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ISSUES FOR PROPOSED WIPO WORK PROGRAM
ON BIOTECHNOLOGY

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I. Introduction

1. The World Intellectual Property Organization (WIPO) has convened a Working Group (the "Working Group") of experts in the field of biotechnology from the private sector and governments of its Member States, for the purposes of identifying issues related to biotechnology and intellectual property rights, which might be included in the WIPO work program beginning in the 2000-1 biennium. The Working Group will strive to base its conclusions on consensus decisions of the group, although lack of consensus should not prevent the Working Group from reporting on its deliberations. Where divergent views exist, they will be reflected whenever justified.

2. The issues to be addressed fall within five generally defined categories:

(a) Legal standards related to the scope and character of patent protection for inventions in the field of biotechnology, taking note of issues previously addressed by the Committee of Experts on Biotechnological Inventions and Industrial Property;

(b) Licensing and other issues related to the use of intellectual property rights in biotechnological inventions;

(c) Administrative and procedural issues related to examination of patent applications directed to biotechnological inventions;

(d) The relationship between patents and other forms of intellectual property protection for biotechnological inventions (e.g., UPOV-style plant variety protection, trade secrets and geographical indications); and

(e) The nature of the relationship between patent systems and certain issues, including the moral or ethical dimensions of commercialization of inventions involving genetic alteration of plants or animals, the conservation and preservation of the environment (including the protection of biological diversity) and the protection of animal and human health (including such issues as biosafety, food security and sustainable development).

3. The five areas of study represent a potentially significant scope of work. Rather than engage in an unproductive effort to define and study an unmanageable number of issues that could be addressed within each category, this paper identifies a small number (i.e., no more than three) well-defined issues within each field of study which might be carried out by WIPO. The selection of and work on specific issues would be conducted in a way that will ensure that the work can be managed and that results from the exercise will have value to the Member States of WIPO.

4. The issues-identification suggested in this paper is not directed at norm-setting or other standards development efforts. Instead, WIPO activities that might be undertaken based on the Working Group's recommendations should focus on information exchange and study undertaken in a manner that will help identify significant issues, and provide a greater mutual understanding of certain issues concerning biotechnology and intellectual property protection.

5. The identification of issues takes into account the relevant Main Activities included in the WIPO Program and Budget for the years 2000-2001, namely Sub-Program 09.1, on the investigation of the desirability and feasibility of a system for the deposit of DNA sequence listings referred to in patent applications, and Sub-Program 11.2, on achieving a clearer

understanding of the social, economic and ethical dimensions of intellectual property protection as applied to biotechnological inventions and genomics and the relationship between intellectual property and biological diversity.

6. Noting this, and desiring to yield practical value for the exercise, it is proposed that the following principles guide WIPO in undertaking activities based on the issues identified by the Working Group:

(a) The activities should be confined to study of topics approved by the Member States of WIPO.

(b) The work should focus on issues that have developed to a point that allows for objective analysis based on an adequate factual record and relevant experience. Work should not be undertaken on issues that may prove difficult to evaluate objectively or for which no practical experience exists in any WIPO Member State (e.g., consideration of the merits of patenting a class of inventions for which patent protection has not been sought or granted).

(c) Work should not be based on isolated events, such as the grant of a particular patent or the merits of a particular dispute.

(d) Topics should be chosen so that deliberations on a selected issue produce information that has practical value to entities to which the issue relates.

(e) Issues that implicate unresolvable conflicts or do not lend themselves to ready conclusions should not be taken up for study.

7. The stages below are suggested in carrying out work on selected projects. The overarching goal is to identify and elaborate issues for further and future work as decided by the Member States of WIPO.

- *Stage one* -- issue definition through informal consultations on November 8 and 9, in Geneva, which will outline the scope of the work project and issues to be addressed;

- *Stage two* -- data collection (i.e., collection of data that is necessary to perform an adequate analysis of the issue) and preparation of a first draft paper on the issues to be addressed;

- *Stage three* -- deliberations on a first draft of a paper produced on the basis of the initial discussions held in Geneva on November 8 and 9, as well as discussions outside WIPO processes, including where appropriate, public events, on the issues for which data has been collected);

- *Stage four* -- development of proposed findings and discussion, and preparation of a report summarizing deliberations and findings.

8. Before initiating work on particular issues, a schedule should be established for taking up and conducting the study of the selected topics. Setting a realistic schedule for when issues will be taken up, and in particular, how work on each topic will be conducted is essential to ensuring that work is conducted efficiently.

II. Proposed Topics for Study

A. Legal Standards Related to Biotechnology

9. There are two issues that may warrant study within the area of legal standards related to biotechnology.

1. Project A1: Prepare a summary of practices related to protection of biotechnology inventions under patent and plant variety protection systems of WIPO Member States.

10. Several international organizations over the past fifteen years have produced reports that provide an overview or summary of the standards and practices concerning the protection of biotechnology inventions under industrial property systems. Examples include the WIPO Committee of Experts on Biotechnological Inventions and Industrial Property (1986 to 1989), the OECD (studies in 1985, 1997 and 1999), and the World Trade Organization (WTO) incident to the 1999 review of Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

11. The information collected through these surveys has helped frame discussions in WIPO and elsewhere on the nature of protection afforded in various countries to biotechnology innovation under patent or plant variety protection systems, as well as procedural issues associated with the examination and grant of rights. To date, these surveys have focused primarily on systems in place in developed countries.

12. It is proposed that, drawing from questions raised in recent studies, a summary be produced of the standards and practices relating to the protection of biotechnology inventions under the patent and plant variety protection regimes of a sufficiently representative number of WIPO Member States. The summary would be produced using input from WIPO Member States and existing materials. The summary would provide a useful starting point for future discussions regarding the nature of protection that is presently available in WIPO Member States. A concerted effort should be made to obtain information from those countries whose systems have not yet been evaluated through these previous exercises, and in particular, developing countries. Doing so will ensure that the evaluation reflects a sufficient critical mass of information to be used as a relevant comparative model.

2. Project A-2: Review application of certain legal standards to early stage and certain other biotechnology inventions under patent standards of WIPO Member States.

13. A second issue that may be relevant for study by WIPO concerns the nature of patent protection -- in particular the scope of patent claims -- that can be obtained for two classes of biotechnology inventions that have stimulated discussions and question; namely:

- certain types of “early stage” biotechnology inventions; and
- structures and compositions derived or isolated from naturally occurring living organisms (e.g., plants, animals, bacteria, yeast, etc).

14. The most frequently cited example of an "early stage" biotechnology invention in the context of patents are inventions consisting of "expressed sequence tags (ESTs)." ESTs are nucleotide sequences of varying length that are produced when a gene is expressed. An EST can be recovered and later used to locate, identify and characterize the full sequence of the particular gene from which it derives. ESTs are an example of an early stage “invention” that has a principal value in the conduct of research.

15. In recent years, a number of public and private sector entities have sought to obtain patent protection for inventions based on disclosures consisting of nucleotide structures corresponding to ESTs. There has been some discussion in certain WIPO Member States concerning the effect of the grant of protection in respect of these types of “early stage” inventions – in particular where the claims in granted patents afford a scope of protection that encompasses later stage or downstream inventions. The context for these discussions has been whether it is consistent with established patent law standards or it represents good public policy to allow a party to obtain a broad scope of patent protection that will encompass later stage inventions on the basis of a disclosure consisting of a research tool that facilitates the production of that later stage invention. In the case of EST-type patent applications, the question has been phrased as whether it is appropriate to grant patent rights that encompass the full sequence of a gene, or expression products of that gene (e.g., a polypeptide), where these later structures will be the ultimately commercialized product, rather than the EST per se.

16. Similarly, the question of where "invention" versus "discovery" lies with regard to certain materials isolated or derived from naturally occurring living organisms has triggered discussions in a number of WIPO Member States. Some of these discussions focus on the question of whether the organism, per se, can be patented and in what form. Other discussions focus on whether substances, including nucleotide sequences corresponding to genes found in the organism, or proteins isolated from that organism, can be patented.

17. The proposed study of this issue would focus on how certain patent law standards apply to these two classes of biotechnology inventions. Representative examples of patent claims would be produced for each class of invention to guide the study of this issue. It is proposed to draw such examples from the evaluation of published patent applications and claims directed to representative inventions in each of the two classes of inventions.

18. It is proposed that three specific patent law standards be evaluated in the course of this study.

(a) Application of the requirement for industrial applicability[1] or “utility”;

(b) Application of the standard of non-obviousness or inventive step; and

(c) Assessment of claim scope in relation to disclosure.

19. The study would seek to evaluate how these three criteria are being applied to the representative examples in a representative number of systems of various Member States of WIPO drawing from the experiences and backgrounds of the participating members of the

[1] When the term “industrial applicability” is used in this paper, the reader may assume that the equivalent standard of “utility” is being addressed.

Working Group. A summary of the relevant criteria would be provided in a general sense to provide some context for the application of the requirement in respect of the representative example.

20. Based on the findings as to how these inventions are treated under current patent law standards, it is proposed that a second stage of the study be undertaken to assess the effect of the grant of patents in respect of these two classes of biotechnological inventions on patentability and commercialization of "later stage" inventions. In this second stage, possible issues to be explored could include whether a prior disclosure of an EST would render unpatentable a full sequence gene, or a downstream product expressed from that gene and whether there are experiences showing that commercialization of such downstream products has been impeded or affected by such practices.

B. Using Intellectual Property Rights in Biotechnological Inventions

1. Project B-1: Study legal regimes and university/government practices related to the use of patents to create technology-based collaborations with the private sector, and evaluate the relative success of different models for technology transfer between the public and private sector, and the role patents play in that process.

21. Intellectual property rights in biotechnology innovation have been used by a number of "public sector" research institutions to stimulate cooperation with the private sector, generate revenue, structure relationships and protect investments. Within the United States and certain other WIPO Member States, the university and Government sector, in particular, have had significant success in using patents to stimulate cooperation with the private sector aimed at developing and delivering new products based on innovation to the market.

22. For example, a recent estimate of the revenue generated through patent licenses by the university sector within the United States showed that universities collected over $365,000,000 through patent royalties, and stimulated over $1.5 billion in university research grants and support. Approximately 80% of this figure comes out of "life sciences" – one of the two principal fields that make up the biotechnology industry.

23. Patents have also been instrumental in the process of forming new companies out of Government or university-sponsored research. Since 1980, it has been estimated that over 1,200 new companies were formed in the United States through use of patents and patent licensing practices. A significant portion of this figure is biotechnology start-up companies.

24. With regard to Government-sponsored research and development, it should be noted that within the United States, the United States Government was the one of the leading recipients of patent grants. In 1998, agencies of the United States Government received over 1,000 patents, making the U.S. Government one of the top 15 recipients by number of patent grants.

25. The success of the universities and the United States Government in creating revenue and technology-based opportunities through patent licensing practices in the United States is remarkable. It is particularly striking, however, when one considers that this source of revenue and opportunity is a relatively recent development attributable to a series of legislative changes in the United States during the 1980s. The so-called "Bayh-Dole" Act of

the United States, in combination with other legislation, created the foundation for the now accepted practices concerning patent licensing and cooperation that resulted in the above cited figures. Similar legislation and practices have existed or been created in a number of other WIPO Members with equally successful results.

26. Many WIPO Members enjoy a strong basic research capacity in various fields of biotechnology through their university sector and through their government-sponsored research institutions.

27. Recognizing this, it is proposed that a study be undertaken of practices followed by universities, research organizations and Governments to facilitate the transfer of technology from basic research into applied research settings, and eventually into the market. The study should focus on the legal infrastructure found in WIPO Member States that is designed to encourage and support effective private-public sector technology partnerships and technology transfer and development. The study should also review practices followed by the university sector and the Government that result in the creation of technology-based partnerships and revenue through patent licensing. It is hoped that the study would be able to provide insights into those practices and legal standards that have proven successful in stimulating private-public sector partnerships and effective revenue sources for the university sector.

28. In addition, the study should look at existing practices concerning international transfer of biotechnology between public and private sector entities, particularly those involving developing countries (as licensors, licensees and both). Special attention should be paid to modalities used in existing relationships that enable the effective transfer and absorption of technological knowledge and know-how, and establishment of international partnerships in the fields of research and commercialization of biotechnological products.

2. <u>Project B-2</u>: Assess modalities for technology commercialization involving biological resources, and prepare studies that may facilitate discussions related to collaboration agreements for conducting research and development of naturally occurring biological materials.

29. Many types of biotechnological inventions draw from and build on information and characteristics of naturally occurring plants, animals and other living organisms. In the realm of pharmaceutical biotechnology, research and development efforts tend to focus on use of information derived from the study of human beings and their biological makeup. Information derived from the study of mammals and other animals also provides value in the process of elucidating the source of human disorders. In other areas of biotechnology, such as agricultural biotechnology, the focus of efforts tends to be the alteration of the genetic makeup of plants to create new plant varieties and species that have value to agriculture or other industrial sectors.

30. Outside the field of biotechnology, there is a long history of pharmaceutical innovation based on "natural products." For example, numerous chemical compounds having value as a pharmaceutical application have been derived from naturally occurring plants and other living organisms (e.g., microbial organisms such as fungi). The pattern of innovation witnessed in the area of natural products chemistry starts with isolation of an active chemical structure, but then ordinarily proceeds to identification of means to synthesize the chemical compound in a manner that can be scaled up to a commercial level. Doing so avoids creating

a dependence on raw materials to simply extract the chemical compound, and thus, tends to be preferable from an ecological conservation perspective.

31. In recent years, a significant amount of attention has been paid to the process by which investigation, research and development of commercial products from naturally occurring biological materials is conducted. Some of this attention has focused on improving the facilitation of cooperation between organizations or individuals in a country having a rich diversity of biological diversity and research institutions, whether from the public or private sector. Similarly, attention has been given to interactions and collaborations between indigenous cultures that possess knowledge about local flora and fauna and entities interested in conducting research and development using that knowledge.

32. Similarly, much attention has been directed to research efforts involving biological materials in certain "biodiversity-rich" developing countries. The unique capacity of these institutions to explore, discover and characterize biological resources gives these organizations a unique position with regard to their ability to stimulate research and development collaborations with other public and private sector research organizations. In many instances, these collaborations play an indispensable role in efforts aimed at discovery and commercialization of new products based on biological resources.

33. There has also been a much greater emphasis placed on ensuring that collection and use of samples of biological materials is done through authorized means with the consent of the host government or organization with some measure of legal jurisdiction over the materials. This goal of establishing openly collaborative and consensual procedures has allowed countries with significant regions of biological diversity to obtain benefits from participants who are interested in conducting research and development using those resources toward a commercial end. Similarly, they have helped ensure that public institutions and universities in countries, especially developing countries, providing the resources will be given the possibility of fully participating in the research and development of biotechnology based on those resources.

34. Some entities have advocated creation of a more formally recognized right to information possessed by indigenous cultures or more discrete and uniform international obligations relating to such knowledge. Others have suggested that such an approach would prove difficult given the diverse character of information and issues involved, among other issues.

35. As a means of providing useful insights into these issues and to facilitate deliberations on the question of promoting collaborations involving naturally occurring biological resources, it is proposed that a study be prepared that addresses three topics:

- a summary of characteristics of existing intellectual property rights that may be relevant to considerations or deliberations related to the protection of traditional knowledge, including those falling within the framework of the Article 8(j) of the Convention on Biological Diversity (CBD); and

- a survey of issues related to how intellectual property rights and contractual terms are used in collaborative agreements related to research and development of naturally occurring biological resources (e.g., how ownership interests in intellectual property rights that arise through the collaboration are addressed and how interests of indigenous

and local communities are defined and addressed); the data obtained in the study referred to in B.1 should be relevant to this topic, particularly in the context of Articles 15 and 19 of the CBD; and

- a survey of legal systems and regulatory or other practices that exist in WIPO Member States and that govern the collection and use of biological resources.

C. Administrative and procedural issues related to patent applications directed to biotechnological inventions

36. A number of administrative and procedural practices have evolved in response to the unique requirements and features of patent applications directed to biotechnology inventions. Two examples of such practices are deposit requirements for biological material designed to ensure an adequate disclosure when a written description of the invention has proven inadequate; and deposit requirements for machine-readable sequence listings in relation to nucleotide or amino acid sequences to facilitate the collection, review and public disclosure of such information.[2]

37. Both of these practices evolved in response to an "evolution" of requirements for adequate disclosure of certain types of biotechnological inventions. Both requirements also are evaluated during the examination of an application, and information disclosed may affect whether the invention for which patent protection is sought satisfies the relevant legal criteria for patentability.

38. Certain other practices relating to identification of ownership interests in inventions have evolved and become common in biotechnology applications. For example, where the United States Government has funded research and through that funding acquired certain rights in an invention, patent applicants will be contractually required to provide a notice to this extent in any patent applications directed to inventions arising out of that sponsored research. In other situations involving multiple sources of interests in patent rights to inventions made through university-private sector collaborations, ownership interests are reflected not through notices within the patent document itself, but through a recordal of such interests in systems maintained by patent offices to reflect such interests in the patent.

39. Finally, as patent offices gained experience in conducting examination of patent applications drawn to biotechnology inventions, they have had to address means for accessing and considering prior art. Most offices have successfully navigated issues relating to finding and applying prior art from traditional sources, such as patents and publications. In recent years, concerns have arisen regarding whether and how offices can evaluate information showing prior public use of an invention.

40. Noting these points, three possible topics related to administrative and procedural issues involving patent applications and patents to biotechnological inventions may warrant study.

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[2] Standards have evolved governing sequence listings within WIPO (e.g., ST.25).

1. <u>Project C-1</u>: Evaluate issues related to establishment of a multilateral system for the deposit and use of machine-readable nucleotide and amino acid sequence information

41. Over the past decade, practices have evolved in a number of patent offices concerning the deposit in machine-readable form of information concerning nucleotide and amino acid sequence listings. Sequence information is often an essential element for adequate disclosure of inventions in the field of biotechnology, yet has proven difficult to evaluate without the aid of computers and data processing systems. These practices evolved in response to the need to analyze sequence information in the course of patent examination have evolved in a coordinated and consistent manner.

42. WIPO has been involved in the development of standards that govern the format for sequence information provided to patent offices pursuant to these practices. WIPO standard ST.25, in particular, has been the subject of extensive work to define a common structure and format for sequence information that is submitted in machine-readable format.

43. WIPO has also been successful in establishing an analogous system designed to facilitate patent procedure in situations where a deposit of biological material is necessary for supporting full disclosure of an invention. The Budapest Treaty and the procedures based on this Treaty have been widely integrated into patent practices of many patent offices, and the framework established by the Treaty has proven to be of significant practical value to patent applicants.

44. A logical next step in terms of the role of WIPO in facilitating the advancement of efficient global patent application procedures would be to explore the feasibility of establishing a coordinated system for deposit and use of sequence information. This point has been recognized by the General Assembly of WIPO through its endorsement of an item in program 9.1 of the Program and Budget to explore the feasibility of establishing a coordinated system for deposit.

45. In taking this issue up for study, it is proposed that the focus be on relevant procedural issues, including:

- acceptable formats for submission of sequence listings, in light of developments in establishment of relevant WIPO standards;
- the interface between national/regional office practices and WIPO in entry, storage, validation and recognition of a sequence listing deposit;
- issues relating to entry and accessibility of deposited sequence listings by examining authorities in WIPO Members other than the authority that receives the original deposit; and
- issues relating to the timing and means of accessibility by third parties and public organizations to deposited sequence listings.

2. Project C-2: Evaluate means for recording ownership interests in inventions arising out of private-public collaborative research and similar projects

46. Certain proposals have been advanced within WIPO and other fora that would envision a requirement that patent applicants disclose certain information relating to biological materials that were used in developing an invention. Some of these proposals appear to be designed to ensure that parties have obtained samples of certain biological materials used in developing an invention legitimately, or seek to require applicants to disclose certain contractual relationships in the patent application. It is unclear, however, whether such a requirement should be dealt with by national laws as being substantive, thus leading to the rejection of the patent application in its absence, or rather a merely procedural one.

47. Certain other practices pertaining to patent applications and patents have become common in the field of biotechnology. One such practice is the disclosure of a "government interest" in certain inventions that are the subject of a later patent application filing. For example, where the United States Government has sponsored research and has certain legal rights in relation to the invention, the relevant sponsoring agency will require the contract recipient to disclose the Government's interest in the invention and thus the patent. The requirement arises not in response to a requirement of patentability of the invention, and cannot give rise to a finding that the patent is invalid or unenforceable. Rather, the requirement has been imposed on a group receiving funding from the United States Government, and serves as a public notice of that sponsorship and Government interest in the patent.

48. Noting these points, it is proposed that to undertake an evaluation of practices and means used to identify and protect the interests of the various parties that take part in research and development of biotechnology inventions that are aimed at an ultimately commercial end (i.e., bringing new products or services to the market based on the invention).

3. Project C-3: Evaluate prior art standards related to undocumented or inadequately document information on prior "public use" and means for facilitating the evaluation of such information during examination of patent applications

49. The definition of "prior art" varies among most patent systems, often to a significant degree. One area where this is the case involves situations where the "prior art" is not documented in a formal sense (e.g., through publication in a scientific journal or published in a patent). Notwithstanding the variation in standards, most patent systems prior public use or disclosure of an invention will normally have some capacity to defeat the novelty of an invention.

50. In recent years, there have been instances in which patent offices have issued patents that claimed inventions which nations, traditional healers, or indigenous peoples groups claimed had been previously invented by them or their predecessors. In some such instances the patents have later been invalidated on the basis of prior art presented by such nations, traditional healers, or indigenous peoples groups.

51. The concerns expressed by these groups have led to some effort to explore the means by which information that would render an invention unpatentable can be better identified

and evaluated by patent offices in the course of their examination of patent applications, or by the legal or procedural systems available in countries to reevaluate the validity of a patent that has been granted. One proposed example has to been to establish and maintain systems for capturing and disseminating prior art held by such groups to patent offices.

52. Evaluating the feasibility of this type of effort will require consideration of a number of factors, including

- patent law standards governing the status of unpublished "prior use" information;

- the feasibility and practicality of collecting, organizing, documenting and evaluating this type of information; and

- the means by which this information can be considered in relation to evaluating patentability of an invention, whether during the examination process or via post-issuance challenges to patent validity.

53. It is proposed that this topic be studied by first preparing a comparative analysis of the prior art status of information relating to prior public use of technology, with a special focus on the status of information that is not published in a traditional medium (e.g., such as a patent or formal publication). This would be followed by an evaluation of possible means for collecting and documenting such information concerning public use of technology, with a particular focus on means that may facilitate consideration of such information during patent examination procedures. Thereafter, it may be appropriate to consider issues related to the evaluation of patents in light of such information after a patent has been granted.

D. Project D-1: Study the relationship between protection afforded to plant inventions through patents and UPOV-style plant variety protection and related issues

54. Inventions in the field of biotechnology may be protected through a variety of intellectual property rights. These include patents, plant variety protection instruments and trade secrets.

55. The use of one type of protection is often not exclusive of use of other forms of protection. For example, trade secret rights and patent rights are often used in a purely complementary fashion to protect technology and technical information. Similarly, it is common in those countries offering protection to plant varieties and patent rights in plants for biotechnology innovators to seek both types of protection.

56. In 1987, WIPO and UPOV jointly produced a study of the protection of plant innovation by both patents and UPOV-styled plant variety rights. Since that time the UPOV Convention has been revised (in 1991) to remove the prohibition in the 1978 Act of UPOV barring dual protection.

57. Within Europe, which is widely credited for being the source of the pre-biotechnology era delineation of special instruments of protection for plant varieties, and the complementary exclusion of patent protection for plant varieties, changes have also occurred. In 1998, the European Union approved the Biotechnology Directive, which specified, among other things that plant and animal varieties would continue to be unpatentable (Article 4(1)), but that patents could be obtained for "[i]nventions which concern plants or animals … if the

technical feasibility of the invention is not confined to a particular plant or animal variety" (Article 4(2)).

58. It is proposed that certain elements of the 1987 UPOV-WIPO study of the relationship between patents and plant variety protection be updated. The issues to be addressed in this updated study should include a review of the nature and effectiveness of protection afforded to plant inventions by each type of instrument and how various WIPO Members have addressed the issue of "dual protection" through patents and plant variety protection under their national or regional laws. As part of this exercise, it would be useful to also provide some comparative analysis between the 1978 and 1991 Acts of UPOV to illustrate the distinctions between the two Agreements, and how parties to it have implemented the 1991 Act. As under issue A-1, the Group should aim at obtaining inputs from a significant number of developing countries, so as to establish sufficient critical mass of information to be used as a relevant comparative model.

E. Project E-1: Review the role of patents in the process of biotechnology innovation and commercialization to provide a greater understanding, and to identify issues of concern, if any, that are unique to the question of patents

59. Patents are used extensively by universities and biotechnology companies to protect investments in research and development. Patents have value in this regard through the exclusive rights they provide their owner. Exclusive rights under a patent can be used to prevent competitors from interfering with the commercial use of the patented technology where there has been no consent to do so provided by the patent owner. Exclusive rights do not block the dissemination of information concerning the invention to the public, which occurs when the patent is granted or the patent application is published. Exclusive rights also do not interfere with non-commercially focused experimental use of the technology.

60. Patent exclusivity also has been shown to provide an essential degree of financial security for investors who support research and development ventures in the field of biotechnology. Most biotechnology research and development initiatives involve work at a very early stage in the scientific or technological development of an invention. As a result, many products that would be the result of the commercialization effort of the venture will never appear on the market. Those that do survive the risky and difficult developmental process often enter the market with only a short period of exclusive rights from the remaining patent term when the product can be sold on the market.

61. At the same time they generate exclusive rights, and thus, like all property rights, may constitute barriers to entry into the commercial market by competitors that wish to use the same invention or technology, patents provide competitors of the innovator with a full disclosure of the protected subject-matter. In this sense, patents are an important tool for competitors who wish to invent around and develop alternative technologies, which not only yields improved products and services becoming available on the market, but ultimately will result in vigorous competition between these new products and services and as a result, lower prices and greater availability.

62. Patents clearly play a significant role in the commercialization process for biotechnological innovation. What has been less clear is how the grant of exclusive rights over commercialization of a particular biotechnological invention may relate to certain societal concerns regarding development and commercialization of biotechnology.

63. For example, when the question of the patentability of a genetically altered mouse was presented before the European Patent Office in the late 1980s and early 1990s, a number of organizations filed oppositions citing ethical concerns related to their opposition to the genetic alteration of mammals. Other groups have raised a claim of "biopiracy" in situations when biological materials are used in the development of an invention that is later made the basis of a patent application.

64. The grant of a patent gives the innovator no positive right to market an invention. Patents, due to their territorial nature and the requirement for novelty, also cannot be used to foreclose the ability of a third group to use materials that are naturally occurring and in no case can be used outside the country in which the patent has been granted.

65. There has been an absence of critical review of the relationship between the grant of patent exclusivity in a biotechnological invention and societal concerns about commercialization of biotechnology. It is therefore proposed that consideration be given to a review of the relationship between patent exclusivity and commercialization of biotechnological inventions to provide greater understanding as to this relationship.

66. It is also proposed that part of this evaluation address the question of whether the societal concerns that have been raised by certain entities about patents on biotechnological inventions can be differentiated in any manner from concerns over commercialization of biotechnology as a general matter.

67. To ensure that the study not prejudge the outcome of the exercise, it is proposed that the issue be presented in an essentially factual manner. To frame the deliberations on this issue, a study should be undertaken of the nature of rights provided in various WIPO Member States through the grant of a patent. Examples of issues that could be taken up for study include:

- the extent to which patent rights can be and are enforced against parties that use the patented technology for different reasons (i.e., to compete in the market with the patent owner to evaluate and study the invention in the course of research);

- the practical effect of limiting patent protection for certain biotechnology inventions vis-à-vis the effect on research and development activities in the realm of biotechnology, including whether the absence of protection leads to greater reliance on trade secrecy or results in an abandonment of research and development activities; and

- whether patents can be or have been used to prohibit the use of naturally occurring plants or to interfere with the practices or customs of indigenous communities.

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