assist in focusing the development of technology to complement or build upon past innovation, rather than duplicating past research. It is also increasingly possible to secure information on the current legal status of patents in certain jurisdictions, as the basis for making assessments about any legal constraints in freedom to operate in those countries, However, this accessibility does not necessarily translate into information about the state of play in other countries, including the indigenous innovation that is taking place, the existence or absence of patents or patent applications, and the legal status of specific patents or applications (i.e. whether they are pending, in force, lapsed or expired, and whether they have been legally challenged, as well as transfers of ownership or licenses). Access to current up to date information about some countries is more difficult or more costly in practice to secure, or may require specialized skills or human resources to search. Skills, in some cases highly specialized legaltechnical skills, may also be required to establish a full patent landscape (presenting both the geographical spread and legal status of, and relationship between patents in a particular field of technology), or to draw legal conclusions from patent information particularly concerning the legal scope of freedom to use patented technologies, and the effective scope and likely validity of specific patent claims.

89. The effective use of such information for research and development often requires contextual knowledge, specific know-how and an research and development infrastructure that may not be in place in the developing country. Unless combined with strong collaborative research and development efforts with developed countries, including the patentee's involvement for certain forms of technology, mere access to patent information does not guarantee access to the necessary tools of interpretation (whether legal or scientific) and the means to turn the information into a functioning product or process. More empirical studies are needed on the extent of actual use of patent data information in research and development in different sectors both in developed and developing countries.

Licensing policies and practices of holders of required technology

90. Once potential technology transfer opportunities have been identified, and information is available as to the geographical coverage, legal status, and scope, of patents covering technology that is of interest, assessment of the opportunities will also be influenced by the licensing policies and practices of the holders of the technology. For instance, as noted above, <u>31</u>/ some patented technology is made available for use through non-exclusive licenses, and may be advertised as such or notified through a mechanism such as a license of right; in other cases, the technology holder exploits the technology directly or through an exclusive license to a single licensee. Again, because intellectual property is defined and exercised on a territorial basis, licensing arrangements may be structured differently in different countries; for example, it may be possible to have favourable licensing arrangements for developing countries (such as lower licensing fees, or no fees), or for other particular contexts (such as humanitarian,

<u>31/</u> See examples cited in notes 28, 29 and 30 above.

public-sector or non-commercial use). Some national laws provide for legal remedies in the event of refusal to license technology altogether, or to license it on reasonable terms, in certain circumstances.

91. As noted above, many technology transfer arrangements will extend to more than one patent or other intellectual property title, constituting a broader technology and enablement bundle, and may need to cover a range of subject matter, potentially including know-how, copyright materials, undisclosed information (trade secrets), test data and other regulatory information, as well as access to background intellectual property and product development skills and capacities. The licensing policies and approaches may therefore need to be considered across this much broader range of subject matter than a simple license under a single patent.

C. Extent of the need for additional know-how and capacity

92. The identification of technology transfer opportunities will also entail a comprehensive needs assessment, with the fill involvement of relevant stakeholders as well indigenous and local communities, which in turn will drive decisions on which partners, and which forms of partnership or other arrangements are needed. The technology transfer opportunity may be as simple as negotiating a license under a single patent (such as a specific research tool), when all other capacities and resources are already available. At the other extreme, the technology transfer opportunity may entail extensive investment by a technology partner, including provision of equipment, processing know-how, other background technology, training, product development support, and regulatory approval support. The extent, and the nature, of the use of intellectual property mechanisms differs widely according to the technology transfer opportunities under consideration. How to reduce the costs and maximize the benefits associated with this will also differ considerably; ultimately, the underlying need is likely to be one of enhanced capacity, so that those involved in strategic planning and specific negotiations to give effect to the technology transfer opportunity have access to high quality information and informed advice on legal and technical matters.

7. Actual transfer of technology

A. Key issues

93. Technology transfer has been defined by UNCTAD as "the transfer of systematic knowledge for the manufacture of a product, for the application of a process or for the rendering of a service and does not extend to the transactions involving the mere sale or mere lease of goods." <u>32</u>/ This definition focuses primarily on the 'actual transfer process' and places less weight on the initial and later stages (i.e. identification and choice of appropriate technologies and technology sources, and the adaptation and diffusion of technology – discussed in the other chapters of this study).

94. From this perspective, technology transfer transactions may include: <u>33</u>/

- (e) The assignment, sale and licensing of all forms of intellectual property;
- (f) The provision of know-how and technical expertise e.g. plans, diagrams, models, instructions, guides, formulae, etc ;
- (g) The provision of technological knowledge necessary to acquire, install and use machinery, equipment, intermediate goods and/or raw materials which have been acquired by purchase, lease or other means; and
- (h) The provision of technological contents of industrial and technical cooperation arrangements.

95. This conceptualization of technology transfer places emphasis on the conditions and means by which technology is sold, shared or offered to other interested users and technology developers. Consistent with the Convention's adoption of a broad notion of technology, it views technology transfer as a "transfer of a system" that includes know-how, procedures and managerial and organizational processes rather than as a "transfer of a product" such as sale of a tractor, seed or software package.

96. Often technology transfer is seen as a "forced process" where the owner is reluctant to make it available to others in need of such knowledge because it constitutes "competitive advantage". This view is not entirely accurate as many large firms and several research institutions in developed and developing countries are establishing technology transfer offices primarily to manage and transfer their technology assets to interested parties at a profit. Similarly, it is not accurate to presuppose that all technology owners are willing to transfer all, some or any of their technologies to some or any interested party. Depending on the firm's business strategy, it may choose whether or not to transfer its technology to others. '34/ A number of firms in biotechnology are generally forced to invent around inventions as the owners either demand a high price or refuse to make the technology available to others. 35/

97. There are other aspects of technology, such as tacit knowledge (or silent knowledge) - a major component in technological learning, that could be a hurdle in technology transfer. <u>36</u> Tacit knowledge refers to the stock of knowledge that is essential for the effective operation of an institution, most of which may not be written down. Such knowledge will be difficult to transfer or buy.

- <u>32/</u> UNCTAD 1985.
- <u>33/</u> ibid

^{34/} Lai, C.H. and Kidwai, A. (1989) Ideas and realities: Selected essays of Abdus Salam, 3rd Ed. World Scientific.

^{35/} USFTC (2003) To promote innovation: The proper balance of competition and patent law and policy, United States Federal Trade Commission Report [hereinafter USFTC, 2003].

<u>36</u>/ Polanyi, M (1958) *Personal Knowledge*, University of Chicago Press, Chicago, USA.

98. The cost of acquiring the technology may also vary by the stage of development. For instance, royalty payments as proportion of sales in health-related inventions range between 0-5% for inventions at the preclinical stage, 5-10% at phase I of clinical trials and more than 20% at the product launch stage, in general. This perhaps reflects the reduction in economic risks as the invention moves towards the market and/or an increase in the estimated market value of the product. These have implications on technology transfer and learning.

99. In general, technology owners use several modes to transfer technology. They may choose to transfer their technologies to related parties (internalized) or to unrelated parties (externalized). The choice of the mode of transfer may be determined by the nature and complexity of the technology, the strategy of the technology owner, government policies and capability of potential buyer/partner to exploit the technology. For instance, the absence of a competent partner or technology buyer or the presence of a competitor in the target country may encourage the technology owner to establish an affiliate firm in the target country to exploit its technology.

100. The business environment of the target country may also influence the technology transfer strategy of firms. For instance, a number of Eastern and Southern African countries had eliminated import duty and value added tax (VAT) on finished pharmaceutical products but had import duty and VAT on inputs needed to produce pharmaceutical products. <u>37</u>/ In addition lengthy regulatory procedures were imposed on locally produced pharmaceuticals and few on imported ones. Taken together, they discourage technology transfer and encourage import of the finished products.

101. Furthermore, technology developers often enter in strategic alliances to access, share, swap and commercialize technologies. These complex networks involving a wide range of enterprises are designed to reduce the risks associated with the development and commercialization of new products. They also facilitate information exchange within the network. All these strategies have varying implications for the actual transfer of technology to parties within and outside such arrangements.

B. Forms of transfer agreements

102. The actual transfer of technology, that is, the transfer of tangible or intangible technology assets, from one party to another often involves some form of *transfer agreement(s)* that specify the rights and obligations of the transferor and transferee. In addition, there are administrative procedures that have to be followed to enable the actual transfer of technologies especially across national boundaries to occur. Intellectual property rights often influence the terms of the agreements and possible access to incentives.

Licensing agreements

103. Technology licensing and partnership agreements are commonly employed in acquiring technologies. In general, licensing agreements indicate the nature of the technology to be transferred, the rights and obligations of the licensor (owner) and licensee (user), the authorized use of the technology and the mode of payment, among others. In other words, a license agreement gives rights to the licensee to use the technology in exchange for fees and/or royalties.

104. Firms may enter into licensing agreements to either gain access to or promote the use of their technologies. Such licensing agreements may focus on out-sourcing (in-licensing) or sub-contracting (out-licensing) to potential partners. A firm may favor in-licence technologies developed by academic

<u>37</u>/ Report and Decisions: Fifteenth Meeting of the COMESA Council of Ministers, 13th -15th March 2003, Friendship Hall, Khartoum, Sudan; See also paragraph 270 - During the 8-10 February 2003 High-Level Mission of Common Market for Eastern and Southern Africa (COMESA) to India, "pharmaceutical companies in India expressed keen interest to collaborate with COMESA on manufacturing drug. However, the companies expressed concern over the lengthy procedure in COMESA member States, to approve drug registration."

institutions, non-profit organizations and specialized research centres to reduce costs and risks of product development, and increase the number of products in its pipeline.

105. Out-licensing is an alternative way of maximizing the value of investment in R&D. Technologies that a firm or centre has developed may be easier to further develop or commercialize by a partner with the complementary technologies, necessary skills, sufficient funding, production capacity and marketing channels. For instance, InsectiGen, an Athens-based biotechnology company, licensed its patented BtBoosterTM technology to Pioneer Hi-Bred International for use in making better pest-resistant crops. <u>38</u>/ By so doing, Pioneer Hi-Bred has increased the range of technologies and reduced the risks, costs and time of product development. Similarly, InsectGen has expanded the value and market for its technology by licensing the technology to a major seed company.

Partnership agreements.

106. Partnership agreements focus on co-development and marketing of technologies. Partnership agreements are common in biotechnology, information technology and automotive industries. These agreements may entail co-development of a new firm, new product or service. For instance, Dow Chemicals and Cargill had to pool their resources to establish NatureWorksLLC (formerly Cargill-Dow) <u>39</u>/ to develop biopolymers from renewable resources by exploiting their complementary technologies.

107. Firms may seek partnerships to spread the cost, risks and uncertainty, especially in knowledge intensive fields such as biotechnology where there are restrictive and lengthy regulatory regimes. They may also enable a firm to strategically position itself to gain access to public and private resources of its partner(s), avoid regulatory and registration hurdles in foreign markets and access to lucrative contracts and market as well as access to the technologies and production platforms of its partners.

Material transfer agreements

108. The exchange or transfer of biological resources is vital to technology development and use. Biological material transfers are usually facilitated by a *material transfer agreement (MTA)*. MTAs regulate the transfer of tangible research materials, especially biological or genetic resources, between two parties. The terms and conditions of transfer, including access to the results and benefits arising from biotechnologies based upon such genetic resources, and the access to and transfer of technologies that make use of these genetic resources, in accordance with Articles 16 (3) and 18 (2) of the Convention, may depend on the nature and source or user of the genetic resources. In general, the transfer of materials from industry to public or private institutions may include more restrictive conditions than if the transfer was between two academic institutions (e.g. universities). 40/

109. MTAs may involve two types of letters (developed by the National Institute of Health (NIH), United States): the Implementing Letter Agreement (ILA) and the Simple Letter Agreement (SLA). The ILA is used in the transfer of materials that are subject to a patent or patent application or have been or are likely to be commercially licensed. The SLA is used in all other forms of transfer of biological materials.

^{38/} Pioneer licenses BtBooster technology (http://www.agriculture.com/).

^{39/} http://www.natureworksllc.com/

<u>40</u>/ See Annex I of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of the Utilization of Genetic Resources for a list of suggested elements for material transfer agreements.

110. In general, MTAs establish the rights of the material providers and recipients, the obligations of the recipient to inform the provider of any patent claims and/or innovations leading to a patent. Often, the ownership remains with the provider, including the rights to transfer to other parties. 41/

111. These conditions differ widely from one institution or country to another. For instance, the Consultative Group on International Agricultural Research (CGIAR) guidelines on MTAs of 2003 states: "The recipient of material provided under this MTA is encouraged to share the benefits accruing from its use, including commercial use, through the mechanisms of exchange of information, access to and transfer of technology, capacity building and sharing of benefits arising from commercialization." 42/

112. Depending on the nature, mandate and orientation of the biological material provider, the MTA may encourage the dissemination and exchange of the materials. Similarly, the nature of the materials and their value (if the material is subject to a patent or to be commercialized) may influence the inclusion of restrictive conditions in MTA.

Bioprospecting agreements

113. Bioprospecting is the search for scientific and economically valuable natural chemicals and organisms. It includes an exploration of biodiversity to seek out of nature commercially viable materials, including genetic resources. Under the Convention, access to genetic resources requires prior informed consent and mutually agreed terms. To meet this requirement and, as a good business practice, parties often conclude a *bioprospecting agreement*.

114. A bioprospecting agreement is a written contract between parties (e.g. a firm and a community/research centre) specifying the terms and conditions governing collection and use of the genetic resources, including prior informed consent of the providing country and the sharing of benefits arising from their use. 43/ As mutually agreed terms, they may also include details of the times, places, methods, quantities, and individuals responsible for collecting genetic resources, as well as how technologies and intellectual property rights are treated during and after the agreement expires. 44/

115. In general, the agreement involves seeking government permit to access genetic resources and get the consent of the community or owner(s). They also seek to clarify who will retain the right to patent or commercialize any technologies or products that may arise from the genetic resources and declare competing interests.

116. Article 15 of the CBD partly states: "... Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention [....]. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. Access where granted shall be on mutually agreed terms."

117. Bioprospecting agreements need to be in line with this provision of the Convention. For example, they may include capacity-building and training programs on collection, storage and preliminary processing of genetic samples. They may also involve the transfer of equipment and gears used in

<u>41</u>/ See the NIH Uniform Biological Materials Transfer Agreement (1995) for details. http://ott.od.nih.gov/NewPages/UBMTA.pdf .

<u>42</u>/ See http://www.cgiar.org/pdf/mta2003_en.pdf

 $[\]overline{43}$ / Guidelines for BIO Members Engaging in Bioprospecting

⁽http://www.bio.org/ip/international/200507guide.asp).

<u>44</u>/ See section IV, sub-section D of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of the Utilization of Genetic Resources, on mutually agreed terms.

sampling soil, water and/or plant materials among others. Some of the benefits, in addition to training and access to technology may include payment made per sample collected by the trainees, collection fees, annual access fees and share in potential sales (e.g. royalties) and, by so doing, promote the conservation of biodiversity and transfer of technology.

118. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising our of their Utilization provide the possibility of joint ownership of intellectual property rights by interested parties. <u>45</u>/ Where the genetic resources or the associated traditional knowledge lead to the development of a technology, parties could co-own the patent for that technology. For instance, Kenyan scientists provided biological materials that were further developed into an HIV/AIDS candidate vaccine by Oxford University (UK) scientists. The resulting patent is co-owned by the two teams of scientists. Such an arrangement may be preferred as one way of ensuring that the provider of genetic resources retains a distinct stake in the outcomes resulting from the access.

119. Bioprospecting agreements generally provide private firms with the rights to patent any technologies developed from the acquired materials. In cases of joint ownership, the provider and user of the resources need to consider how the responsibilities flowing from co-ownership of intellectual property rights will be apportioned, as ownership generally brings with it the costs and responsibilities of securing and maintaining rights, as well as enforcing them. 46/

Patent pools

120. Patent pools are voluntary agreements between two or more patent holders to license one or more of their patents to one another or third parties based on a predetermined formula. Patent pools have existed at least since the 19th Century. In a way, patent pools try to set a fair market for technology, eliminate the problems associated with blocking patents and patent stacking and facilitate technology transfer, including sharing know-how not covered by patents. <u>47</u>/

121. However, patent pools could also be used to manipulate the price of technology and harm competitors outside such arrangements. In the United States, the following guidelines have been used to assess patent pools:

- The patents in the pool must be valid and not expired,
- No aggregation of competitive technologies and setting a single price for them,
- An independent expert should be used to determine whether a patent is essential to complement technologies in the pool,
- The pool agreement must not disadvantage competitors in downstream product markets, and
- The pool participants must not collude on prices outside the scope of the pool, e.g., on downstream products. <u>48</u>/

^{45/} Bonn Guidelines, Annex II, paragraph 2 (q).

<u>46</u>/ For instance, in 1997, a Californian court ruled that the information shared by the inventors could be considered evidence that the invention was not original, and thus the patent could be revoked. In 2004, the US passed a legislation to protect joint patents (http://www.washingtonpost.com/wp-dyn/articles/A6085-2004Nov22.html)

 $[\]frac{47}{}$ USPTO (2000) Patent pools: A solution to the problem of access in biotechnology patents? United States Patent and Trademarks Office.

<u>48</u>/ *Ibid* USPTO.

122. The other advantages of patent pools include the reduction in litigations associated with patent infringements, reduction in the number of technology transactions (i.e. one negotiates for one or a collection of patents at once rather than with individual technology owners) and enable patent owners to share the risks and benefits associated with technology commercialization. However, patent pools could package essential and non-essential patents together in technology transfer transactions, shield invalid patents and may be complex in case of litigations. 49/

123. Patent pools in developing countries are rare or still emerging partly because these countries do not invest heavily in technology development. National governments could force the formation of patent pools (e.g. under compulsory licensing arrangements). A better approach will be to negotiate for key patents needed for the sustainable use of genetic resources and development of value-added products by a number of developing countries. For instance, public institutions within a region or country could be encouraged to negotiate for access to and use of key technologies collectively, as well as share any technologies and materials they develop. They could also use such materials to gain access to knowledge resources developed by other parties, in a way, creating a patent and materials pools for users.

C. The costs associated with actual technology transfer

124. The transfer process is not entirely cost free even if the technology was donated free. These costs could be divided into two broad categories:

- Transfer costs (e.g. tax liabilities and service fees)
- Cost of the technology itself (e.g. equipment and patents)

Tax and service fees liability

125. Technology can be transferred from one country to another through a change of ownership (e.g. sale), through licensing or leasing, or through the provision of services. Depending on the nature of the technology (tangible, intangible or skills and knowledge) the transfer itself may occasion immediate tax liabilities.

126. In the exporting country, immediate tax liability occasioned by the transfer of technology may involve transfer pricing rules, disallowance of expenditures incurred in creating the technology and failure to allow tax sparing credits. These could increase the cost of transfer and reduce the returns of the transferor. The lease or license of technology in return for recurring payments in the form of rents or royalties may attract transfer taxes.

127. In the importing country, excessive import duties, taxation of dividends, royalties and technical fees, and excessive taxation of expatriate employees may also increase the cost of transfer. In practice, the transferred assets, whether they are tangible assets such as machinery or intangibles such as patent rights, will often have already been used by the transferor and will have lost some of their original value, so that no gain arises. However, the contribution of technology assets to the capital of the recipient in return for shares in the importing company will technically be treated as a sale.

128. There are also service fees that may be occasioned by the transfer of technology. These may include special handling and storage requirement either imposed by the nature of the technology, equipment or material being transferred. In some cases, service fees for installing, training and maintaining the technology could substantially increase the cost of technology transfer.

<u>49</u>/ Homiller, D. P. (2006) Patent misuse in patent pool licensing: from national harrow to "the nine no-nos" to not likely, iBrief, Duke L. & Tech. Rev. 0007.

Cost of proprietary technology

129. The cost of proprietary technology has been a major subject of debate since the 1970s. Although the cost of producing a particular technology is a major factor in the pricing of the technology, there are other factors that influence the market price of a technology such as the perceived potential gains to be made by and how competitive it will make the buyer, the size of the target market, and political and economic relations of the supplier and buyer etc. In other words, different buyers may pay different prices for the same technology depending on the perceived gains and negotiating power.

130. In addition, technology owners may agree to transfer the technology under special conditions. Such conditions may include transfer as a 'turnkey project', use of the transferor's recommended intermediate products, inclusion of 'grant-back' provisions and the use of services and spare parts from the supplier. Other than limiting the choices of the buyer - sometimes for good reasons such as maintaining a firm's reputation - such measures ultimately increase the cost of the transfer.

131. The increase in cost of the actual transfer indirectly discourages technology transfer and development of a sound technological base. For example, the technology may be packaged in a way that the owners may have a degree of control over source of inputs, quantity, protection of the firm image and access to future improvements made using the technology, among others. Such practices increase the cost of technology transfer, discourage technology diffusion and development of a sound domestic technological base.

132. In order for the transfer to occur, the technology owners must be willing to provide the technology at a fair price that the buyer can afford. In the event the intellectual property owner is not willing to provide the technology on a fair basis, or if the denial of access to technology has other negative effects, such as uncompetitive practices, national laws, including intellectual property laws and competition laws, can provide remedies to address the matter. For example, the TRIPS Agreement provides for governments or judicial authorities to approve use without the authorization of the patent holder in certain circumstances, provided that "prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". 50

D. Advantages and disadvantages of intellectual property during transfer

133. Intellectual property rights play an important role in the actual transfer of technology. Intellectual property rights are often used as a "currency" in access to and transfer of technology. As discussed above, firms and centres may use their intellectual property on technologies to seek partners or develop strategic alliances. Such alliances and partnerships may involve teams with complementary technologies, skills and managerial techniques.

134. Intellectual property rights may also be used to secure funding for further development or be sold to interested parties for a fee to fund other technology development goals. However, all these arrangements ultimately encourage technology transfer to other parties.

135. There are several countries that provide incentives to their firms and institutions that seek to acquire advanced foreign technologies. For example, Malaysia grants a five-year tax holiday for approved research companies or institutions, and a double deduction of research expenditure may be claimed in some circumstances. Similarly, India allows a "super deduction" (of 125 per cent) of certain scientific research expenses and for R&D-related capital expenditures. Such privileges encourage

<u>50/</u> Article 31 (b).

technology transfer and intellectual property rights may play a role in determining the qualifying expenditure. 51/

136. As explained in chapter 5 above, intellectual property rights also facilitate the identification of the nature of the technology and the technology owner(s). Such information contained in publicly available patent databases would not be accessible if the knowledge was protected by trade secrets or completely unpublished. Importantly, this information about technology is also used by the buyer to negotiate for part of the technology stock of the supplier that the buyer is interested in acquiring. This could ultimately also reduce the cost of the actual transfer process.

137. Co-ownership of intellectual property rights derived from traditional knowledge and genetic resources is not widespread for many reasons but could be handled by an intermediate agent (see box 1 for an example). Intellectual property rights could help improve the reputation of institutions involved and attract funding and political support. More importantly, a significant amount of knowledge and skills are learned in addition to any tangible and intangible technologies shared during co-development of technologies (such as in bioprospecting and R&D partnerships).

138. However, intellectual property rights also present many challenges in technology transferespecially for products developed by public institutions, in the context of the increasing trend for public sector institutions themselves to pursue intellectual property protection of their research outcomes, with a view to leveraging access to other, related technologies, to generate research and development funding, or to construct practical pathways to technology diffusion when this entails some use of private sector resources, as in the case of public-private partnerships for development of pharmaceuticals addressing neglected health needs. At the research stage, intellectual property plays a minor role since the use of patents belonging to others in public research institutions may be allowed. However, once the product is ready to transfer to users, the interest of the intellectual property owners have to be taken into consideration.

139. For instance, the development of "Golden Rice" utilized about 70 intellectual property rights and/or inventions belonging to 32 different companies and universities. To enable those who will acquire Golden Rice and/or its technology "freedom to operate" (being a humanitarian product), the developers needed to obtain free licenses. Whilst one acknowledges that Golden Rice would possibly have not been developed that quickly if the patented inventions were not publicly available or kept secret, negotiating through this maze or "thicket" of patents was tasking. In the case of Golden Rice, public pressure and the use of a private partner proved to be vital. 52/

^{51/} UNCTAD (2005) Taxation and Technology Transfer: Key Issue, United Nations (Geneva and New York)

Potrykus, I. (2001) Golden Rice and Beyond. *Plant Physiol, Vol. 125, 1157-1161.*

Protecting traditional knowledge: the case of TIBRI

The scientists from the Tropical Botanical Garden and Research Institute (TBGRI) have been heralded for the development of Jeevani from the Arogyappacha (*Trichopus zeylanicus*) plant. The product was patented in 1995 by TBGRI and licensed out to Arya Vaidya Pharmacy for a period of seven years. TBGRI used the traditional knowledge of the Kani community and in return shared with them 50 per cent of the license fee and of the royalties gained by TBGRI from the drug.

TBGRI has about 9 patents based on traditional medicinal knowledge and genetic resources. By so doing, it has added value to natural resources, and promoted their sustainable use and protection. Without intellectual property, it would have found it difficult to find commercial partners for its products.

However, TBGRI did not register Jeevani as a trademark in the US and European markets. By 2004, a controversy had emerged over a registered Jeevani trademark in the US by a US-based firm, highlighting the important role intellectual property plays in benefit sharing. By so doing they have promoted the sustainable use of genetic resources and traditional knowledge.

Source: UNCTAD 2004, The Biotechnology Promise. Capacity building and participation of developing countries in the bioeconomy (United Nations: Geneva and New York) <u>53</u>

140. Patent thickets or de facto monopolies could also be used to block or discourage others, in particular potential competitors, in a field of interest or stifle technology development and transfer. 54/ These views were summed by Peter Ringrose, Chief Scientist at Bristol-Myers as follows: "*there are more than 50 proteins possibly involved in cancer that the company [Bristol-Myers]* was not working on because the patent holders either would not allow it or were demanding unreasonable royalties." 55/ Further information on, and analysis of, the overall trends in this areas, and consideration of the incentive implications for transfer of technology under the CBD, may provide useful clarifications.

141. National laws take various approaches to dealing with situations in which the patented technology is not made reasonably available, or otherwise is withheld in a manner that is injurious to competition. These remedies under national law are guided by various standards in the TRIPS Agreement and the Paris Convention, such as the TRIPS requirement referring to cases where the intellectual property owner is not willing to provide the technology on a fair basis, that is, on reasonable commercial terms and conditions. However, some users that may fail to obtain technology on reasonable and fair terms are unlikely to exploit protected technology using the flexibility provided by the TRIPS Agreements for fear of legal costs associated with the need to prove that the terms and period of negotiation were unreasonable.

^{53/} This case study was extensively reviewed in an UNEP and WIPO joint study: Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge; WIPO publication 769(E), available at http://wipo.int/tk/en/publications/769e_unep_tk.pdf

^{54/} USFTC, 2003 (available at <u>http://www.ftc.gov/</u>).

^{55/} Thompson, N. (2002). "Where are all the new meds gone?" *The New Republic Online*, October, 2002.

8. Technology adaptation

142. The purpose of the previous chapters of this study was to analyze the potential advantages (or "benefits") and disadvantages (or "costs") of intellectual property protection throughout various phases of CBD-related technology transfer: technology development, the identification of transfer opportunities, and the actual transfer of technology. It is important to note that, with the actual transfer of the relevant technology, the process of transferring technology is by no means complete. Experiences in a number of newly industrialized countries have shown, since the mid-1980s, that the actual transfer per se was not sufficient to create local capacities. Rather, it was perceived decisive whether the transferred technology could actually be adapted to local conditions in the target country.56/ Such technology absorption will generally make sure the domestic industry can effectively use foreign technology to its own benefit 57 or. in the case of technology transfer under the Convention, make sure that technology users can bring the imported technology to effective use to foster the objectives of the Convention. For example, technologies used for genetic engineering, such as the modification of genes to make plants pest- or climate-resistant, cannot merely be transferred to another country. They need to be understood by local researchers with a view to accommodating them to the actual conditions prevailing in a given country (e.g. differences in climate or pest existence), and to introduce them into viable crop varieties suitable for that environment. Thus, the potentials and obstacles relating to technology adaptation to the local context should be considered at the outset of the transfer process. Collaborative frameworks and incentive schemes are needed to encourage research into the identification of appropriate technology within a developing country region or industrial sector. 58/

143. As explained in chapter 2 above, the provisions of the Convention on technology transfer also include technology based on genetic resources, and foresee that technology transfer shall be one of the means to attain the third objective of the CBD (i.e. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, see Article 1, CBD). According to the Convention, a Contracting Party, in exchange for providing genetic resources, should be granted access to and transfer of technology making use of those resources (Article 16.3); participation in related biotechnological research (Article 19.1); as well as priority access to the results and benefits from biotechnologies based upon those genetic resources (Article 19.2). In a sense, the actual dissemination of technology can be interpreted as providing an incentive for Contracting Parties to provide access to their genetic resources.

144. Intellectual property rights and particularly patents might affect the ways in which other parties may use, disseminate and adapt protected technologies to their domestic needs. First of all, the simplest way of disseminating technology, i.e. through mere copying, is no longer possible, as the use of the protected material and the production of the protected product are reserved to the patent holder. Copying may be authorized under a licensing agreement, but will in general require the payment of licensing fees, which may be too high for some technology users, in particular in developing countries. Remedies may

^{56/} See P. Roffe/T. Tesfachew, "Revisiting the Technology Transfer Debate: Lessons for the New WTO Working Group", Bridges Monthly, ICTSD, February 2002, p. 7 (see http://www.ictsd.org/monthly/bridges/BRIDGES6-2.pdf).

The Republic of Korea is an example for the generally successful absorption of foreign technologies by the 57/ domestic industry. Important factors for this success were the high level of education among Korean workers and a relatively low level of IPR protection, see L. Kim, "Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience", UNCTAD-ICTSD Issue Paper No. 2, Geneva, 2003 (available at http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies) [hereinafter Kim]. For a more mixed picture, see the situation in the Thai electronics industry, where even after 40 years of foreign direct investment, many domestic firms have not been able to actually absorb the foreign technology, which often remains under foreign control. See "Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Electronics Industry in Thailand", United Nations, New York and Geneva, 2005 (available at <http://www.unctad.org/Templates/Page.asp?intItemID=3428&lang=1>).

⁵⁸ The Global Environment Facility's (GEF) Small Grants Programme as implemented by the United Nations Development Programme (UNDP) offers some lessons in this respect, including adaptations to climate change, while addressing the possible impact on CBD objectives in reconciling large plantations with the conservation of biodiversity. See http://sgp.undp.org/index.cfm.

be available for abusive licensing practices. Patented technology is fully disclosed to the public and is therefore free to use in those countries where no patent is in force. Most patents are applied for in only a small minority of countries worldwide.

145. With the introduction through the TRIPS Agreement of a general obligation to provide for product patents (Article 27.1), the legality of reverse engineering of products for commercial purposes depends on the authorization by the patent holder, unless a country's patent law provides for an exception to exclusive rights in this regard.59 Patent holders will usually charge fees for the use of their technology to recoup the costs of their R&D investment for developing the technology. For developing country users of technology, such fees might in many cases constitute important access barriers. On the other hand, there is no legal constraint on a researcher in a developing country to fully reverse engineer a foreign technology that is patented elsewhere, but not in her/his own country. But it is precisely in such 'lacunae' contexts that the patentee of the same technology in other countries has little incentive to enter into collaborative relations for the transfer of associated know-how, with adverse impacts on efforts towards technical and scientific cooperation under Art 18 of the CBD, in particular through the promotion of joint research programmes and joint ventures for technology development. As governments of market-based democracy have only limited, if any, options to mandate private companies to actually engage in cooperation and transfer relevant technologies to developing countries, incentive schemes could be used

^{59/} For a review of current practice in some jurisdictions, see F. Bor, "Exemptions to Patent Infringement Applied to Biotechnology Research Tools", European Intellectual Property Review Vol. 28, Issue 1 (January 2006). See also Garrison, "Exceptions to Patent Rights in Developing Countries", UNCTAD-ICTSD Issue Paper No. 17, Geneva, 2006. For instance, § 11 of the German Patent Act (exceptions to granted rights) only refers to acts done for experimental purposes (German Patent Act of 16 December 1980, last amended 21 January 2005). Under the pre-2005 Indian patent law, reverse engineering was legal, as the law did not provide for product patents. However, with the introduction of the new Indian Patent Act in 2005, product patents have to be made available, which "will close the option of reverse engineering which has largely contributed to the excellent growth and progress achieved by the Indian drug industry since 1972", see http://66.249.93.104/search?q=cache:UWQtYkjD9zwJ:www.idma-

assn.org/Patents.html+New+Indian+Patent+Law+of+2005+reverse+engineering&hl=de>. The lack under national patent laws of express references to reverse engineering may be explained by the fact that reverse engineering has traditionally been used as a balancing tool in the area of trade secrets, rather than patents. As explained in chapter 4 above, information subject to trade secrecy does not enter the public domain, as opposed to patented information. In order to prevent perpetual monopolies, trade secrets law usually authorizes the legitimate purchaser of a product to find out about its underlying technology by means of reverse engineering (see P. Jones, "Software, reverse engineering and the law", available at ">http://lwn.net/Articles/134642/>). In patent law, the balance of interests between the right holder and third parties is struck differently: the patent applicant is obliged to disclose his invention to the public, in exchange for the grant of a temporary monopoly right. But with the extension of patents to subject matter traditionally not patentable (such as genetic resources in many jurisdictions, or pharmaceutical products under the TRIPS Agreement), the importance of reverse engineering as a tool to promote immediate access to technological information has increased considerably. It has been argued in the literature that reverse engineering of patented products should not be considered a patent infringement, as the legitimate purchaser of a product is free to disassemble the product as he wishes, considering that the patentee's right to exclusive use of the product has been exhausted ("first sale doctrine"). See P. Samuelson/S. Scotchmer, "The Law & Economics of Reverse Engineering", Yale Law Journal, April 2002, available at http://ist-socrates.berkeley.edu/~scotch/re.pdf> [hereinafter Samuelson/Scotchmer]. While the exhaustion of an exclusive right does extinguish the right holder's entitlement to control distribution of the particular item sold to a third party, it does not confer to the latter the right to start producing like products, incorporating the protected technology. Interpretations to consider reverse engineering as falling under an exception to patent rights for experimental use are qualified by the fact that such exception does not necessarily encompass research leading to the development of a commercial product (see Samuelson/Scotchmer, in footnote 40, with references to U.S. patent law). A notable exception is the recent Industrial Property Bill of Uganda, which makes express provision for an experimental use exception for commercial purposes (see Uganda Law Reform Commission, The Industrial Property Bill, 2004, at para. 46 (a)). The new Swiss draft patent law in its Article 9 exempts from patentability research done for both non-commercial and commercial purposes, as long as the objective of the research is to reveal new knowledge about the patented invention. For details see Thumm, "A statutory research exemption for patents", in Healthy IPRs. A Forward Look at Pharmaceutical Intellectual Property, edited by M. P. Pugatch and A. Jensen, Stockholm Network, London, 2007, pp. 116-129.

to promote such collaboration, pursuant to relevant provisions of the CBD $\underline{60}$ / and Art 66.2 of the TRIPS agreement. $\underline{61}$ /

146. Finally, an overly broad scope of the granted exclusive right may inhibit technology absorption through follow-on innovation. $\underline{62}/$ Where certain biological research tools are deemed patentable, any technology produced by using this tool is likely to be subject to an exclusive right and thus usage fees, which may have a chilling effect on inventive activity and technology adaptation. This is particularly important in the area of genetic resources. For example, medical research into human diseases such as asthma, Alzheimer's or cancer critically depends on the use of human genetic resources for the purposes of diagnosis and treatment. Genes in this respect function as tools for essential research. However, where gene sequences are patentable, the entitlement to use these sequences for the purpose disclosed in the patent specification is taken out of the public domain. As opposed to other technologies, genetic engineering may not rely on various sources of information, the only relevant source being the (patented) gene. The patenting of human genes may therefore make access to essential medical information dependent on the ability of researchers or hospitals to pay certain licensing fees. This is particularly problematic where patents have been granted for inventions that do not meet a national patent law's patentability criteria. $\underline{63}/$

147. Having outlined some possible negative effects of patents on technology dissemination, it is equally important to stress that on the other hand, intellectual property rights may have a positive impact on technology absorption. In fact, according to some empirical evidence the strengthening of intellectual property laws and enforcement is likely to shift firms' activity away from exports and foreign direct investment toward licensing. 64/ Depending on the licensing terms (for more details on this issue, see below), the licensee is afforded an important opportunity to use the protected technology and thereby absorb it, much more than where a foreign direct investor keeps tight control over the relevant technology. One important precondition, however, is that the licensee has acquired a certain level of own technological expertise, without which he would be unable to understand the technology disclosed to him.

148. Two important conditions can be identified in order to promote a mutually beneficial balance between intellectual property protection on the one hand and technology diffusion on the other hand. First, national intellectual property and in particular patent laws are in many cases designed in a way that reflects a balance between incentives to invent and possibilities for technological followers to use/adapt

<u>60</u>/ The CBD programme of work on technology transfer and scientific and technological cooperation foresees the "provision of incentives to private-sector actors as well as public research institutions in developed country Parties, with a view to encourage the transfer of technologies to developing countries and countries with economies in transition" (activity 3.2.6).

<u>61</u>/ Article 66.2 obligates developed country Members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." The Council for TRIPS adopted, on 19 February 2003, a decision concerning the implementation of this Article which lays down an obligation for developed country Members to submit reports on actions taken or envisaged (including any specific legislative, policy and regulatory framework) to provide such incentives. Such reports are to be updated annually, and new detailed reports have to be submitted every third year. Under the CBD, Parties have a reporting obligation in accordance with Article 26 of the Convention, which includes reporting on the implementation of its provisions on technology transfer and cooperation.

 $[\]underline{62}$ / In the United States, concerns have recently been expressed about the negative effects of overly-broad patents and associated higher licensing costs on follow-on innovation. See USFTC, 2003, pp. 5 et seq. of the executive summary.

<u>63</u>/ See, for instance, J. Paradise, L. Andrews, and T. Holbrook, "Patents on Human Genes: An Analysis of Scope and Claims", in *Science*, vol. 307, 11 March 2005, p. 1566/1567, arguing that according to their survey, 38% of patent claims on human genetic resources were identified as problematic in terms of lacking written description, enablement and/or utility.

<u>64/</u> See Maskus, "Encouraging International Technology Transfer", UNCTAD-ICTSD Issue Paper No. 7, Geneva, 2004, p. 25 (available at http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies).

technologies, thus preserving the public domain to secure follow-on research (see below for details). Second, with respect to those technologies that do not fall into the public domain, national laws in many cases include provisions for the control of anti-competitive practices in licensing agreements (see below for details) to ensure actual diffusion of protected technology.

149. Empirical evidence suggests that in order to promote technology absorption, it is important to adjust the degree of national patent protection to the level of a country's technological development. As stated by Kim with regard to the policies successfully applied by the Republic of Korea to promote the absorption of foreign technologies:

"[...] strong intellectual property rights protection will hinder rather than facilitate technology transfer and indigenous learning activities in the early stage of industrialization when learning takes place through reverse engineering and duplicative imitation of mature foreign products. [...] only after countries have accumulated sufficient indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation [...] intellectual property rights protection becomes an important element in technology transfer and industrial activities." <u>65</u>/

150. The TRIPS Agreement makes available important flexibilities to adjust a national patent regime to a country's technological development. Where a country chooses to maintain as much information as possible in the public domain to enable follow-on R&D and innovation, it may choose to narrowly define the scope of patentable subject matter. Members are granted the freedom to refuse the patenting of genetic materials to the extent that these are considered pre-existing in nature, as opposed to an invention which requires a degree of technical intervention.66 In addition, TRIPS does not define the three basic patentability criteria of novelty, inventive step and industrial applicability. Members have the discretion to design these criteria narrowly to keep as much knowledge as possible in the public domain as a base for follow-on research and innovation.

151. In particular, Members may

- apply a standard of universal novelty;
- apply high standards of "inventive step", for instance by requiring some technical progress as the result of the invention;67
- limit the protection through product patents to those specific functions (uses) of both gene sequence and proteins that are disclosed in the patent application;68

<u>65/</u> See Kim, ibid, p. 5-6.

<u>66/</u> This differentiation between patentable invention and non-patentable discovery is not expressly made in the TRIPS Agreement, which does not provide a definition of "invention". National laws often require some technical intervention for a product or process to be patentable (on top of the basic three patentability criteria of novelty, inventive step and industrial applicability). For instance, the German Patent Act in its § 1 para. 2 excludes mere discoveries from patentability. Under Article 27.3(b), TRIPS Agreement, Members are obligated to provide patent protection to micro-organisms. A "micro-organism" may be defined as "a Member of one of the following classes: bacteria, fungi, algae, protozoa or viruses" (UNCTAD-ICTSD Resource Book, chapter 21, p. 392). Genes therefore do not constitute micro-organisms and do not fall under this TRIPS obligation (UNCTAD-ICTSD Resource Book, chapter 21, p. 393). However, in many countries the patenting of genetic material has become common practice, to the extent that genes are claimed in a non-naturally occurring form, i.e. in isolated or purified form (ibid). This is the requirement to satisfy the traditional patentability condition of "technical intervention".

 $[\]underline{67}$ / See Article 56 of the European Patent Convention: "An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. [...]" Under German patent law doctrine, technical progress is an indication for inventive step.

- construe the patent claims in a rather literal way, instead of applying a broad doctrine of functional equivalents;69
- apply a strict standard of industrial applicability, requiring the product/process for which patent protection is sought to produce a technical effect or to be capable of technical use in a business, or to be of substantial utility for a specific use (as opposed to some general utility for a variety of undefined uses).70 This may prevent the patenting of gene-based research tools such as expression sequence tags (ESTs) and single nucleotide polymorphisms (SNPs). <u>71</u>/

152. Where an invention does meet the above, rather strict patentability standards, it will be subject to an exclusive right. The patented technology may then only be used (and thereby absorbed and disseminated) by other parties where the patentee agrees to issue a license. Whether or not the other party will actually benefit from the protected technology largely depends on the concrete terms of the licensing agreement. In general, the licensing of proprietary technology should create win-win situations, providing the license to use and thereby absorb and disseminate new technologies 72/ for the purpose of the objectives of the CBD.

153. On the other hand, the intellectual property right holder might be tempted to collect the licensing fees without providing the licensee with the appropriate means to fully benefit from the technology. Whenever his intellectual property comes close to a monopoly right over a new technology, he/she might use the associated bargaining power to make third parties accept unfavourable licensing terms. In the CBD context, such behaviour by the right holder might impede adequate adaptation of imported technology with a view to fully support the objectives of the CBD.

<u>71</u>/ Ibid.

<u>68/</u> See Article 8c (1) of the Swiss draft revised patent law, which reads: "If the invention concerns a nonsynthetically developed sequence or partial-sequence of a gene, the effect of the patent is restricted to the function of the sequence as concretely described in this patent." Under French and German patent law, the scope of human gene patents is limited to the specific function disclosed by the patent applicant in the patent application. See Article L. 613-2-1 (France) and § 1a (4) of the Patents Act (Germany); both provisions are supposed to implement the EU Biopatent Directive (98/44/EC), in particular Article 5 (3) on the limitation of the scope of patents on gene sequences. For more information, see I. Schneider, "Civil Society Challenges Biopatents in the EU", Newsletter of the Property Regulation in European Science, Ethics and Law Project, No. 1, Summer 2005 (available at <u>http://www.propeur.bham.ac.uk/1stnewsletter.pdf</u>). This represents an important deviation to the approach traditionally taken under most national patent laws, according to which a product patent covers not only the product itself, but equally all *processes* for the making of the product and all possible *uses/functions* of the product, even if these were not known to the patentee at the time of filing the patent application nor expressly referred to in the application. The above laws waive the traditional protection of all *uses* of the protected product. On the Swiss draft law, see <u>http://www.ige.ch/E/jurinfo/documents/j10018e.pdf</u>.

<u>69</u>/ The patent claims determine the extent of the exclusive right. Under some jurisdictions, the claims are construed literally; i.e. all acts by third parties that do not literally reproduce the technical solution as expressed in the claims will fall outside the patent's scope of protection. On the other hand, other jurisdictions apply the doctrine of functional equivalents, considering acts that are equivalent to the technical solution described in the patent application as falling within the scope of the exclusive right. See UNCTAD-ICTSD Resource Book, chapter 17, p. 353. The broader the definition of "equivalent", the larger is the scope of the patent. Many jurisdictions define as "equivalent" those technical solutions that to a person skilled in the art seem obvious from reading the patent application.

<u>70</u>/ The notion of technical effect/technical use in the context of the industrial applicability criterion is based on German patent law doctrine, but not defined under the TRIPS Agreement (UNCTAD-ICTSD Resource Book, chapter 17, p. 361).

<u>72</u>/ See, e.g., introductory paragraph 5 of the Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty [establishing the European Community] to categories of technology transfer agreements [hereinafter EC Regulation on TOT]: "Technology transfer agreements concern the licensing of technology. Such agreements will usually improve economic efficiency and be pro-competitive as they can reduce duplication of research and development, strengthen the incentive for the initial research and development, spur incremental innovation, facilitate diffusion and generate product market competition."

154. As explained in chapter 4 above, this potential risk is recognized by the TRIPS Agreement in both Articles 8.2 and 40.1, which authorize WTO Members to take appropriate measures, consistent with the Agreement, to prevent or control restrictive practices in licensing agreements.73/ The TRIPS Agreement leaves Members wide discretion as to the implementation of these rights. 74/ In Article 40.2 it refers, in a non-exhaustive manner, to the following restrictive practices:

- exclusive grantback conditions: such clauses relate to obligations on the licensee to grant an exclusive license to the licensor or a third party designated by the licensor in respect of its own improvements or new applications of the licensed technology; 75/ Such qualification is likely to prevent or hinder effective dissemination of the improved technology to local researchers and users, as the licensor will maintain exclusive control over the distribution.
- no-challenges clauses: such clauses relate to obligations on the licensee not to challenge the validity of IPRs held by the licensor; 76/ To the extent that exclusive rights increase the cost of users to access, use, and adapt technology to local conditions, the obligation on the licensee to tolerate IPRs that should not have been granted in the first place may be considered as imposing illegitimate costs upon society at large.
- coercive package licensing: such clauses were defined in the UNCTAD Draft Code of Conduct on the Transfer of Technology as restrictions "imposing acceptance of additional technology, future inventions and improvements, goods or services not wanted by the acquiring party or restricting sources of technology, goods or services, as a condition for obtaining the technology required [...]." 77/ Such practices also impose additional (financial) burdens on the licensee, thus obliging him to pass on this burden to third parties (e.g., through higher sub-licensing fees), which may have a chilling effect on actual technology dissemination.

155. Other restrictive practices potentially affecting the international transfer of technology were listed in the UNCTAD Draft Code of Conduct. $\underline{78}$ / The proposed list included the three above mentioned practices that were reproduced under TRIPS as parts of a list of 14 practices parties to licensing agreements should avoid. This list included other practices directly relevant to technology adaptation and dissemination, such as:

- $\underline{75}$ / See also Article 5.1(a) of the EC Regulation on TOT.
- $\underline{76}$ / See also Article 5.1(c) of the EC Regulation on TOT.
- 77/ See Roffe, p. 292. On the Code of Conduct, see below.

 $[\]underline{73}$ / Article 8.2, TRIPS Agreement reads: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." Article 40, TRIPS Agreement reads in relevant part:

[&]quot;1. "Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

^{2.} Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member."

<u>74</u>/ For details, see UNCTAD-ICTSD Resource Book, chapter 29; P. Roffe, "Control of Anti-competitive Practices in Contractual Licenses under the TRIPs Agreement", in: Intellectual Property and International Trade: The TRIPs Agreement, Kluwer Law International 1998, pp. 261-296 [hereinafter Roffe]; UNCTAD, "The TRIPS Agreement and Developing Countries", United Nations, New York and Geneva, 1996, pp. 54-56.

 $[\]underline{78}$ / Negotiations on the Code of Conduct were conducted under the auspices of UNCTAD between 1976 and 1985, when they came to a halt, due to disagreements on the formulation of a number of international principles on technology transfer. For a detailed historical overview and analysis, see Roffe, with references to other literature (p. 266, fn. 20).

- Restrictions on adaptations.
- Restrictions on research: research is essential to find out how to adapt technologies to local conditions.
- Export restrictions: such restrictions limit the range of potential beneficiaries of new technologies and thus inhibit effective dissemination. <u>79</u>/

156. While the TRIPS Agreement authorizes Members to address restrictive licensing practices through appropriate measures, it offers no guidance on the actual implementation of such right. The TRIPS Agreement is a trade -related agreement, and in order for its intellectual property rights disciplines to unfold their potentially beneficial effects in terms of innovation and technology transfer, it needs to be accompanied by a detailed set of national competition rules, implemented by experienced competition authorities on the national level. This is a major challenge for developing countries. Whether or not internationally binding competition rules provide any assistance in this respect is controversial. In any case, there seems to be a need for intellectual property-related technical assistance to improve developing countries' capacities to control the abuse of monopoly rights and to use intellectual property licensing for technology transfer purposes through the development of appropriate competition rules, policies and institutions. <u>80</u>/

<u>79</u>/ The complete list included the following 14 practices: (i) grant-back provisions; (ii) challenges to validity; (iii) exclusive dealing; (iv) restrictions on research; (v) restrictions on use of personnel; (vi) price fixing; (vii) restrictions on adaptations; (viii) exclusive sales or representation agreements; (ix) tying arrangements; (x) export restrictions; (xi) patent pooling or cross-licensing agreements and other arrangements; (xii) restrictions on publicity; (xiii) payments and other obligations after expiration of industrial property rights; and (xiv) restrictions after expiration of arrangements. See Roffe, p. 290/291.

^{80/} See Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights, London, 2002, p. 149 (available at <u>http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf</u>).

9. Conclusions

A. General conclusions

157. The present note provided a succinct review of the different impacts, and the associated benefits and costs, of intellectual property rights that may arise during the different phases of technology transfer under the Convention, that is, at the stage of technology development, when identifying transfer opportunities, during the actual transfer, and during the phase of adapting the transferred technology to local needs and conditions. Throughout the analysis, the concepts of "benefits" and "costs" were interpreted in a broad sense. They were not restricted to the direct financial costs and benefits that are associated with commercial activities.

158. In general terms, one important conclusion of the present study is that a specific judgment on the costs or benefits of any specific intellectual property mechanism is likely to be difficult to establish, because of the variability in the manner of definition, administration, exercise and use of different forms of intellectual property rights, and the great diversity of practical technology transfer scenarios. To some extent, the actual costs or benefits experienced may depend on policy and legal settings, institutional capacity and the availability of resources and expertise, the broader regulation of technology (including, in the biotechnology domain, regulation of ethical, environmental, and human plant and animal health aspects of technology provider and technology user (and its evolution over time) may determine the effect of specific intellectual property mechanisms.

159. Intellectual property laws and mechanisms do not constitute a single, stand-alone form of knowledge management, necessarily to be adopted or rejected in their entirety, or to be used to the exclusion of other forms of knowledge management, innovation promotion and technology diffusion. Consequently, the benefits or disadvantages of intellectual property in the context of access to and transfer of technology will not necessarily depend on binary questions of the presence or absence of intellectual property altogether, but the net effect of successive decisions and determinations, as well as the impact of broader regulatory questions such as research exceptions, as well as regulatory measures, consistent with Article 40 of TRIPS, which deal with licensing practices or conditions which may impede the transfer and dissemination of technology, for instance, safeguards against anti-competitive practices and abusive licensing practices.

160. Accordingly, most practical technology transfer mechanisms involving intellectual property will also touch on a combination of other non-IP elements, ranging from capacity development and training, to laws governing investment and legal remedies against abusive licensing practices. Hence, the actual effect and operation of intellectual property in the context of access to and transfer of technology within the terms of the CBD will likely depend on the concrete choices made on a wide range of specific choices elements: (i) decisions to take out or to forego intellectual property protection in each discrete jurisdiction concerned; (ii) choices concerning ownership and management of relevant intellectual property portfolios; and (iii) approaches to licensing and enforcement of intellectual property rights, including degrees of exclusivity and non-exclusivity (such as for instance license arrangements that give non-exclusive access to interested parties), favourable terms for public-interest or non-commercial use, or for use in developing countries (e.g. licensing practices such as equitable access licenses for low and medium income countries) - approaches that may be relevant to implement concessional or preferential terms as foreseen in Article 16 (2) of the Convention. In this context, it would appear worthwhile to further explore existing obstacles, such as a lack of legal expertise, foreign investor pressure, or lack of infrastructure, which are preventing developing country actors in fully exploiting the exemptions and safeguards within intellectual property regimes.

161. Inappropriate patenting outcomes, where they occur, such as patenting of already disclosed traditional knowledge related to biodiversity, or patents that are invalid for other reasons, such as lack of novelty or inventive step, may constrain legitimate access to and use of technology. It is difficult, both in terms of time and money, for a concerned third party to obtain the revocation of patents that were erroneously granted. Specific legal requirements, such as for instance those governing the recognition of prior art, will have an impact; moreover, irrespective of the particular legal design of the national patent and intellectual property system, the provision of adequate institutional capacity – in terms of staff and financial endowments for national authorities governing the intellectual property system and in particular the grant of patents – seems to be an important general precondition to minimize the number of erroneously granted patents.

162. Moreover, patents that are drawn too broadly may encroach on the public domain and therefore may inhibit the use of public domain technology, even where a patent is considered to be invalid due to unreasonable breadth (since the costs of credibly and effectively challenging a doubtful or borderline patent may be beyond the reach of public sector or developing country institutions). The benefits of the system are enhanced by precise patent claims that focus wholly on genuine inventions and genuine new contributions to the technological base, while costs may arise from the deterrent effect of patents that cover public domain material, or obvious applications of known technology. The calculations of costs and benefits may differ considerably depending on the technological focus and economic status of one country or a sector within one country.

B. Specific conclusions pertaining to individual phases of technology transfer

Technology development

163. On *technology development*, the study noted that the core policy rationale of the patent system is to facilitate and to provide incentives for technology development, including both research and development, for technologies that require a degree of private sector investment. The judicious deployment of intellectual property mechanisms helps in garnering and effectively focusing the necessary resources, as part of a broader incentive structure. To the extent that commercialization and commercial processes are relied upon for the dissemination and practical availability of the technologies in question, the clarity and predictability that is brought by a well functioning patent system may be considered a benefit, while any difficulties created by obscurity or uncertainty in the system, such as with regard to the assessment of novelty and non-obviousness in the context of prior art searches concerning tradition-based inventions, may be considered a cost.

164. Several aspects of patent information may be considered relevant to the development of technology relevant to implementation of the CBD, including not only the access to information on 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, but also information on the legal status of patented technology required to make an assessment of freedom to operate and potential obstacles to research and development, the information on broader trends in the development of such technologies, including information on the strengthening of national capacities and particular new research directions; and the identification of potential research partners or technology providers through their patenting activity. Monitoring patent information has also provided access to information about claimed inventions that make use of genetic resources and associated traditional knowledge that are in tension with the objectives or legal provisions of the CBD. However, the effective access to and use of such information requires a range of resources – information technology, access to data, and capacity in informatics and necessary analytical skills, as noted below.

165. Developing research partnerships or other cooperative activities incurs costs, ranging from travel and logistical costs to engaging the specialized legal expertise that may be required to ensure the

arrangements serve the interests of all parties. Some of these may be specifically attributable to intellectual property mechanisms, for instance, in undertaking background searches and other due diligence processes relating to intellectual property, and negotiating intellectual property issues such as warranties on the validity and non-infringement of intellectual property, as well as obligations concerning the management of project-related intellectual property and access to background intellectual property and the associated licensing costs.

166. In addition, complex factual situations and patent claims over key technologies may create transaction costs in determining and negotiating freedom to operate or legal barriers have been cited as a potential obstacle to innovation; for instance, a clustering of patents on technologies that are necessary inputs to the desired technology development process ('patent thickets'). Patent pooling or a web of non-exclusive cross-licensing is one response proposed to this scenario. Debate and empirical analysis continues on the scope and extent of these problems, and the practical impact of such patterns of ownership. Costs and benefits may depend in part on licensing practices and the precision of claims granted concerning the relevant inventions. It could be worthwhile to further explore how companies in developing countries, with their special constraints for instance in terms of legal expertise and capacity, poor access to capital markets etc, deal with these problems.

167. Viewed from another angle, intellectual property mechanisms may also be used to lower transaction costs, for example in clarifying workable structures for ownership, access to and development of relevant technologies. Intellectual property mechanisms may be used, for instance, in cooperative partnerships including material transfer agreements and bio-prospecting arrangements for clarifying rights and responsibilities, and determining the scope and boundaries of agreed entitlements and obligations.

168. Inter alia, this observation may play a role in the appropriate and beneficial utilization of genetic resources, and in structuring mutually agreed terms, and access and benefit-sharing arrangements accordingly, including the transfer of technology and access to benefits from technologies derived from genetic resources. Commentators have questioned the appropriateness and suitability of a wholly bilateral approach to settling these issues, and stress the need for overarching principles and legal obligations that would provide a surer safeguard for the equity and legitimacy of specific arrangements. Even so, the arrangements made for defining each party's rights, interests and obligations regarding derivative intellectual property, and for managing relevant patenting activity, can be one important aspect of ensuring that these agreements operate to generate new technologies and new benefits, shares those benefits equitably, and respects the interests and concerns of the resource providers.

169. Alternative, open-source based modes of innovation are evolving in the marketplace and are also proposed to be applied in the field of biotechnology. The role of intellectual property rights within these new innovation frameworks requires more in-depth analysis.

Identification of transfer opportunities

170. One of the principal aspects of the patent system is the transparency it confers to technology development processes and hence to the *identification of transfer opportunities* with regard to proprietary technologies. This significant potential impact will occur at both the macro level (in determining the overall state of the art in a given area of technology and in monitoring trends), and at the micro level, that is, in determining who in particular is working on a specific technology, and who may be approached either to seek a license and further background technology and know-how, or to propose a more complex technology partnership (potentially involving cross-licensing or pooling complementary technologies, or arranging for licensing back of improvements or adaptations).

171. The practical benefits of this transparency depend, however, on the actual accessibility, cost and quality of the patent information, as well as capacity to make use of the information. Recent initiatives and technological developments have greatly enhanced the availability of patent information, including at

the early stages of international filing, which includes not only information about the technology itself, but also details of inventor and applicant/patentee, which may be used in contacting potential technology partners. However, this accessibility does not necessarily translate into information about the state of play in other countries, including the indigenous innovation that is taking place, the existence or absence of patents or patent applications, and the legal status of specific patents or applications (i.e. whether they are pending, in force, lapsed or expired, and whether they have been legally challenged, as well as transfers of ownership or licenses). Access to current up to date information about some countries is more difficult or more costly in practice to secure, or may require specialized skills or human resources to search. Skills, in some cases highly specialized legal-technical skills, may be required to establish a full patent landscape or to draw legal conclusions from patent information particularly concerning the legal scope of freedom to use patented technologies, and the effective scope and likely validity of specific patent claims.

172. Hence, unless combined with strong collaborative research and development efforts with developed countries, including the patentee's involvement for certain forms of technology, mere access to patent information does not guarantee access to the necessary tools of interpretation (whether legal or scientific) and the means to turn the information into a functioning product or process. More empirical studies are needed on the extent of actual use of patent data information in research and development in different sectors both in developed and developing countries.

Actual transfer of technology

173. On the role of *the actual transfer of technology* of relevance to the Convention, the study reviewed a number of forms of arrangements that are relevant for the Convention, in particular, licensing and partnership agreements, material transfer agreements, and bioprospecting agreements. It also examined the potential role of joint patents, pointing to a number of practical problems and limitations, as well as the potential role of patent pools, which could be advantageous if a number of conditions are met.

174. Intellectual property rights play an important role in the actual transfer of technology, as they are often used as a "currency" in access to and transfer of technology. Firms and centres may use their intellectual property on technologies to seek partners or develop strategic alliances. Such alliances and partnerships may involve teams with complementary technologies, skills and managerial techniques. Moreover, intellectual property rights may also be used to secure funding for further development or sold to interested parties for a fee to fund other technology development goals. While such arrangements ultimately encourage technology transfer to other parties, it would not be accurate to presuppose that all technology owners are willing to transfer all, some or any of their technologies to some or any interested party, as this will depend on the firm's business strategy.

175. Different cost types are associated with the actual transfer of proprietary technology, including transfer costs and the actual cost of the technology. The cost of acquiring the technology may also vary by the stage of development. In the exporting country, immediate tax liability occasioned by the transfer of technology may involve transfer pricing rules, disallowance of expenditures incurred in creating the technology and failure to allow tax sparing credits. In the importing country, excessive import duties, taxation of dividends, royalties and technical fees, and excessive taxation of expatriate employees may also increase the cost of transfer. Differentiated value added taxation and regulatory procedures for imported and local products may also discourage technology transfer.

176. In addition to the cost of producing a particular technology, there are other factors that influence the market price of a technology such as: the perceived potential gains to be made by the buyer, the size of the target market and, political and economic relations of the supplier and buyer etc. In addition, technology owners may agree to transfer the technology under special conditions. Such conditions may

include transfer as a 'turnkey project', use of the transferor's recommended intermediate products, inclusion of 'grant-back' provisions and the use of services and spare parts from the supplier.

177. Other than limiting the choices of the buyer - sometimes for good reasons such as maintaining a firm's reputation- such measures ultimately increase the cost of the transfer. For example, the technology may be packaged in a way that the owners may have a degree of control over source of inputs, quantity, protection of the firm image and access to future improvements made using the technology, among others. Such practices increase the cost of technology transfer, discourage technology diffusion and development of a sound domestic technological base.

178. Patent thickets or de facto monopolies, already mentioned above, could also be used to block or raise the costs for others, in particular potential competitors, in a field of interest or stifle technology development and transfer. While the TRIPS Agreement does provide some relief in cases where the intellectual property owner is not willing to provide the technology on reasonable commercial terms and conditions, many users that may fail to obtain technology on such terms are unlikely to exploit protected technology using the flexibility provided by the TRIPS Agreements for fear of legal costs associated with the need to prove that the terms and period of negotiation were unreasonable. It would be useful to undertake further examinations of the overall trends in this area and their incentive implications for transfer of technology under the CBD.

Technology adaptation

179. The study also notes that intellectual property rights may have a positive impact on *technology absorption and adaptation*. According to empirical evidence, the strengthening of intellectual property laws and enforcement is likely to shift firms' activity away from exports and foreign direct investment toward licensing. Depending on the licensing terms, the licensee is afforded an important opportunity to use the protected technology and thereby absorb it, much more than where a foreign direct investor keeps tight control over the relevant technology. One important precondition, however, is that the licensee has acquired a certain level of own technological expertise, without which he would be unable to understand the technology disclosed to him.

180. However, intellectual property rights and particularly patents will also affect the ways in which third parties may use, disseminate and adapt protected technologies to their domestic needs. The simplest way of disseminating technology, i.e. through mere copying, is no longer possible, as the use of the protected material and the production of the protected product are reserved to the patent holder. Copying may be authorized under a licensing agreement, but will in general require the payment of licensing fees, which may be too high for some technology users, in particular in developing countries. Furthermore, with the introduction through the TRIPS Agreement of a general obligation to provide for product patents, the legality of reverse engineering of products for commercial purposes depends on the authorization by the patent holder, which will usually charge fees for the use of their technology. And finally, an overly broad scope of the granted exclusive right may inhibit technology absorption through follow-on innovation, in particular where certain biological research tools are deemed patentable.

181. Two important elements can be identified for the promotion of a mutually beneficial balance between intellectual property protection on the one hand and technology diffusion on the other hand. First, empirical evidence suggests that in order to promote technology absorption, it is important to adjust the degree of national patent protection to the level of a country's technological development. Accordingly, national intellectual property and in particular patent laws are in many cases designed in a way that reflects a balance between incentives to invent and possibilities for technological followers to use/adapt technologies, thus preserving the public domain to secure follow-on research. Such approach is endorsed by the TRIPS Agreement, which makes available important flexibilities in that respect. 182. Second, as regards those technologies that do not fall into the public domain, the TRIPS Agreement allows WTO Members to take appropriate measures, consistent with the Agreement, to prevent or control restrictive practices in licensing agreements that would impede technology adaptation, such as exclusive grantback conditions, no-challenges clauses, or coercive package licensing. However, the TRIPS Agreement offers no guidance on the actual implementation of such rights. In order for its intellectual property rights disciplines to unfold their potentially beneficial effects in terms of innovation and technology transfer, they needs to be accompanied by a detailed set of national competition rules, implemented by experienced competition authorities on the national level. This is a major challenge for developing countries.

C. Potential options to increase synergy and overcome barriers to technology transfer and cooperation

183. As explained above, the variability in the manner of definition, administration, exercise and use of different forms of intellectual property rights, and the great diversity of practical technology transfer scenarios, makes the general establishment of costs and benefits of intellectual property rights for technology transfer exceedingly difficult. For the very same reasons, it is also challenging to identify specific options that would generally increase synergy between the entire variety of intellectual property systems and mechanisms, including the variety of relevant transfer provisions and agreements, and the provisions of the Convention on technology transfer.

184. Notwithstanding this caveat, the following elements could be taken into consideration as practical measures to increase synergy and overcome barriers to technology transfer and cooperation related to intellectual property systems and mechanisms.

185. The study frequently pointed to the important role of a well-designed broader regulatory framework addressing questions such as research exceptions as well as licensing practices or conditions that may impede the transfer and dissemination of technology, for instance, safeguards against anti-competitive practices and abusive licensing practices, consistent with the TRIPs Agreement. It seemed that such a framework would have a considerable impact of the ratio of costs and benefits associated with the intellectual property system for technology transfer. In light of the constraints faced by many developing countries in designing and implementing such a system, technical support and capacity building for enhancing the regulatory framework governing the use of intellectual property mechanisms would seem to be very useful. Such technical support and capacity building could be informed by an examination of the existing obstacles which prevent developing country actors in fully exploiting the exemptions and safeguards within intellectual property regimes.

186. In addition, and irrespective of the particular legal design of the national patent and intellectual property system, the provision of adequate institutional capacity - in terms of staff and financial endowments - for national authorities governing the intellectual property system and in particular the grant of patents seems to be an important general precondition to minimize the number of erroneously granted patents.

187. Capacity building and training on legal-technical skills could also be provided to relevant actors in developing countries with a view to maximize the usefulness of the enhanced access patent information provided in electronic patent databases. It was noted that highly specialized legal-technical skills may sometimes be required to establish a full patent landscape or to draw legal conclusions from patent information particularly concerning the legal scope of freedom to use patented technologies, and the effective scope and likely validity of specific patent claims. Such capacity building could be informed by empirical studies on the extent of actual use of patent data information in research and development in different sectors, both in developed and developing countries.

188. Moreover, there seems to be a need for intellectual property -related technical assistance to improve developing countries' capacities to use intellectual property licensing for technology transfer purposes through the development of appropriate competition rules, policies and institutions.

189. The study has underlined the importance of the specific bilateral arrangements, in particular licensing agreements or other agreements of relevance to the Convention, such as material transfer agreements or bio-prospecting agreements, in defining each party's rights, interests and obligations regarding derivative intellectual property, and for managing relevant patenting activity. Without giving prejudice to the appropriateness and suitability of a wholly bilateral approach, based exclusively on private contracts, to settling these issues, and, conversely, to the need for overarching principles and legal obligations that would provide a surer safeguard for the equity and legitimacy of specific arrangements, identified by some commentators, the design of such arrangements seems to be an important factor for ensuring that they operate to generate new technologies and new benefits, shares those benefits equitably, and respects the interests and concerns of the resource providers. Against this background, capacity building could be provided to relevant actors in developing countries with a view to enhance their skills for the negotiation of technology transfer agreements/provisions/clauses, including in the context of contractual agreements relating to access to genetic resources and associated traditional knowledge and the fair and equitable sharing of benefits arising out of their utilization – bearing in mind that overarching principles and legal obligations may also become important in light of potentially large differences in bargaining strength between the Parties to the contract, including expert knowledge and expertise, and associated bargaining skills.

190. As one concrete follow-up work to this study, it could be useful to compile and analyze existing technology transfer agreements or technology transfer provisions/clauses in other agreements, such as for instance contractual agreements relating to access to genetic resources and associated traditional knowledge and the fair and equitable sharing of benefits arising out of their utilization. This compilation and analysis could also include existing templates for standard technology transfer agreements/provisions/clauses, and could be used to develop international guidance that could act as reference for good/best practice on the application of technology transfer agreements/provisions/clauses in such agreements.

191. The institutional, administrative, legal and policy frameworks of countries that provide and that receive technologies could be reviewed with a view to ensure that they support and encourage the utilization of intellectual-property mechanisms for the sharing of benefits, such as: the provision of broad access to research tools (through free or preferential access or non-exclusive licenses; joint patents with stakeholders in countries of origin of genetic resources or joint research programmes with institutions in such countries; and the discouraging of reach-through provisions.

192. The establishment of research consortia among research institutions in developing countries could be supported, including through for instance the establishment and work of patent pools.

193. Countries that provide technologies could implement measures and mechanisms that provide incentives to the private sector to enhance technological cooperation and the transfer of pertinent proprietary technology. In particular, existing guidelines for eligibility to research-oriented tax breaks or deferrals could be adapted to generate incentives for private sector actors that engage in research making use of genetic resources, to implement adequate mechanisms for implementing Article 16 as well as for the promotion and advancement of priority access to the results and benefits arising from the biotechnologies that result from such research, in accordance with Article 19 (2) of the Convention.

194. In a similar vein, the principles and guidelines that govern the funding of public research institutions could also be reviewed and developed further so that they fully reflect the pertinent provisions and guidance of the Convention on technology transfer. In particular, the guidelines could foresee the implementation of adequate mechanisms for implementing Article 16 as well as for the

promotion and advancement of priority access to the results and benefits arising from the biotechnologies that result from such research, in accordance with Article 19 (2) of the Convention.

195. The development and implementation of *sui generis* intellectual property systems could be encouraged, with a view that these systems serve as safeguards to indigenous and local communities that their knowledge – including traditional technologies – will not be misappropriated when disclosed to research institutions or companies. Technology partnerships, such as transfer of technology and access to benefits from biotechnology, may need to take full account of existing laws and emerging international standards governing the protection of traditional knowledge.
