

WIPO/GRTKF/IC/1/8
ANNEX I

**DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

of 6 July 1998

on the legal protection of biotechnological inventions

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF
 THE EUROPEAN UNION,

Having regard to the Treaty establishing the European
 Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social
 Committee ⁽²⁾,

Acting in accordance with the procedure laid down in
 Article 189b of the Treaty ⁽³⁾,

(1) Whereas biotechnology and genetic engineering are
 playing an increasingly important role in a broad
 range of industries and the protection of
 biotechnological inventions will certainly be of
 fundamental importance for the Community's
 industrial development;

(2) Whereas, in particular in the field of genetic
 engineering, research and development require a
 considerable amount of high-risk investment and
 therefore only adequate legal protection can make
 them profitable;

(3) Whereas effective and harmonised protection
 throughout the Member States is essential in order
 to maintain and encourage investment in the field
 of biotechnology;

(4) Whereas following the European Parliament's
 rejection of the joint text, approved by the
 Conciliation Committee, for a European
 Parliament and Council Directive on the legal

protection of biotechnological inventions ⁽⁴⁾, the
 European Parliament and the Council have
 determined that the legal protection of
 biotechnological inventions requires clarification;

(5) Whereas differences exist in the legal protection of
 biotechnological inventions offered by the laws and
 practices of the different Member States; whereas
 such differences could create barriers to trade and
 hence impede the proper functioning of the
 internal market;

(6) Whereas such differences could well become
 greater as Member States adopt new and different
 legislation and administrative practices, or whereas
 national case-law interpreting such legislation
 develops differently;

(7) Whereas uncoordinated development of national
 laws on the legal protection of biotechnological
 inventions in the Community could lead to further
 disincentives to trade, to the detriment of the
 industrial development of such inventions and of
 the smooth operation of the internal market;

(8) Whereas legal protection of biotechnological
 inventions does not necessitate the creation of a
 separate body of law in place of the rules of
 national patent law; whereas the rules of national
 patent law remain the essential basis for the legal
 protection of biotechnological inventions given that
 they must be adapted or added to in certain
 specific respects in order to take adequate account
 of technological developments involving biological
 material which also fulfil the requirements for
 patentability;

(9) Whereas in certain cases, such as the exclusion
 from patentability of plant and animal varieties
 and of essentially biological processes for the
 production of plants and animals, certain concepts

⁽¹⁾ OJ C 296, 8.10.1996, p. 4 and OJ C 311, 11.10.1997, p. 12.

⁽²⁾ OJ C 295, 7.10.1996, p. 11.

⁽³⁾ Opinion of the European Parliament of 16 July 1997 (OJ C 286, 22.9.1997, p. 87). Council Common Position of 26 February 1998 (OJ C 110, 8.4.1998, p. 17) and Decision of the European Parliament of 12 May 1998 (OJ C 167, 1.6.1998). Council Decision of 16 June 1998.

⁽⁴⁾ OJ C 68, 20.3.1995, p. 26.

in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

- (10) Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes;
- (11) Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world; whereas the patent system should likewise be used to encourage research in these fields; whereas international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted;
- (12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)⁽¹⁾ signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;
- (13) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such, such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely;
- (14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;
- (15) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes *a priori* the patentability of biological matter;
- (16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;
- (17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;
- (18) Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem;

⁽¹⁾ OJ L 336, 23.12.1994, p. 213.

- (19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;
- (20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;
- (21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;
- (22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;
- (23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;
- (24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;
- (25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;
- (26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;
- (27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;
- (28) Whereas this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented product;
- (29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;
- (30) Whereas the concept 'plant variety' is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;
- (31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;
- (32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;
- (33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;

- (34) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law;
- (35) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability;
- (36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;
- (37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against *ordre public* or morality must also be stressed in this Directive;
- (38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;
- (39) Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;
- (40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against *ordre public* and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;
- (41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;
- (42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;
- (43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;
- (44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;
- (45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;
- (46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities,

the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself;

- (47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorise the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ⁽¹⁾;
- (48) Whereas only the fee envisaged under Community law relating to plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;
- (49) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against a breeder who has developed a plant variety incorporating the protected invention if the latter fails to adhere to his commitments;
- (50) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use protected livestock for agricultural purposes;
- (51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;
- (52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be

granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;

- (53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;
- (54) Whereas Article 34 of the TRIPs Agreement contains detailed provisions on the burden of proof which is binding on all Member States; whereas, therefore, a provision in this Directive is not necessary;
- (55) Whereas following Decision 93/626/EEC ⁽²⁾ the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Article 3 and Article 8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;
- (56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity',

⁽¹⁾ OJ L 227, 1.9.1994, p. 1. Regulation as amended by Regulation (EC) No 2506/95 (OJ L 258, 28.10.1995, p. 3).

⁽²⁾ OJ L 309, 31.12.1993, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

Article 4

CHAPTER I

Patentability

Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

1. For the purposes of this Directive,

- (a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
- (b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

1. The following shall not be patentable:

- (a) plant and animal varieties;
- (b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;

- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 7

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

CHAPTER II

Scope of protection

Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

CHAPTER III

Compulsory cross-licensing

Article 12

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

- (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
- (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

CHAPTER IV

Deposit, access and re-deposit of a biological material

Article 13

1. Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

- (a) the biological material has been deposited no later than the date on which the patent application was filed with a recognised depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty', shall be recognised;
- (b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;
- (c) the patent application states the name of the depositary institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

- (a) up to the first publication of the patent application, only to those persons who are authorised under national patent law;
- (b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

- (c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

- (a) not to make it or any material derived from it available to third parties; and
- (b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

Article 14

1. If the biological material deposited in accordance with Article 13 ceases to be available from the recognised depositary institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER V

Final provisions

Article 15

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 16

The Commission shall send the European Parliament and the Council:

- (a) every five years as from the date specified in Article 15(1) a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded;
- (b) within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late

publication of, papers on subjects which could be patentable;

- (c) annually as from the date specified in Article 15(1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

Article 17

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 18

This Directive is addressed to the Member States.

Done at Brussels, 6 July 1998.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

R. EDLINGER

**DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL
ON THE LEGAL PROTECTION OF THE BIOTECHNOLOGICAL INVENTIONS**

**Explanatory note on recital 27 concerning the indication of the geographical origin of
biotechnological inventions (animal and plant aspects)**

Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions was adopted on 6 July 1998.

The final date for transposition of the Directive into the national law of the Member States of the European Union was set at 30 July 2000.

The preamble of this Directive, and in particular recital 27, lays down that, if an invention is based on biological material of plant or animal origin, or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Recital 27 of Directive 98/44/EC has to be regarded as being an encouragement to mention the geographical origin of biological material in the patent application, along the line indicated by Article 16(5) of the Convention on Biological Diversity.

Information about the geographical origin of a biological material being the subject of an invention can be helpful for the process of equitable benefit-sharing of the resources of biological diversity.

However, to provide such information is not an obligation under Community law. Nor does the failure to provide such information have, as such, any legal consequence for the processing of patent applications, or on the validity of rights arising from granted patents.

[End of Annex II, Annex III follows]

**REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)
OF THE TRIPS AGREEMENT**

**COMMUNICATION BY THE EUROPEAN COMMUNITIES AND THEIR
MEMBER STATES ON THE RELATIONSHIP BETWEEN THE
CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRIPS AGREEMENT**

1. The relationship between the TRIPS Agreement and the Convention on Biological Diversity (hereinafter "CBD") has become a major focus of discussion in the TRIPS Council within the context of the review of Article 27.3(b). It has been argued, at one end, that the agreements are incompatible and that the TRIPS Agreement should be amended so as to bring it in line with the CBD, while at the other end, it has been claimed that there is no conflict.
2. The European Communities and their Member States (hereinafter "EC/MS") hold the view that issues such as sustainable development, environmental sustainability, human development, human rights, sound economic policies and ethical norms may all have a bearing on the legitimate exercise of intellectual property rights and should be carefully considered. From this perspective, the EC/MS agree that concerns voiced by developing country Members within the context of the review of Article 27.3(b) of the TRIPS Agreement should be properly addressed. The present review exercise may not be a vehicle capable of producing definitive solutions to all the issues raised in this context.
3. The present communication sets forth a first set of thoughts by the EC/MS on the relationship between intellectual property and biodiversity related matters. It does not represent a negotiation position on these issues. The EC/MS is looking forward to concrete proposals from Members which have raised specific concerns in the TRIPS Council in the context of the review of Article 27.3(b).

I - The legal relationship between the TRIPS Agreement and the CBD

4. The EC/MS believe that, from a legal perspective, the CBD and the TRIPS Agreement do not conflict with each other. They have different objectives, they do not deal with the same subject matter and they are of a different legal nature.
5. The CBD's objectives are: the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. The main objectives of the TRIPS Agreement are to set minimum standards of intellectual property protection within WTO Members and to ensure that states make available to rights holders judicial and/or administrative procedures to enforce their intellectual property rights.
6. In the same vein, the two treaties do not deal with the same subject-matter. The CBD deals with protection of and control over biological diversity. The TRIPS Agreement deals with standards of intellectual property law, not addressing the issue of commercialisation of products protected under IPR law.

7. The CBD stipulates that states have sovereign rights over their genetic resources and have the authority to determine access to their genetic resources as well as to establish mechanisms for the fair and equitable sharing of the benefits arising from the use of genetic resources. It is stipulated that access is granted on “mutually agreed terms”, subject to “prior informed consent” of the supplier of the resources. Biological or genetic resources can serve as a basis for the production of derived products such as medicines or genetically modified organisms.
8. The TRIPs Agreement obliges Members to provide minimum protection to, inter alia, literary and artistic works, trademarks, geographical indications or inventions that meet the criteria of patentability. Genetic resources can serve as a basis for inventions, which may be subject to intellectual property rights, and in particular patents or to new plant varieties which can be protected by plant variety rights. It needs to be recalled that, in principle, neither naturally occurring genetic resources as they exist in their natural environment, nor related traditional knowledge, can constitute patentable subject matter in themselves, because they do not meet the basic criteria of patentability (and in particular, novelty and inventive activity). A patent application claiming naturally occurring material as such in its natural state, would be liable to refusal, and if granted, to revocation, for want of novelty and/or inventive step. To be protected, genetic resources must be isolated from their natural environment or produced by means of a technical process, so as to meet the criteria of patentability.
9. The CBD provides a general framework and policy objectives within which states can act to fulfil their objectives. For instance, with regard to benefit sharing, the CBD is not prescriptive about how it is to take place, except to say that it must be mutually agreed. By contrast, the TRIPs Agreement provides legal minimum standards that must be enacted in national law, with an enforcement mechanism and sanctions available for non-compliance under WTO rules. Each of the agreements can be implemented through specific implementing provisions.
10. Neither treaty specifies that it is subject to the other. The CBD and the TRIPs Agreement do not expressly refer to each other. Article 16(5) of the CBD however recognises that intellectual property rights, the subject matter of the TRIPs Agreement, “may have an influence on the implementation” of the CBD. It obliges states to cooperate in order to ensure that intellectual property rights are “supportive of and do not run counter to” the objectives of the CBD. At the same time Article 16(2) states that the technology transfer process is to be consistent with “the adequate and effective protection of intellectual property rights”. Thus, Article 16 of the CBD preserves the entitlements of intellectual property owners as they are defined in, inter alia, the TRIPs Agreement.
11. The TRIPs Agreement does not directly refer to the subject matter of the CBD. However, the preamble and Article 8 refer to principles such as developmental objectives, and Article 66.2 refers to transfer of technology.

12. According to the analysis of the EC/MS there is nothing in the provisions of either agreement that would prevent a state from fulfilling its obligations under both. The CBD, for example, does not prohibit patents on inventions using genetic material. In the same vein, the principle of state sovereignty over genetic resources in the CBD does not conflict with the TRIPs Agreement. The latter, in its turn, does not prevent signatories to the CBD from exercising their right to regulate access to their genetic resources, to require prior informed consent or to share in the benefits arising from their use. Although the TRIPs Agreement does not contain provisions on the protection of traditional knowledge, it does not prevent states from enacting a *sui generis* protection system for traditional knowledge.

II - The interaction between the CBD and the TRIPs Agreement

13. Despite their difference in coverage there is considerable *interaction* between the rights referred to in the TRIPs Agreement and the subject matter of the CBD. There is a range of issues upon which both agreements do have implications such as biotechnology, plant varieties, environmental technology relating to conservation and sustainable use, information relating to conservation and sustainable use, traditional knowledge and benefit sharing.
14. The main area of interconnection between intellectual property rights and biodiversity-related matters is to be found in section 5 of the TRIPs Agreement which deals with patents. It is clear that implementation of patent legislation may impact on the implementation of the CBD. In particular, to the extent to which an invention developed on the basis of a biological resource provides a valuable and practical means of exploiting that resource, the exercise of the rights in any patent granted on such an invention could have positive implications for benefit sharing.. This is the reason why Article 16.5 of the CBD requires Parties to ensure that intellectual property rights are supportive of and do not run counter to the objectives of the CBD. In this regard, we would like to confirm that the EC/MS are in favour of granting the CBD Secretariat ad hoc observer status in the TRIPs Council. In the same vein the EC/MS believe that enhanced cooperation between the WTO secretariat and the CBD secretariat would be very important in view of a mutually supportive implementation of both agreements.
15. The EC/MS believe that, from the point of view of their implementation, the TRIPs Agreement and the CBD should not undermine each other's objectives; they should, accordingly be implemented in a mutually supportive way. It should be remembered that the Conference of the Parties to the CBD of 15-26 May 2000 have called for "*case studies on the relationships between intellectual property and CBD objectives, including technology transfer and benefit-sharing with indigenous and local communities*". Sound empirical data about the actual use of intellectual property rights and the long run effects of that use on the objectives of the CBD would indeed be extremely helpful in further analysing interconnections between the CBD and the TRIPs Agreement.

16. In accordance with Decision 26 of the fifth Conference of the Parties (CoP V) to the CBD, on 5 February 2001 the EU submitted to the CBD Secretariat a paper on the relationship between Intellectual Property Rights (IPRs) and Biodiversity. The paper, which is annexed herewith, is not a statement of the EU position. However, it identifies in some detail the main aspects of the IPR/Biodiversity debate and is a first step towards shaping such a position. Intensive discussions on access and benefit-sharing took place under the CBD on 19-22 of March in Montreal in a Panel of Experts' meeting devoted to this issue. Further discussion will be held in the near future as the Panel will report to an Ad Hoc Open-ended Working Group which will meet in Bonn in October 2001. The Working Group has a broad mandate to develop guidelines or other approaches on virtually all aspects of the access and benefit-sharing issue. It can be expected that the relationship between IPRs and CBD will be one of the main elements to be discussed in the context of the broader debate on access and benefit-sharing. The EU and its Member States intend to co-operate actively in order for the above-mentioned Working Group to be able to develop guidelines or other approaches to be submitted to CoP VI in April 2002. The EC/MS attach great importance to this work and intend to participate actively in order for the above-mentioned Working Group to be able to develop guidelines or other approaches to be submitted to CoP VI in April 2002.
17. In themselves, the provisions of the TRIPs Agreement appear neutral in terms of their impact on the objectives of the CBD. Hence the TRIPs Agreement should not in practice undermine the achievement of the objectives of the CBD such as conservation, sustainable use, benefit sharing and protection of traditional knowledge. In its implementation the TRIPs Agreement can in fact be used to support the objectives of the CBD, such as the sharing of benefits (of e.g. knowledge obtained from research or income created by the exploitation of patented inventions). An important objective of the TRIPs Agreement is to promote effective and adequate protection of intellectual property rights, including by providing incentives to inventors through the provision of exclusive rights on a temporary basis. Intellectual property rights are instruments to ensure an adequate level of transparency and openness regarding all kinds of inventions, including those using genetic material. Without transparency, economic operators, research and development institutions and inventors cannot benefit from the knowledge which can be derived from the use of genetic material in innovative processes and activities. Innovative creations would be kept secret and non-available to the public because there would be no economic incitement to disclose them. This might lead to increased business secrecy and an anti-competitive contractual environment e.g. by increasing the use of secrecy agreements between commercial operators.
18. Furthermore, intellectual property rights, and in particular patents are instruments, but not the only ones, that can be used by providers of genetic material to obtain benefits from commercial operators who depend on genetic material to develop new products. Patents can be used as an instrument between the parties to agreements on access to genetic resources to secure remuneration to the provider country for the use of genetic resources on a long term basis. It should, in this context, be remembered that intellectual property is only one of many complicated aspects concerning access to genetic resources and benefit sharing.

19. Finally, the TRIPs Agreement leaves scope to WTO Members to determine the degree of exclusivity conferred by patents. Members remain free to provide for exclusions allowing utilisation of the product for research. The same applies to plant variety protection under UPOV 91 as regards the utilisation for further plant breeding and the farmers' privilege. In themselves, such provisions contribute to the sharing of benefits arising from innovation on (plant) genetic resources. This has been acknowledged in the ongoing negotiations for the revised FAO International Undertaking on Plant Genetic Resources.

III - Disclosure requirements

20. It has been argued by several Members within the context of the ongoing review that Article 27 of the TRIPs Agreement should incorporate requirements in the CBD concerning access authorisation from the government of the country providing a genetic resource used in an invention, prior informed consent, benefit sharing, protection of traditional knowledge and technology transfer. Proponents of this measure argued that this would ensure that source countries' laws on access and benefit sharing and on protection of traditional knowledge would be respected by patent applicants and would prevent abusive patenting of existing traditional knowledge by parties other than the holders of the traditional knowledge. This issue was also discussed in the Autumn of 2000 at the WIPO General Assembly, which agreed to establish a special Intergovernmental Committee to consider the relationship between intellectual property and genetic resources, as well as traditional knowledge and folklore. The first meeting of this Intergovernmental Committee will take place from 30 April to 5 May 2001.
21. In this context, it should be noted that intellectual property rights do not aim to regulate the access and use of genetic resources, to regulate the terms and conditions for bioprospecting or the commercialisation of IPR-protected goods and services. In the same vein, patent authorities are there to examine whether an invention meets the objective patentability criteria; they are not there to act as an enforcement agency for a third country's legislation on access to genetic resources.
22. Therefore, the EC does not favour incorporating into the TRIPs Agreement overly complex requirements which would oblige patent applicants to provide, in their patent application, an official certificate of the source and origin of the genetic material and the related traditional knowledge used, evidence of fair and equitable benefit sharing and evidence of prior informed consent from government or local communities for the exploitation of the subject matter of the patent. It should be borne in mind that the number of countries which have enacted legislation on access to genetic resources is still rather limited. Hence, only few countries are currently in a position to deliver such certificates. However, the EC/MS are open to examine possible effects of the patent system and look into different ways of how to positively support states in achieving the objectives of the CBD, in particular benefit sharing, while maintaining existing standards and level of intellectual property protection and not unduly increasing the burden on patent applicants and taking into account the outcome of the above-outlined negotiation process which is taking place in the framework of CBD. As already mentioned

above, further discussions on access and benefit-sharing will take place under the CBD.

23. In this respect, the EC/MS are prepared to engage in a positive manner in an attempt to agree, within the appropriate fora, on a multilateral system and/or other solutions for disclosing and sharing information about the geographical origin of biological material relied on in patent applications. Such discussions could also address the issue of a self-standing obligation for patent applicants to disclose the geographical origin of biological material relied on in patent applications. Once such a system or solution is in place, attention can then be focussed on how and to what extent it needs to be included in the TRIPs Agreement.
24. It should be stressed that such a system could never on its own be a satisfactory guarantee of the sharing of benefits arising from the use of genetic resources. In that perspective, the disclosure of origin should be considered as complementary to the main legal instrument in this respect, *i.e.* the enforcement of sound and effective *national legislation* in the countries providing genetic resources, laying down the conditions for access and benefit sharing and protection of traditional knowledge. In that respect, the EC/MS believe that national legislation on access to genetic resources and benefit sharing should provide for easily accessible and transparent application systems for access to genetic resources, including flexible procedures for prior informed consent; make sure that access and benefit sharing are granted on mutually agreed terms as provided by CBD; and be in conformity with the WTO obligations and other international undertakings.
25. The ability of EC/MS to effectively address the issue of disclosure of origin would depend in practice on the existence of sound access legislation. The EC/MS are aware that many developing country Members may require assistance to build their capacity to put in place and implement appropriate and effective legislation. The EC/MS are, if requested, prepared to provide such assistance.

IV - Protection of traditional knowledge

26. Article 8(j) of the CBD encourages signatories to protect traditional knowledge. Article 8(j) does not provide a ready-to-use framework but is open-ended about the means that states might employ for the protection of such knowledge. As said above, nothing in the TRIPs Agreement prevents the WTO Members from setting up a protection regime, either by applying their existing intellectual property regimes to indigenous knowledge (to the extent that such regimes are adequate to that effect) or through the enactment of a specific model of protection effectively regulating and enforcing access to, protection of, and reward for the use of traditional knowledge.

27. The EC/MS therefore support the development of an international model for the legal protection of traditional knowledge. The EC/MS believe that a broader scope of protection including elements of particular interest to developing countries, and in particular traditional knowledge, would improve confidence in the international IP system. It is hoped that the new WIPO Intergovernmental Committee referred to above will take up this issue, in close co-operation with the CBD and this Council. Once a model is in place, attention can then be focussed on how and to what extent the protection of traditional knowledge can be included in the TRIPs Agreement.
28. Meanwhile, it should be examined how to make more information available on traditional knowledge to patent offices (through databases or registration) so as to allow patent examiners to take them into account as prior art, in order to reduce the risk of abusive patents.
29. It should be kept in mind that except for certain cases, traditional knowledge can, in itself, not be patented, because it usually does not respond to the basic criteria of patentability. Were parties other than traditional knowledge holders to obtain patent protection for traditional knowledge, the patent should be cancelled. The situation is different when traditional knowledge is used as a basis for further innovations. In such case, these innovations, where they meet the relevant criteria, are perfectly patentable. The existence of a patent would however not override accompanying national requirements to obtain authorisation from the owners of the traditional knowledge from which the invention is derived and to reward them for the use of it or share the benefits of its use.
30. In the context of traditional knowledge, the EC/MS would also like to point out the complementary role that can be played by geographical indications in protecting traditional products under certain circumstances. It may also be useful to examine their possible role in achieving other goals of the CBD. The latter recognises the existence of geographically defined areas that are regulated to achieve conservation objectives (see the definition of “protected area” in Article 1). Products originating from such areas may perhaps also be identified as geographical indications, if producers decided to link their collective production standards and related traditional knowledge to conservation goals.

V - Conclusion

31. The EC/MS stand ready to consider any difficulty WTO members may meet with regard to the relationship between the TRIPs Agreement and CBD relating to the practical implementation of the two. The EC/MS are of the opinion that the search for solutions to the developing countries’ concerns expressed within the context of the review of Article 27.3(b) of TRIPs does not necessarily lie within the scope of that Article itself, but may rather be found:

32. 1) in developing appropriate international instruments to achieve the objectives of the CBD (in particular access to genetic resources, benefit sharing and protection of traditional knowledge) and those objectives of the TRIPs Agreement which, in the view of the developing countries, have not sufficiently been promoted by the industrialised countries (*i.e.* transfer of technology and know how);
33. 2) in providing technical assistance to developing countries to implement the CBD through sound and effective internal legislation; and
34. 3) through the possible negotiation of measures within the IPR system (in particular in the context of WIPO and, where and when relevant, the TRIPs Agreement) aimed at facilitating benefit sharing and protecting sovereign access rights (e.g. to insert a provision on the disclosure of origin or to develop protection of traditional knowledge).
35. Therefore, while the EC/MS remain prepared to participate constructively and in a positive manner in the discussion on the relationship between the TRIPs and the Convention on Biological Biodiversity within the TRIPs Council, they believe that the review of Article 27.3(b) may not be a vehicle capable of producing definitive solutions to all the issues raised in this context. Further progress can however be made on the basis of Article 71.1 of the TRIPs Agreement, in WIPO, in the CBD, the FAO or in the context of a new round of multilateral trade negotiations in the WTO. It goes without saying that work pursued in other bodies referred to should be closely followed by the TRIPs Council.

[End of Annex III, Annex IV follows]



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A - General and international affairs
ENV.A.4 - Development and environment



*The Swedish
Presidency*

eu2001.se

Brussels, 2 February 2001

Subject: Intellectual property rights and access to genetic resources and the sharing of benefits arising from their use

Dear Mr. Zedan,

In response to your request on the basis of Decision V/26, paragraph 15 a), please find here attached an EU paper on the relationship between intellectual property rights (IPRs) and access to genetic resources and benefit-sharing. This paper seeks to factually analyse the situation and is not a formal statement of the views of the EU.

Work on access and benefit sharing has implications for, and should contribute to, the conservation and sustainable use of biological diversity. Moreover, intellectual property implications are only one aspect of access and benefit sharing requiring attention under the Biodiversity Convention.

Nevertheless, the EU attaches great importance to the complex relationship between IPRs and access and benefit-sharing. There are many different types of benefit and processes by which genetic resources may deliver benefits in different economic and scientific sectors. There are different types of end products and of IPRs that may be applied to those products. The link between the original genetic resource and the end product can be simple, complex, direct or indirect. IPRs are a crucial incentive for the creation of some type of benefits. They are not, as such, the mechanisms to share benefits resulting from the use of the original genetic resource. They provide the incentive for private companies to invest in the creation and development of new products and processes, without which such investment and the resultant benefits would be significantly lower.

Further work on access and benefit-sharing in the Ad Hoc Open-Ended Working Group should take full account of relevant work in other fora, in particular:

- the negotiations being conducted in the FAO to revise the International Undertaking on Plant Genetic Resources for Food and Agriculture;
- relevant work in WIPO, in particular the WIPO Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; and
- relevant work which is or may be undertaken in OECD, WTO and UPOV.

With regard to decision V/26 in relation to the development of guidelines and other approaches, it might be useful to address the issue under the three following categories.

1) Protection of Traditional Knowledge

- the definition of “traditional knowledge”;
- the relevance of the concept of ownership for the protection of traditional knowledge;
- the level (individual, collective or common) at which such rights could be established;
- the extent to which existing intellectual property rights are able to meet the objective of protecting such knowledge;

2) Scope of the Protection Afforded by IPRs to Inventions Using Genetic Resources

- the impact of IPRs on use of the genetic resources employed to generate the protected innovation;
- the possibility and the extent of any limitations to the protection afforded by IPRs;

3) IPRs as an Instrument for the Implementation of Article 15.7 of the CBD

- the role of IPRs as a possible economic incentive for benefit-sharing, e.g. through agreements between providers and users of genetic resources; and/or national procedures or legislation on IPRs and access to genetic resources;
- the role of IPRs as a means for verifying compliance with the provisions of the CBD, in particular with regard to :
 - prior informed consent;
 - mutually agreed terms.

Yours sincerely

Linda Hedlund
Ministry of Environment, Sweden

Christoph Bail
European Commission

RELATIONSHIP BETWEEN IPRs AND ACCESS TO GENETIC RESOURCES AND SHARING OF BENEFITS ARISING FROM THEIR USE

1. Economical, legal and institutional context

1.1 Use and benefits

The complexity of access to genetic resources (plant, animal or microbial) and of the sharing of benefits that arise from their use is widely recognised. This is due to a number of factors.

First, the benefits arising from the use of genetic resources are diverse, including benefits for a) science, research, education and training; b) food, agriculture, fisheries and forestry; and c) industrial purposes, including pharmaceuticals. Some benefits are already being shared, independently from the provisions of the CBD, for example, the results of scientific research are usually published through scientific journals or through the description of innovations required when filing for intellectual property rights.

Second, the processes through which the use of genetic resources generate benefits are also very diverse. Such processes differ for plant, animal or microbial genetic resources due to their different biological features. It is important to remember that unless commercialised in its original state benefits are not generated by the genetic resource itself, nor by the IPR itself. Benefits are generated by a succession of stakeholders and activities which identify the features of the genetic resource and an associated industrial application. Where an innovative process or product is defined, an application for protection by an IPR can be made. This would be followed by production, distribution and commercialisation before the end product can be marketed.

Third, the end product can be living (e.g. a plant variety) or non-living (e.g. a pharmaceutical product) biological material. It can be scientific or technical information. Several intellectual property protection objects, such as a gene, a variety or a process, can contribute to the end product. Intellectual property protection can take different forms which, subject to the legal system of the country in which protection is sought, can be patents, protected varieties, geographical indications etc. Intellectual protection can involve the material itself and/or an associated technology for identifying or using the material and/or scientific knowledge.

Lastly, the link between the end product and the genetic resource is not always direct or exclusive. Different categories of industrial products and processes can require a single or several genetic resources, a single or repetitive contribution of the genetic resource and, in some cases, recourse to synthetic substitutes for the genetic resource. The arrangements for the sharing of benefits must take account of these complexities, and define as a first step the respective rights and investments of the stakeholders involved with regard to the utilisation/ use of genetic resources.

1.2 Access

In the context of the CBD, IPRs are often mentioned as a possible means for achieving the objectives of Article 15. However, IPRs, particularly patents, were not designed to regulate access to genetic resources or to regulate the conditions for bioprospecting although they may have an influence on access and benefit sharing arrangements as recognised in Article 16.5. The CBD makes clear that these are matters for national legislation.

IPRs, particularly patents and plant variety rights, are a crucial incentive for the creation of some types of benefits. They are not, as such, the mechanisms to share benefits. Without such an incentive, private investment in the creation of new products or processes from genetic resources would be significantly lower, with a consequent reduction in the creation of benefits that could be shared.

A patent provides a negative, time-limited right, allowing the holder to prevent commercial use of his invention without his permission. A patent is not a licence for the right-holder to exploit his invention, since any such exploitation must comply with the conditions laid down in other relevant legislation. A patent cannot be obtained on a mere discovery, even if an invention could be developed on the basis of natural biological materials. The granting of a patent is subject to strict criteria of novelty, inventiveness and industrial application.

Specific legislation or other solutions have a role to play in access and benefit-sharing arrangements. These can include upstream measures (research inconsistent with ethics, access to genetic resources) and downstream measures (conditions for the marketing of products from research in biotechnology, sharing of benefits from the use of genetic resources) so that IPRs are not detrimental to individuals, local and

indigenous communities, or to the entire country of origin of the biological resources used in the protected innovation. The development of national, regional or global solutions aimed at fulfilling the objectives of the CBD needs to take account of relevant existing legislation, particularly that in fields related to the objectives of the CBD.

The complexity of the relationship between genetic resources, generated benefits and IPRs warrants an in-depth study, which should consider the scope of the different situations, in preparation for the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing. This study should help in the design of a framework for solutions enabling the fair and equitable sharing of benefits arising from the use of genetic resources among all stakeholders involved in the various processes, particularly those that have ensured the conservation and availability of genetic resources.

This preparatory work should take full account of relevant work in other fora, as recognized by decision V/26, in particular:

- the negotiations being conducted in the FAO to revise the International Undertaking on Plant Genetic Resources for Food and Agriculture, which are based on the principle of a multilateral approach to access and benefit-sharing, consistent with the IPRs relevant to this area (especially on plant varieties), the rights of farmers and the provisions on benefit-sharing in the CBD; and
- work which is or may be undertaken in WIPO (including the WIPO Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore), OECD, WTO and UPOV following the invitation of COP V to relevant international organisations to analyse the issue of IPRs in relation to access and benefit-sharing, and to take into account the relevant CBD provisions in their work on IPRs.

With regard to Decision V/26 in relation to the development of guidelines and other approaches, it may be useful to consider the following issues.

2. Main issues in the debate

2.1 Intellectual Property Rights and the Protection of Traditional Knowledge

Most existing IPR systems, in their present form, are not geared to the protection of all the various aspects of traditional knowledge.

To properly analyse this issue it is first important to try to establish a legal definition for “traditional knowledge” which takes into account the potential dangers of freezing what are often evolutionary practices within a legal framework. Second, it needs to be determined whether such rights should be established at the individual, collective or common level. Third, the extent to which existing IPRs (patents, plant varieties, geographical indications, copyright, industrial designs, trademarks and the protection of confidential information) are able to meet the objectives of protecting traditional knowledge could be studied, together with the possibility of establishing new *sui generis* types of property rights.

Finally, it is important to clarify how the granting of an IPR to a third person may affect local communities and indigenous populations, directly or indirectly, in continuing to apply their historical and customary practices.

2.2 Scope of the Protection Afforded by IPRs to Inventions using Genetic Resources

Previous documents elaborated within the CBD have identified a number of issues relating to patents. However, it is important also to fully consider other forms of protection including, in particular, plant breeder’s rights and geographical indications. It is suggested that study of the following issues, which are not intended to be exclusive, might help clarify the debate:

- Impact of IPRs on the use of the genetic resource employed in the development of the protected innovation, particularly traditional uses of the genetic resource.
- Limitations on the protection afforded by an IPR. Some existing IPR legislation provides for such limitations, for example provisions which allow free use of patented products and processes for research (the “research exemption”) and for self-sufficiency purposes (the “farmer’s privilege”). Within the CBD, some have argued that such limitations should be extended, for example by granting

compulsory licences under favourable or preferential terms to the country or community which supplied the genetic resource, or for biodiversity conservation purposes.

2.3 IPRs as an Instrument for the Implementation of Article 15.7 of the CBD

Within the CBD some delegations have tended to view IPRs as:

- a possible economic incentive. It has been suggested that the filing or granting of an IPR could be used as a trigger for benefit-sharing (through an undertaking by the developer of a genetic resource to pay or negotiate royalties if the resultant product is protected by an IPR; through the joint ownership of the IPR; or through fees). Such a mechanism could be implemented through:
 - agreements between providers and developers of genetic resources (e.g. between partners in research programmes);
 - national procedures or legislation on IPRs or on access to genetic resources.
- a legal instrument for the verification of compliance with the CBD on:
 - Prior informed consent. It has been suggested that proof of prior informed consent should be a condition of granting an IPR. Evidence of prior informed consent could also be provided by means of an information system. Other options could also be studied.
 - Mutually agreed terms. Non-compliance could be punished through the cancelling of any related IPR, civil action for damages or criminal proceedings. Other options could also be studied.