Anja von Hahn (ed.)

Implementing the Convention on Biological Diversity

Analysis of the Links to Intellectual Property and the International System for the Protection of Intellectual Property

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Analysis of the Links to Intellectual Property and the International System for the Protection of Intellectual Property

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and

Collection of Relevant Materials

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Contents

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Intellectual property issues play an important and controversial role in the international debate on the protection and sustainable use of biological diversity, on the corresponding agreement – the Convention on Biological Diversity (CBD) – and on its further implementation. The following overview will establish the relationship between these issues and will discuss the possible future role of intellectual property rights in the further implementation of the CBD, using the relationship as a background for the discussion.

The overview is based on the assumption that the Convention links biological diversity, genetic resources, knowledge and technology and at the same times gives these issues a certain order. It first briefly points towards their characteristics from an economic point of view, then deals with the basic mechanisms for assigning assets in public international law (I). Due to the great significance of intellectual property for the understanding of the analysis, its legal and economic basis are outlined (II). Then the overview turns to the manner in which the CBD orders these different assets and assigns them (III). From this starting point the possible connection between the goals and ideas of the CBD and intellectual property rights is considered on the basis of the international debate. The potential for mutual supplementation and possible fields of conflict as well as suggestions with regard to the patent application process are examined (IV).

Over and above such connections and proposals, the intensity of the international debate on intellectual property rights in the CBD points to tensions in the international economic relationships caused by developments in the field of biotechnology. There was a strong awareness of these tensions when the CBD was negotiated and concluded, and the CBD takes into account many of the controversial issues; hence, the CBD strives to share the benefits of using genetic resources in a balanced and just manner. Therefore, it is further explored how the CBD might contribute to solving the conflicts, subject to the specialized powers of the WTO and WIPO, the competent international organisations (V). This is followed by final conclusions and recommendations (VI).

I. Assets and Concepts of Public International Law

As an international agreement, the CBD establishes a connection between biological diversity, genetic resources, knowledge and technology and gives these topics a certain order, while at the same time recurring to known structures of public international law. Before turning to the links established, these main assets – biological diversity, genetic resources, knowledge and technology – and in particular their characteristics and economic structures will be examined. Following this examination, the overview will look at the basis in public international law for determining who owns and may use goods.

A. Biological Diversity and Genetic Resources

As defined in Art. 2 CBD, **biological diversity** comprises the variety of living organisms, no matter what their origin, and the diversity within a species and between the species, as well as the diversity of ecological systems. From an economic point of view, biodiversity contributes in two different ways: as part of the ecological system and as a resource. From what we know today, in most cases it is not possible to assess the market value of the eco-system contributions.

By **genetic resources**, the CBD means "genetic material of actual or potential value". Genetic material is "any material of plant, animal, microbial or other origin containing functional units of heredity". The main achievement of genetic resources is to store information. They have the character of a public asset insofar as they cannot be used up. Factually, others may only be excluded from using the information if one person attains full control over the material which contains the information.

In the international debate, a **link** is often created between the conservation of biological diversity and the utilization of genetic resources – or rather the sharing of the income from their fair and equitable utilisation. This link is based on the idea that assigning rights to genetic resources may create incentives to preserve these resources. In favour of this point of view is the fact that genetic resources are a contribution made by biodiversity and it is generally possible to own them, because it is at least theoretically possible to bar others from using them. To this end, the CBD rightly confirms national sovereignty over the different biological and genetic resources.

The right to genetic resources can only help conserve biological diversity if it allows the generation of sufficient financial means to cover the costs of this conservation. There are two reasons why this is unlikely to be achieved: Firstly, revenues can only be expected after lengthy and risky R&D-processes. Secondly, many species, genotypes, biochemical substances and genes occur on the territory of more than one state. This leads to competition between the different providers which cannot even be offset effectively by creating cartels.

In any case, the implementation of the right to the resource will be accompanied by substantial transaction costs. Finally, it should be noted that there is no obligation whatsoever to use funds acquired by providing genetic material to conserve biological diversity.

B. Knowledge and Technology

Alongside biological diversity and genetic resources, knowledge and technology play a major role in the relationship between questions of intellectual property and the broad implementation of the CBD. These issues are not defined in the Convention, but are referred to in various ways.

Knowledge is any form of structured and systematic, or understood, information. Any possible use or value given to knowledge by individuals, groups or societies today or in the future is irrelevant for the definition of the term "knowledge". Nor does knowledge have to be related to any particular application. By contrast, **technology**, in the sense of a "technical doctrine", is knowledge which states how to solve a particular technical problem. The defining purpose is decisive: technology can be viewed as the knowledge that describes the measures and actions necessary to reach a certain goal. The terms knowledge and technology are not restricted to the perceptions of them generally current in an industrial society. They also comprise "innovations, knowledge and practices" of indigenous and local communities, as stated in Art. 8 lit. j of the CBD, for which the term "traditional knowledge" is commonly used. From a matter-of-fact point of view, however, it might be better to use the term "indigenous technology", because at least part of the group's knowledge does have practical relevance or a potential practical application, as the demand for this knowledge demonstrates.

C. Public International Law as a Basis for Determining the Allocation of Goods

The international system is an order of equal states. These states all claim to have a right to settle their own affairs. To create their own legal, social and economic structures is as much part of these affairs as the treatment of the terrestrial and marine environment within the sovereign territory of each state. This power to create and freely dispose, which is both absolute and not subject to any higher authority, is called sovereignty. The international order thus outlined has evolved significantly since the Second World War. Especially significant in this context are the developments which can be described as an international order governing the allocation of goods. This order comprises both **elements of a national allocation of certain assets** and **structures of a mutual disposal** and use.

D. The Sovereign Right over Natural Resources

Rights of the single states to their resources play an important role for the link between the rights to intellectual property and the further implementation of the CBD. These rights of the single states are the basis for the idea of a sovereign right to genetic resources as referred to in Art. 16 para. 1 of the CBD. There are different ideas and demands concerning the formulation of this right which are linked to the term "continuing sovereignty over natural resources". In essence, they relate to the states' right to **freely regulate how their natural resources are exploited**. The development of appropriate economic processes, amongst others questions of developing licensing mechanisms, of levying duties, and specifically of controlling foreign influences over the exploitation of resources, is part of this right.

As well as the right to guide the relevant economic processes in a beneficial way by means of regulations, the demands which pertain to the principle of continuous sovereignty over national resources additionally **obligate** the purchaser or **user states** to put the resource

states in a position to exploit their resources in a manner beneficial to them. Besides a claim against user states – usually western industrial states – to tolerate the sovereign regulation of economic relations by resource states, and not to take detrimental measures or countermeasures, it has often been demanded that western industrialised states should assist other states in their efforts to take the utilization and exploitation of resources into their own hands through different **cooperation** measures. To this extent, an obligation to grant **technological aid** and to **transfer technology** was created.

In international environmental law, one often comes across the statement that states are responsible for ensuring that activities within their sovereign territory do not harm the environment of other states or of areas outside any state's sovereignty. But at the same time, it is pointed out that **international obligations** concerning the environment are subject to the **reservation** that states have full sovereignty over their natural resources. This national right to resources is often linked to each state's right to development.

E. Models for Mutual Utilization

The allocation of assets or resources to different states is, however, only one aspect in the international order of assets. Besides this, there are **different ways in which states jointly exploit and use natural resources.** The term **common heritage of mankind**, which has been used in different contexts (Antarctica, outer space, deep sea bed), stands for the most well-known form of power, exercised jointly by different states, to exploit and use resources. These different approaches to a joint exploitation and use of certain assets and goods have also shaped developments in international environmental law, which at its first stage of development was based on the belief that it was every state's own affair how it used its own resources. Consequentially, international environmental law merely regulated those manifest conflicts arising out of certain uses which had transboundary effects.

Once the international community became aware not only of the transboundary implications of impediments and pollution of the environment, but also of their regional and global implications, many different kinds of regulations were developed. In these regulations there is an understanding, that **certain environmental components** exist which constitute **common international assets**. These regulations therefore provide preventive steps to jointly and systematically conserve the environment and take fair distribution aspects into account by requiring different contributions from each state.

F. Science and Technology in Public International Law

Modern public international law also addresses science and technology. They are seen as major factors in the **economic and social development**. Rules governing economic cooperation in the sense of technical aid are a fixed part of the multilateral treaties, although their legal content is still subject to some discussion. Technology transfer, by means of which commercially relevant technologies should be transferred from industrialised states to developing countries, has taken a place next to the classical instrument of development or technological aid. It is assumed that this transfer should be completed by means of the private economy and that industrialised countries should take it as their responsibility either to create favourable conditions for this transfer or to raise the incentives for private actors to transfer technology by granting them monetary advantages. The question of how to develop

technology rights so that they benefit developing states is also closely connected to these issues.

Science and technology also play an important role in the developing international environmental order. Scientific findings and research are needed in order to acquire a better understanding of the positive and negative ecological effects of certain environmental assets and to base political decisions on these findings. Therefore, a growing number of international environmental documents contain detailed provisions about scientific cooperation between states. But in addition to these developments, technological cooperation and technology transfer are playing an increasing role in international environmental law.

II. Intellectual Property: Legal Construction and Economics of Intellectual Property Rights

Because of the connection between intellectual property rights and the further implementation of the CBD, **important foundations** for the intellectual property rights are briefly presented, especially the prerequisites for and scope of patent protection, including the protection of specific biotechnological inventions, plant variety and trademark protection, as well as the protection of geographic indications and of trade secrets.

Depending on their prerequisites and scope of protection, the different intellectual property rights refer to different objects. They only partially protect "knowledge" and "technology". It is evident that there are **two ways to legally assign knowledge and technology**: On the one hand, proprietal rights to knowledge and technology can be acquired. On the other hand, private individuals are barred from acquiring any form of ownership right to knowledge and technology which is already publicly known. Therefore, the legal order establishing intellectual property rights indirectly protects this kind of public knowledge in the public interest. This area of free, non-acquirable knowledge is often called "public domain".

Intellectual property rights are granted by national legal systems. It is only within the area of these national legal systems that intellectual property rights are valid. **The international regime governing the protection of intellectual property** rights, with its different agreements under the WIPO, mainly provides for minimum standards to guarantee a certain degree of protection and, for example, the coordination of the patent application processes for national patents.

The conclusion of the Agreement on Trade-related Aspects of Intellectual Property Rights (**TRIPs-Agreement**) within the framework of the WTO is a further important step forward in the international system of intellectual property rights protection. It contains newer, more strict standards of patent protection in the WTO Member States. These new rules have removed many of the suspension possibilities concerning agriculture, food and medicine which states formerly had under the Paris Convention.

In this context, **Art. 27** of the TRIPs-Agreement, which in its para. 1 determines that **patents** should generally be available on all sectors of technology and only provides for very narrow exceptions, mostly concerning **biotechnology**, in its para. 3, is particularly noteworthy. However, if both paragraphs are taken together, it becomes evident, that it must in principle be possible to patent biotechnological inventions in the same way that it is possible to patent inventions in other areas (Art. 27 para. 1).

The Member States may, however, exclude patent protection for "diagnostic, therapeutically and surgical methods of treatment for humans or animals" (Art. 27 para. 3 lit. a TRIPs) or for "plants and animals" as such. Concerning patents on scientific methods, it is mainly biological methods of plant cultivation or animal breeding that may be excluded; conversely, non-biological and microbiological processes are to be granted patent protection (Art. 27 para. 3 lit. b TRIPs). As an exception to the exception in Art. 27 para. 3 lit. b TRIPs, Member States must ensure that plant species are adequately protected, either through patents, or by implementing an effective **sui generis** system, or by combining the two alternatives. In intellectual property law, "*sui generis* rights" are commonly understood to be

those specific forms of protection which exist beside the known categories of patent, copyright and trademark law.

This regulation clearly contradicts the previous law of many states, in particular of developing states. With a view to the far-reaching and extensive transformation methods which TRIPs has made necessary in many states, different deadlines for implementation have been granted to different categories of states.

In addition, Art. 27 para. 3 lit. b, sentence 2 TRIPs-Agreement, provides for a specific review mechanism. This mechanism is not to be misunderstood as being a revision process. The main objective of the review is to make sure that the provisions of Art. 27 para. 3 lit. b have been put into effect. In contrast to a frequently expressed view, the review is limited to a scrutiny of these regulations. Therefore, according to its meaning and purpose, the review mechanism does not include any further issues, not even the protection of traditional knowledge. The TRIPs Council initiated a review process in December 1998. After the Member States had been asked to submit certain information, consultations took place in the TRIPs Council in 1999. In view of the Conference of Ministers in Seattle in November 1999, the consultations were not continued and have not made any significant progress since. It is interesting to note that while the review mechanism in Art. 27 para. 3 lit. b TRIPs is limited, as outlined, it does not bar any further initiatives to discuss other possible forms of intellectual property rights in the framework of the WTO and its competent organs or to initiate negotiations under other provisions.

Intellectual property rights limit the society's use of assets which could under normal circumstances be used by any individual, thereby offsetting the advantage that every individual gains through that asset. When the right in question is a patent which protects technology, the **incentive** due to the prospect of gaining a **competitive advantage** – the exclusive right to use this technology – is used to justify the granting of this patent.

III. The Order of Assets in the CBD

The assets (biological diversity, genetic resources, knowledge and technology), which were discussed in detail above, are all addressed in the CBD. The Convention contains rules about access, utilization, conservation and cooperation, which can be understood as a means of allocating assets.

A. Lines of Development

These rules and the CBD as a whole are the result of a consultation process during which the concept and objective of the Convention were changed and broadened numerous times. At first, the plan was to create a comprehensive treaty containing special rules of public international law concerning the protection of species and areas. But soon, the consultations and the treaty included questions of biological diversity and biotechnology.

The CBD refers to this notion of international and common goods in its Preamble, where it declares that "the conservation of biological diversity is a **common concern of humankind**". But under closer scrutiny, this statement is a lot less far-reaching than similar provisions under other international environmental regimes. This narrower meaning is already expressed in the wording of the treaty which instead of using broad terms, such as "heritage" or "good", uses the narrower term "concern". The narrow meaning becomes even more obvious through the limitation in scope to the „conservation" of biodiversity.

Moreover, the CBD creates a **link** between the idea of protection and **sustainable development** by addressing not only the conservation of biological diversity, but also the **sustainable use** of **biologica**l and specifically of **genetic** resources. In addition to the very general and basic link of these two terms in the provision that determines the purpose of the Convention (Art. 1) and in the general provisions on sustainable development (Art. 10) and incentives (Art. 11), there is also a special provision in Art. 8 lit. j. which aims to respect, preserve and maintain local and indigenous ways of cultivation because of their importance for the conservation and sustainable use of biodiversity.

Unlike a classical ownership right would, the Convention does not assign biological diversity as a whole to a certain owner. Instead, it imposes certain conservational duties. But the Convention does provide that **states should assign** certain **components** of biodiversity, partly called "resources", to individual owners. There is a corresponding provision for **biological resources** in para. 4 of the Preamble.

The **genetic resources**, which, under the aforementioned definition in the Convention, are also components of biological diversity, are of a far greater importance than biological resources. In view of genetic resources, the CBD **refers** to the **general public international law principle** of sovereignty over national resources in its Art. 15. The CBD then names extensive rules which serve the objective laid out in Art. 1 CBD, which is defined as follows:

> "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate

transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

These goals are mainly to be found in Art. 15 to 19 of the CBD.

According to the ordinary meaning of their wording, the diverse orders, claims and duties address States. And, they indeed only directly address States, dealing with means and instruments of cooperation between States. But in addition, they also include the **shape** that the **relevant transactions between private actors** must take and therefore indirectly address these private actors.

B. The Rights of Indigenous and Local Populations to Their Traditional Knowledge

The CBD not only refers to biological diversity in its entirety and to biological and genetic resources as parts of it, but also to **knowledge** and **technology**. In this context, traditional knowledge has an important meaning. It addresses different entitled persons. So far, only states and their rights to freely dispose of the assets described have been looked at. But in the area of traditional knowledge, the rights of certain groups of **ingenious and local communities** are in dispute. Therefore, Art. 8 lit. j CBD is also significant because the CBD takes up more general international developments towards strengthening the rights of indigenous peoples in this provision.

In the terms of classical allocations of goods, Art. 8 lit. j CBD indirectly exclaims that indigenous or local communities **should have the right to decide what to do with their knowledge**. This follows from the statement that the use of traditional knowledge should only occur "with the approval and involvement of the holders of such knowledge". But this provision does not contain an actual ownership right to knowledge.

Initially, traditional and social observations and findings – not only those of indigenous groups – were customarily **inquired into, evaluated, collected, published and commercialised industrially and economically** without paying any obvious attention to the ideas and expectations of the affected groups.

Indigenous and local communities have mainly put forward **two demands**: Firstly, their claim to dispose freely over their knowledge must be guaranteed by only granting limited access to this knowledge. Secondly, the freedom of the traditional knowledge and its status as a common good accessible to the general public must be ensured. Therefore, third parties must be barred from acquiring exclusive ownership rights to this knowledge.

C. Technology, Transfer of Technology and Intellectual Property

The CBD addresses **technology** in the special provision of Art. 8 lit. j CBD. But it also refers to technology in a more general sense in Art. 16. This provision regulates the transfer of technology. In general, it does not regulate who may exercise ownership rights to technology, but instead governs the circumstances under which the transfer of technology should take place. For the meantime, the existence of the system of disposal of technology will be assumed. But Art. 16 CBD does not only contain rules governing what kind of

technology should be transferred, what the conditions for this transfer are to be and to who's benefit the transfer should take place. Art. 16 para. 5 also contains a ruling according to which "patents and other intellectual property rights **may have an influence on the implementation** of this Convention ...", and according to which Contracting Parties "shall cooperate in this regard ... in order to ensure that such rights are supportive of and do not run counter to its objectives." Therefore, the provision obviously applies not only to questions concerning the transfer of technology referred to in Art. 16, but is broader in scope, although the exact content of the provision remains disputed. In recent times, a clear tendency, which views the provision as an order to States to examine thoroughly or to cooperate, has emerged. This order affects the relationship between the protection of intellectual property and the goals of the CBD as a whole. To this effect, the organs of the CBD, and especially its Conference of the Parties, have comprehensively addressed questions of intellectual property with reference to said provision.

D. National implementation

The different approaches for creating an order, which were just discussed above, are only vaguely outlined in the CBD. This order must be given further shape by the national states. This does not only result from the fact that each state, due to its full sovereignty over national resources, has the right to autonomously determine the exact context and scope of these rights. Previous efforts in this field have focused on questions concerning access and on questions concerning the protection of indigenous knowledge.

Currently, there are especially two regulations which are subject to intense debates at the international level: Decision 391 of the Andean Community to create a joint system of access to genetic resources and Philippines Executive Order No. 247.

IV. Conclusions I: The CBD and the Intellectual Property System: Potential for Conflict or Possible Harmonization?

Having given an outline of the system of intellectual property rights and the foundations for the international order within the CBD, it is now time to discuss the relationship between these two regimes. The current discussion about the role of intellectual property and the TRIPs-Agreement in connection with the goals of the CBD was already anticipated in Art. 16 para. 5 of the CBD.

The provision therefore assumes that these issues are in some way related and that this relationship is based on the attempt to support the goals of the CBD by means of the intellectual property rights regime. But the provision also envisages possible contrary developments and obligates the Contracting Parties to act according to a principle of cooperation.

A. Genetic Resources and Intellectual Property Rights

1. Completion – Collision – Devaluation ?

When looking at the use of genetic resources and how their benefits are shared in accordance with Art. 1 CBD, one might at first conclude that patents on results of the use of genetic resources, for example new pharmaceutical products, which should ensure benefits, meaning profits, are necessary for creating these benefits and therefore have a **supportive function**. Moreover, they create incentives to innovate and thus to use genetic resources.

But when examining whether intellectual property rights conflict with the rights to genetic resources one must nonetheless take into consideration what intellectual property rights actually aim to protect. One indication for such a conflict of intellectual property rights and genetic resources rights is the fact that, while from an economic point of view genetic information is the essential component of genetic resources, patents and plant breeders' rights protect other related knowledge, i.e. technology. However, the patent right, unlike protection methods for discoveries, does not protect genetic information derived from the material itself, but instead only protects a commercial application which is based on this genetic information and has been described. Therefore, **there is no direct legal collision**.

Genetic information and the protection of plant varieties stand a lot closer to each other. However, third persons may explore the genetic information contained in the material and use it freely for any purpose other than reproduction. Conversely, the States in which the original material was found may still grant further access to the material.

However, the statement that there is only a very limited potential for possible direct legal clashes does not fully answer the question whether there generally are conflicts. In other constellations and beyond the area of direct legal collisions, one must examine the **effectiveness and assertiveness of the rights**. In this context, it is of some significance that intellectual property rights can be secured and asserted globally, though in practice this is

may entail huge efforts and hold little promise for effective protection. Despite all difficulties in the legal practise, this clearly sets the assertiveness of intellectual property rights apart from the assertiveness of the ownership rights over genetic resources. These are even difficult to implement in fact because the amount of basic material can be minuscule, and the prospecting and transmission procedures are not always easy to perceive. Furthermore, within the scope of regulations concerning access, ownership rights can only be asserted on the territory of the resource state.

It is only possible to take civil or criminal actions against uses and commercializations of genetic resources which were unlawfully acquired or which took place abroad. The prospects of such actions are rather slim. Unlike the situation for the real owner of an intellectual property right, who could normally rely on some form of legal protection against unauthorized use of his property, ownership of a resource right does not entitle the owner to any form of patent or trademark protection. Neither a state's sovereign right to genetic resources, nor an ownership position derived from an access granted by a resource state constitutes a form of legitimization in the above sense. Therefore, the owners of resource rights cannot make any of the aforementioned claims.

2. Proof of Origin or Access in the Patent Application Process?

For the purpose of supporting the aims of the CBD, there has been a discussion on whether **data concerning the origin** of the basic materials which underlie an invention should be requested in the **patent application process** in order to achieve a better level of protection for rights to genetic resources. This information on the origin and subsequent publication of this information might improve the control over the use and results of genetic resources.

Such a requirement to state the origin of used genetic materials in the patent application process has been discussed within different **organs of the WIPO** and of the **WTO**. Recently, a **very weak version** of this concept has also turned up in **decisions of the CBD organs**.

It has also been addressed in **Directive 98/44/EG** concerning the legal protection of biotechnological inventions. But because the requirement was only mentioned in a recital of the Directive, and due to the ordinary meaning of the wording of the Directive – with a special emphasis on the term "should" – the requirement is **not a legally binding obligation**. Besides, it has been stated *expressis verbis* that this requirement will have no effect on the review of patent applications and the rights flowing from such patents.

Decision 391 of the Andean Pact provides for a **stricter regulation**: Patent authorities may act on specific evidence and demand that a copy of the access agreement underlying the use of genetic material for the invention in question must be handed out to them. The handing out of the contract is a condition for the granting of a patent right.

There are **different ways of shaping** such a requirement to provide information. The different possibilities concern the content of such a requirement, procedural steps and effects and, above all, a possible examination. In all, two options seem feasible: to demand evidence of the origin of the genetic material used (**proof option**) or to simply publish such information (**publication option**).

The first option is to make the granting of a patent dependant on some form of **proof** that the relevant genetic resources have been **legally used**. The evaluation of such proof could be simplified by creating international standardized certificates of access to genetic resources. But it might suffice to rely solely on the **publication of the information provided by the patent applicant**. In this constellation, it would remain within the responsibility of the owner of the resource right to check the information and make his own claims. Though the two options have **different effects**, they would both create a more or less strong incentive only to use genetic resources which have been acquired legally.

But on the other hand, it must, in both cases, be noted that the **use of genetic resources does not always depend on an authorization**. In particular, the **CBD does not apply retroactively**, and therefore does not regulate the use of old supplies of genetic resources. All possible arrangements concerning requirements to state the origin of genetic resources must take this into account.

In addition, as has already been put forward, most countries have not yet created clear regulations concerning access to genetic resources. This also holds true for the big international agricultural research centres with their extensive collections. In their case, the proof option might create serious problems for examining the legitimacy of the users. Indeed, it might even lead to a moratorium on the use of genetic resources.

Considering the different ways of implementing the proof option, it must be noted that the international system for the protection of intellectual property rights does have a number of **special rules** for regional and international registration procedures. At present, these procedures do not provide for compulsory information on the origin. But they could be **amended in this respect** and might provide a suitable basis for introducing an obligation to provide information on the origin of used genetic resources. But they do not preclude national states from introducing their own requirements for national registration procedures, either.

However, the **TRIPs-Agreement raises some general concerns**. The list of conditions for granting a patent right contained in Art. 27 para. 1 TRIPs, which mirrors German and European patent law requirements, is exhaustive. The proof option amounts to such an additional requirement for granting a patent right. Therefore, it very probably **contradicts the TRIPs agreement**.

But it is also doubtful whether the **publication option** is compatible with the TRIPs-Agreement, even if it does not affect the granting of patent rights. In this context, it is important to bear in mind the regulation in **Art. 62** of the TRIPs-Agreement. In itself, the right of Member States to regulate the procedure for granting patents according to para. 1 does not sufficiently justify the publication option, because this regulatory right does not free states from their obligation to abide by the Agreement (para. 1, sentence 2). The decisive factor is the way in which publication and the patent requirements of Art. 27 TRIPs-Agreement interrelate. Even a regulation which provides for publication without interfering with patent requirements might violate the TRIPs-Agreement in two different ways: On the one hand, depending on the exact shape of the publication option and its procedure, the publication requirement itself, or the sanctions which replace it when a state does not fulfil its obligations, might be classified as a factual obstacle to exercising the patent right. On the other hand, Art. 62 para. 1 TRIPs-Agreement and its reference to other provisions in the agreement shows that the procedure must be based on the exhaustive list of criteria in Art. 27

para. 1 TRIPs-Agreement and that it may only serve to check these criteria. This is the more convincing of the two arguments.

In sum, the proof model is clearly inadmissible under the TRIPs-Agreement, and it is highly doubtful whether the publication model without any effect for the granting of patent rights is compatible with the TRIPs-Agreement.

B. Traditional Knowledge and Intellectual Property

The protection of indigenous knowledge is also an important feature in the international debate on the further implementation of the CBD. Indigenous knowledge can be promoted more effectively by ensuring that trade secrets are guarded more closely, as provided for, *inter alia*, in Art. 39 of the TRIPs-Agreement.

Furthermore, trademarks and geographic indications which are in a broad sense part of intellectual property can play an important and supportive role where indigenous or local groups wish to use their traditional knowledge themselves in order to produce and market products.

In essence, the discussion about adequate protection of traditional knowledge revolves around a two-fold problem. On the one hand, indigenous and local communities should retain their ownership rights, but on the other hand others should be able to use this knowledge if the indigenous and local communities want them to. Many suggestions for solving this two-fold problem have been made and are frequently discussed. In these debates, the question of how to prevent third parties from acquiring ownership rights always plays a decisive role. In addition to the suggestion that relevant information should be published, which is disadvantageous because it precludes further proprietal use of the material, it has been put forward that a new, special form of ownership right to indigenous knowledge must be created (*sui generis* right). The suggestions all boil down to a construction which, in its scope of protection, is similar to a patent. However, such a wide scope of protection cannot be justified by deferral to the classical economic theories used for explaining the existence of patent rights. And any implementation of such a right faces considerable practical problems.

However, the introduction of such a right *sui generis* might be deliberated **for other reasons**, for example with the aim of achieving **justice**. Such goals can hardly be measured in economic terms. Still, a decision whether to introduce such *sui generis* rights might take into account the costs of such a right or its direct benefit for the groups or individuals, who will acquire certain monetary benefits due to the right. Finally, the selection of appropriate measures requires some further thought.

V. Conclusions II: A Just Order?

The relationship between intellectual property and the CBD cannot be exhaustively explored by only looking at specific problems and possible methods of harmonization. Beyond these details, it becomes evident that these issues are related to **general questions concerning economic relations**. These must be explored in order to acquire an overall picture in relation to the further implementation of the CBD. The intense and conflict-rifled debate cannot be explained only by examining the different fields of conflict. It must be examined on the background of the existing tensions in the general economic relations. Many of these are related to recent developments in biotechnology, because they affect central economic sectors which are crucial for further economic and social development.

The **transfer of technology**, which is fully addressed in Art. 16 of the CBD, is especially significant for economic and social development. Art. 16 para. 1 CBD obligates the states to make it easier to access and transfer technology. This includes state measures to ensure that private actors readily transfer technology. Measures which reach even further have, however, hardly been discussed so far.

But as the demand for indigenous and local communities' knowledge illustrates, modern biotechnology makes it possible to access, understand and commercialize this knowledge. With that, biotechnology also offers a chance to bring together traditional and modern knowledge. This "**reversed" exchange of technology** is not limited to the special case of local and indigenous communities' knowledge.

There was a large response to cases which did not concern particular knowledge of specific indigenous or local communities, but instead dealt with the use and **patentability of knowledge which was readily available throughout the society** (e.g. the cases turmeric and neem). According to the existing intellectual property rights regime, it is generally not possible to acquire a patent on knowledge which is not new, but already known. However, as these few cases show, it is **in practice not always possible to prevent** such patents from being granted. But there are a number of **borderline cases** in which the relevant, generally available knowledge has only been used as a basis for an altogether different invention or in which the invention concerns completely different aspects.

There was a strong awareness of these tensions when the CBD was negotiated and concluded, and the **CBD takes into account many of the controversial issues.** In the area of genetic resources, the CBD strives to share their benefits in a balanced and just manner. In doing so, the CBD can make an important contribution towards solving the conflicts, subject to the specialized powers of other competent international organisations, above all the WTO and WIPO.

Collection of Relevant Materials

A. Decisions and Documents of Bodies of the Convention on Biological Diversity and of Other International Organizations

1. Third Conference of the Parties to the Convention on Biological Diversity, Buenos Aires 1996

Decision III/17 on Intellectual property rights:

The Conference of the Parties,

Recognizing that intellectual property rights are relevant to and may have implications for the implementation of the Convention and the achievement of its objectives,

Noting that intellectual property rights are the focus of other international agreements and organizations,

Recalling Article 16, paragraph 5, of the Convention,

Recognizing the importance of implementing intellectual property rights-related provisions of the Convention on Biological Diversity and of international agreements relating to intellectual property rights in a mutually supportive way,

Recalling decision II/12 of the second meeting of the Conference of the Parties,

1. *Encourages* Governments, and relevant international and regional organizations, to conduct and communicate to the Executive Secretary, for dissemination through means such as the clearing-house mechanism, case studies of the impacts of intellectual property rights on the achievement of the Convention's objectives, including relationships between intellectual property rights and the knowledge, practices and innovations of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Such studies could:

(a) *Take into account* the information and options for future work contained in the preliminary study prepared by the Executive Secretary, contained in document UNEP/CBD/COP/3/22;

(b) *Take into consideration* existing and potential interrelationships between intellectual property rights and other aspects of the Convention.s implementation, including, for example, implementation of Articles 8 (j), 15 and 16;

(c) *Involve*, through consultation or cooperation, relevant international organizations, as well as relevant regional and national bodies, stakeholders, and others with relevant expertise, as appropriate;

(d) *Consider* the role and the potential of existing intellectual property rights systems in achieving the objectives of the Convention, including, inter alia, in facilitating technology transfer and in arrangements by which interested parties including indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and countries may determine access to and share equitably the benefits of genetic resources or knowledge, innovations and practices;

(e) *Consider* the development of intellectual property rights, such as sui generis systems/approaches, or alternative forms of protection that could promote achievement of the Convention's objectives, consistent with the Parties' international obligations;

(f) *Reflect* the importance of coordinating efficiently with work undertaken pursuant to other elements of the work programme of the Conference of the Parties and work programmes of other relevant organizations;

2. *Notes* that the possible establishment of a new international intellectual property rights regime for databases could have implications for scientific and technical cooperation related to conservation and sustainable use of biological diversity, and calls for an open and transparent evaluation of these implications;

3. *Requests* the Executive Secretary to contact relevant international organizations, particularly the World Intellectual Property Organization, to invite them to take into account in their development cooperation programmes, where appropriate, the need to build capacity to achieve the objectives of the Convention on Biological Diversity as related to intellectual property rights;

4. *Requests* the Executive Secretary to transmit to the Secretariat of the World Trade Organization, for use by appropriate World Trade Organization bodies, decisions of the third meeting of the Conference of the Parties, as well as the documents placed before the third meeting of the Conference of the Parties, and to endeavour to undertake further cooperation and consultation with the World Trade Organization Secretariat, as appropriate. The documents shall be accompanied by the note from the Conference of the Parties included as the annex to this decision;

5. *Welcomes* the decision of the Committee on Trade and Environment of the World Trade Organization to de-restrict and transmit documents to the Executive Secretary relating to its work, and invites the Committee on Trade and Environment to transmit future relevant documents to the Executive Secretary as they are produced;

6. *Requests* the Executive Secretary to apply for observer status in the Committee on Trade and Environment of the World Trade Organization, for the purpose of representing the Convention on Biological Diversity in meetings whose agendas have a relationship with the Convention;

7. *Notes* the potential mutual benefits of exchanging information related to Article 16 of the Convention on Biological Diversity and the laws and regulations received by the Council on Trade-related Aspects of Intellectual Property Rights pursuant to the notification requirement of Article 63 of the Agreement on Trade-Related Aspects of Intellectual Property Rights;

8. *Recognizes* that further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights 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.

Annex: The Convention on Biological Diversity and the Agreement on Trade-related Aspects of Intellectual Property Rights

The Conference of the Parties hereby transmits to the Secretariat of the World Trade Organization, for use by appropriate bodies of the World Trade Organization, the decisions of the third meeting of the Conference of the Parties, as well as the documents placed before the third meeting of the Conference of the Parties. In particular, attention is drawn to document UNEP/CBD/COP/3/22, entitled "The impact of intellectual property rights systems on the conservation and sustainable use of biological diversity and on the equitable sharing of benefits from its use", and document UNEP/CBD/COP/3/23, entitled "The Convention on Biological Diversity and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs): Relationships and synergies". These documents were prepared for the consideration of the Conference of the Parties and their inclusion does not imply full endorsement by the Conference of the Parties. They are offered as contributions to what is hoped will be a continuing process of consultation and cooperation, aimed at promoting the harmonious implementation of the two agreements.

2. Fourth Conference of the Parties to the Convention on Biological Diversity, Bratislava 1998

Decision IV/15 on the relationship of the Convention with the Commission on Sustainable Development and biodiversity-related conventions, other international agreements, institutions and processes of relevance in excerpts:

9. *Stresses* the need to ensure consistency in implementing the Convention on Biological Diversity and the World Trade Organization agreements, including the Agreement on Trade-Related Intellectual Property Rights, with a view to promoting increased mutual supportiveness and integration of biological diversity concerns and the protection of intellectual property rights, and invites the World Trade Organization to consider how to achieve these objectives in the light of Article 16, paragraph 5, of the Convention, taking into account the planned review of Article 27, paragraph 3 (b), of the Agreement on Trade-related Aspects of Intellectual Property Rights in 1999;

10. *Emphasizes* that further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights 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.

Decision IV/8 on access and benefit-sharing in excerpts:

The Conference of the Parties ...

1. *Requests* the inter-sessional open-ended meeting referred to in decision IV/16, paragraph 2, to explore options for access and benefit-sharing mechanisms and to start work on paragraph 10 of decision IV/15 and to make recommendations for future work; ...

3. Inter-Sessional Meeting of the Contracting Parties on the Operations of the Convention on Biological Diversity, Montreal, 1999

Report of the Inter-Sessional Meeting on the Operations of the Convention, UNEP/CBD/COP/5/4, 9 July 1999, Annex:

Recommendations adopted by the Inter-Sessional Meeting on the Operations of the Convention

3. The relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) and the Convention on Biological Diversity

1. The Inter-Sessional Meeting considered decisions IV/8 and IV/15 of the Conference of the Parties on the need for further work to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity.

2. The Inter-Sessional Meeting recognized the linkages, the need to ensure mutual supportiveness between the TRIPs Agreement and the Convention on Biological Diversity and the need to promote synergy between the two agreements.

3. The Inter-Sessional Meeting further recognized that intellectual property rights have implications for the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from the utilization of genetic resources, and that these implications need to be further explored by the Convention on Biological Diversity to create a better knowledge base for decision making in relevant forums.

4. The Inter-Sessional Meeting further took note of ongoing intergovernmental processes addressing these issues (in forums such as the World Trade Organization, the World Intellectual Property Organization, the Food and Agriculture Organization of the United

Nations, the Union for the Protection of New Varieties of Plants) and underlined the need for cooperation in order to avoid duplication of efforts.

5. The Inter-Sessional Meeting recognized the importance and urgency for the Convention on Biological Diversity to achieve observer status in the TRIPs Council of the World Trade Organization (WTO).

6. Possible follow-up activities for the consideration of the Conference of the Parties. The Inter-Sessional Meeting suggested that the Conference of the Parties may wish:

(a) *To consider* the issue of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity and to develop ways and options to closely follow work done by the World Intellectual Property Organization and the World Trade Organization, and provide inputs to this work when relevant. Such inputs should be based on information-gathering and assessments from the perspective of the Convention on Biological Diversity;

(b) *To recognize* the importance of systems such as sui generis and others for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions, and transmit its findings to the World Trade Organization and the World Intellectual Property Organization;

(c) *To invite* the World Trade Organization to acknowledge relevant provisions of the Convention on Biological Diversity and take into account the fact that TRIPs provisions and the objectives of the Convention on Biological Diversity are interrelated, and to further explore this interrelationship.

4. First Expert Panel on Access and Benefit-Sharing

Report of the First Panel of Experts on Access and Benefit-Sharing of the CBD, UNEP/CBD/COP/5/8, 2 November 1999

VIII. Key conclusions of the Panel

A. General conclusions

155. The Panel considered intellectual property rights in line with item 3.2 of its agenda. The Panel acknowledged that intellectual property rights may have an influence on the implementation of access and benefit-sharing arrangements and may have a role in providing incentives for users to seek prior informed consent. The Panel was not able to come to any conclusions about these issues, and therefore suggests that the Conference of the Parties consider these matters further. To guide this further consideration the Panel developed a list of specific issues that require further study, which are contained in paragraphs 127-138 ...

VII. Conclusions of the Panel of Experts

E. Intellectual Property Rights ...

2. Intellectual property and traditional knowledge related to genetic resources

130. The Panel considers that, in relation to the protection of traditional knowledge, the Conference of the Parties should consider how to facilitate progress in relation to the following issues:

(a) How to define relevant terms including subject matter of traditional knowledge and scope of existing rights;

(b) Determining whether existing intellectual property rights regimes can be used to protect traditional knowledge;

(c) Options for the development of sui generis protection of traditional knowledge rights.

131. The Panel also felt that there was:

(a) A need to study the relationship between customary laws governing custodianship, use and transmission of traditional knowledge, on the one hand, and the formal intellectual property system, on the other;

(b) A need for pilot projects by means of which holders of traditional knowledge, including indigenous peoples, may test means of protection of traditional knowledge based on existing intellectual property rights, sui generis possibilities, and customary laws;

(c) A need to ensure that granting intellectual property rights does not preclude continued customary use of genetic resources and related knowledge;

(d) A need to take into account the work of all relevant bodies, including at the community, national, regional and international levels, and in particular the work of bodies under the Convention on Biological Diversity, such as the Ad Hoc Open-ended Working Group on Article 8(j) and Related Provisions and the clearing-house mechanism, and the work of other international organizations such as the United Nations Educational, Cultural and Scientific Organization (UNESCO), WIPO, the World Trade Organization (WTO) and FAO.

3. Intellectual property rights and access and benefit-sharing agreements

132. The Panel acknowledges that intellectual property rights may have an influence on the implementation of access and benefit-sharing agreements. The Panel considers that when entering into such agreements, it must be on mutually agreed terms. It also has to be taken into account that contractual arrangements must be consistent with national and international law.

133. In particular, the following issues could be considered as guiding parameters for contractual agreements:

(a) Regulating the use of resources in order to take into account ethical concerns;

(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;

(c) Provision for the exploitation and use of intellectual property rights include joint research, obligation to work any right on inventions obtained or provide licenses;

(d) Taking into account the possibility of joint ownership of intellectual property rights.

134. Traditional knowledge may be protected as a trade secret or as a form of know-how as appropriate and may be subject to licensing.

135. Potential parties to an access and benefit-sharing agreement may consider the usefulness of licenses to secure continued control by providers over genetic resources.

4. Scope, prior art and monitoring

136. Some Panel members expressed concerns regarding the obtaining of intellectual property rights where there is potential misapplication of the formal requirements for protection.

137. Some Panel members expressed concerns that the scope of protection under intellectual property rights regimes may prejudice the legitimate interests of indigenous and local communities in respect of their knowledge, innovations and practices.

138. Panel members agreed that the development of registers of traditional knowledge could promote the identification and accessibility of prior art.

5. Second Expert Panel on Access and Benefit-Sharing

Report of the Panel of Experts on Access and Benefit-sharing on the work of its second meeting, UNEP/CBD/WG-ABS/1/2, 9 April 2001

Part Two. Conclusions of the Panel of Experts

Agenda Item 3.1. Assessment of user and provider experience in access to genetic resources and benefit-sharing

E. Intellectual property rights, traditional knowledge and access and benefit-sharing

76. Recalling decision V/26 A, in which the Conference of the Parties invited Parties and relevant organizations to submit information on the role of intellectual property rights in the field of access to genetic resources and the sharing of benefits, the Panel of Experts emphasizes the importance of Parties and relevant organizations submitting such information to the Executive Secretary.

77. The Panel of Experts further examined the following issues:

a. Introducing requirements into existing intellectual property rights procedures, such as in the filing of patent applications (e.g. specification of the country of origin or source of the genetic materials and resources), may be a possible way to track compliance with prior informed consent and mutually agreed terms on the basis of which access was granted. In this regard, seeking intellectual property rights may be one indicator of commercial intent;

b. Protection measures for traditional knowledge, innovations and practices must be further explored to guarantee the rights of traditional knowledge holders. Further work is needed for the protection of traditional knowledge by means of intellectual property rights, *sui generis* systems, and other approaches, taking into account the work of the Ad Hoc Working Group on Article 8(j) and the World Intellectual Property Organization (WIPO);

c. In order to build trust among providers and users of genetic resources, the current intellectual property rights system must be properly applied to avoid the inappropriate granting of intellectual property rights. Various measures can be taken in this regard including placing such information in the public domain and/or protection through traditional knowledge registers. However, it should be taken into account that some of these measures may result in the loss of novelty and the waiving of the possibility to acquire exclusive rights to commercial exploitation;

d. Contractual agreements are currently the main legal mechanism to facilitate access and benefit-sharing arrangements and intellectual property rights clauses also play a fundamental role in such agreements. There is therefore a need for awareness and capacity-building at all levels, as well as a need to develop up-to-date model intellectual property rights clauses. WIPO may be a relevant organization to assist in this regard for these purposes.

78. The Panel of Experts recognizes that the protection of traditional knowledge and access to genetic resources and benefit-sharing are related, and recalls that the issue of traditional knowledge is being addressed by the Ad Hoc Working Group on Article 8(j).

79. In examining the above-mentioned issues, the Panel of Experts recognizes that access-and-benefit-sharing issues related to plant genetic resources for food and agriculture are best dealt with by FAO.

80. The Panel of Experts invites the Executive Secretary to present the reports of the first and second meetings of the Panel to the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO.

81. The Panel of Experts recommends that the Executive Secretary invites WIPO to share its expertise by exploring options for addressing the above-mentioned issues and to report back to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

82. The Panel of Experts invites the Executive Secretary, in consultation with the Bureau of the fifth meeting of the Conference of the Parties, to ensure a continued flow of information between the Convention on Biological Diversity and the World Trade Organization on matters related to access and benefit-sharing.

6. Fifth Conference of the Parties to the Convention on Biological Diversity, Bratislava 1998, Nairobi, 2000

Decision V/26 on access to genetic resources in excerpts:

A. Access and benefit-sharing arrangements

The Conference of the Parties ...

4. *Recognizing* the importance for Parties to promote trust-building and transparency in order to facilitate the exchange of genetic resources, particularly with regard to the implementation of Article 15 of the Convention:

(a) *Urges* Parties to pay particular attention to their obligations under Articles 15, 16 and 19 of the Convention, and requests them to report to the Conference of the Parties on the measures they have taken to this effect;

(b) *Notes* that legislative, administrative or policy measures for access and benefit-sharing need to promote flexibility, while recognizing the need for sufficient regulation of access to genetic resources to promote the objectives of the Convention;

(c) *Notes* that all countries are providers and recipients of genetic resources, and urges recipient countries to adopt, appropriate to national circumstances, legislative, administrative or policy measures consistent with the objectives of the Convention that are supportive of efforts made by provider countries to ensure that access to their genetic resources for scientific, commercial and other uses, and associated knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity, as appropriate, is subject to Articles 15, 16 and 19 of the Convention, unless otherwise determined by that provider country;

(d) *Recognizing* the complexity of this issue, with particular consideration of the multiplicity of prior informed consent considerations, invites Parties to cooperate further to find practical and equitable solutions to this issue; ...

5.*Notes* that the promotion of a comprehensive legal and administrative system may facilitate access to and use of genetic resources and contribute to mutually agreed terms in line with the aims of the Convention; ...

11. *Decides* to establish an Ad Hoc Open-ended Working Group, composed of representatives, including experts, nominated by Governments and regional economic integration organizations, with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, inter alia: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to in situ and ex situ conservation and sustainable use; mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, *inter alia*, work by the World Intellectual Property Organization on intellectual property rights issues.

The above-mentioned elements should, in particular, serve as inputs when developing and drafting:

(a) Legislative, administrative or policy measures on access and benefit-sharing; and

(b) Contracts or other arrangements under mutually agreed terms for access and benefit-sharing.

The results of the deliberations of the Working Group, including draft guidelines and other approaches, shall be submitted for consideration by the Conference of the Parties at its sixth

meeting.

The work of the Working Group shall take into account the reports of the Panel of Experts on Access and Benefit-sharing and other relevant information.

The Working Group will be open to the participation of indigenous and local communities, non-governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations.

The Working Group shall maintain communication and exchange of information with the Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity; ...

12. *Notes* that information is a critical aspect of providing the necessary parity of bargaining power for stakeholders in access and benefit-sharing arrangements, and that, in this respect, there is a particular need for more information regarding:

(a) User institutions;

(b) The market for genetic resources;

(c) Non-monetary benefits;

(d) New and emerging mechanisms for benefit-sharing;

(e) Incentive measures;

(f) Clarification of definitions;

(g) Sui generis systems; and

(h) "Intermediaries"; ...

15. *Noting* that the Panel of Experts on Access and Benefit-sharing was not able to come to any conclusions about the role of intellectual property rights in the implementation of access and benefit-sharing arrangements, and that the Panel developed a list of specific issues that require further study (UNEP/CBD/COP/5/8, paras. 127-138):

(a) *Invites* Parties and relevant organizations to submit to the Executive Secretary information on these issues by 31 December 2000;

(b) *Requests* the Executive Secretary, on the basis of these submissions and other relevant material, to make available for the second meeting of the Panel, or the first meeting of the Ad Hoc Open-ended Working Group, a report on these specific issues;

(c) *Recalls* recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention, and requests the Executive Secretary to prepare his report in consultation with, inter alia, the Secretariat of the World Intellectual Property Organization;

(d) *Invites* relevant international organizations, including the World Intellectual Property Organization, to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of

genetic resources, if known, when submitting applications for intellectual property rights, including patents;

(e) *Requests* relevant international organizations, for example, the World Intellectual Property Organization and the International Union for the Protection of New Varieties of Plants, in their work on intellectual property rights issues, to take due account of relevant provisions of the Convention on Biological Diversity, including the impact of intellectual property rights on the conservation and sustainable use of biological diversity, and in particular the value of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;

(f) *Requests* the Executive Secretary to explore experience and possibilities for synergistic interactions resulting from collaboration in research, joint development and the transfer of technology following access to genetic resources.

B. The relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity

The Conference of the Parties,

Noting recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention, concerning the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention,

1. *Reaffirms* the importance of systems such as sui generis and others for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention, taking into account the ongoing work on Article 8(j) and related provisions;

2. *Invites* the World Trade Organization to acknowledge relevant provisions of the Convention and to take into account the fact that the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity are interrelated and to further explore this interrelationship;

3. *Requests* the Executive Secretary to transmit the present decision to the secretariats of the World Trade Organization and the World Intellectual Property Organization, for use by appropriate bodies of these organizations, and to endeavour to undertake further cooperation and consultation with these organizations;

4. *Renews* its request to the Executive Secretary of the Convention to apply for observer status on the Council for the Trade-related Aspects of Intellectual Property Rights, and requests him to report back to the Conference of the Parties on his efforts.

7. Annual Report 1999 of the Council for Trade-Related Aspects of Intellectual Property Rights of the WTO

Annual Report (1999) of the Council for TRIPS, WTO Doc. IP/C/19 of 22 October 1999 in excerpts:

Review of the provisions of Article 27.3(b)

In December 1998, the Council initiated the "review" of the provisions of Article 27.3(b) of the Agreement. Members that were already under an obligation to apply Article 27.3(b) were invited to provide information on how the matters addressed in this provision were presently treated in their national law. Other Members were invited to provide such information on a best endeavours basis. While it was left to each Member to provide information as it would see fit, having regard to the specific provisions of Article 27.3(b), the Secretariat was requested to provide an illustrative list of questions relevant in this regard in order to assist Members to prepare their contributions. The Secretariat was also requested to contact the FAO, the Secretariat of the Convention on Biological Diversity and UPOV, to request factual information on their activities of relevance. By the time of the Council's meeting in October 1999, information had been received from 33 Members as well as from the three intergovernmental organisations referred to. The Council had before it, in July, an informal note containing a structured summary overview of the information presented by these Members, which the Secretariat had prepared in response to a request from the Council. Some Members commented on the contents of this overview. Views were expressed on the present provisions of Article 27.3(b), including on their relation to the protection and use of biodiversity, and on possible changes to these provisions that might be considered. In October, the Council received submissions from two Members, had a further exchange of views and agreed to revert to the matter at its next meeting, taking into account the outcome of the Seattle Ministerial Conference.

B. The Relevant International and European Legal Framework

1. Paris Convention for the Protection of Industrial Property

Paris Convention for the Protection of Industrial Property of March 20, 1883 (as revised at BRUSSELS on December 14, 1900, at WASHINGTON on June 2, 1911, at THE HAGUE on November 6, 1925, at LONDON on June 2, 1934, at LISBON on October 31, 1958, and at STOCKHOLM or, July 14, 1967, and as amended on October 2, 1979)

Article 1 Establishment of the Union; Scope of Industrial Property

(1) The countries to which this Convention applies constitute a Union for the protection of industrial property.

(2) The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.

(3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

(4) Patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.

Article 2 National Treatment for Nationals of Countries of the Union

(1) Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.

(2) However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any industrial property rights.

(3) The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved.

Article 3 Same Treatment for Certain Categories of Persons as for Nationals of Countries of the Union

Nationals of countries outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union.

Article 4 [A to I: Patents, Utility Models, Industrial Designs, Marks, Inventors' Certificates: Right of Priority. G: Patents: Division of the Application]

A. (1) Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed.

(2) Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or multilateral treaties concluded between countries of the Union shall be recognized as giving rise to the right of priority.

(3) By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application.

B. Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession. Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union

C. (1) The periods of priority referred to above shall be twelve months for patents and utility models, and six months for industrial designs and trademarks.

(2) These periods shall start from the date of filing of the first application; the day of filing shall not be included in the period.

(3) If the last day of the period is an official holiday, or a day when the Office is not open for the filing of applications in the country where protection is claimed, the period shall be extended until the first following working day.

(4) A subsequent application concerning the same subject as a previous first application within the meaning of paragraph (2), above, filed in the same country of the Union. shall be considered as the first application, of which the filing date shall be the starting point of the period of priority, if, at the time of filing the subsequent application, the said previous application has been withdrawn, abandoned, or refused, without having been laid open to public inspection and without leaving any rights outstanding, and if it has not yet served as a basis for claiming a right of priority. The previous application may not thereafter serve as a basis for claiming a right of priority.

D. (1) Any person desiring to take advantage of the priority of a previous filing shall be required to make a declaration indicating the date of such filing and the country in which it was made. Each country shall determine the latest date on which such declaration must be made.

(2) These particulars shall be mentioned in the publications issued by the competent authority, and in particular in the patents and the specifications relating thereto.

(3) The countries of the Union may require any person making a declaration of priority to produce a copy of the application (description, drawings, etc.) previously filed. The copy, certified as correct by the authority which received such application, shall not require any authentication, and may in any case be filed, without fee, at any time within three months of

the filing of the subsequent application. They may require it to be accompanied by a certificate from the same authority showing the date of filing, and by a translation.

(4) No other formalities may be required for the declaration of priority at the time of filing the application. Each country of the Union shall determine the consequences of failure to comply with the formalities prescribed by this Article, but such consequences shall in no case go beyond the loss of the right of priority.

(5) Subsequently, further proof may be required. Any person who avails himself of the priority of a previous application shall be required to specify the number of that application; this number shall be published as provided for by paragraph (2), above.

E. (1) Where an industrial design is filed in a country by virtue of a right of priority based on the filing of a utility model, the period of priority shall be the same as that fixed for industrial designs

(2) Furthermore, it is permissible to file a utility model in a country by virtue of a right of priority based on the filing of a patent application, and vice versa.

F. No country of the Union may refuse a priority or a patent application on the ground that the applicant claims multiple priorities, even if they originate in different countries, or on the ground that an application claiming one or more priorities contains one or more elements that were not included in the application or applications whose priority is claimed, provided that, in both cases, there is unity of invention within the meaning of the law of the country. With respect to the elements not included in the application or applications whose priority is claimed, the filing of the subsequent application shall give rise to a right of priority tinder ordinary conditions.

G. (1) If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.

(2) The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized.

H. Priority may not be refused on the ground that certain elements of the invention for which priority is claimed do not appear among the claims formulated in the application in the country of origin, provided that the application documents as a whole specifically disclose such elements.

I. (1) Applications for inventors' certificates filed in a country in which applicants have the right to apply at their own option either for a patent or for an inventor's certificate shall give rise to the right of priority provided for by this Article, under the same conditions and with the same effects as applications for patents.

(2) In a country in which applicants have the right to apply at their own option either for a patent or for an inventor's certificate, an applicant for an inventor's certificate shall, in accordance with the provisions of this Article relating to patent applications, enjoy a right of priority based on an application for a patent, a utility model, or an inventor's certificate.

Article 4bis Patents: Independence of Patents Obtained for the Same Invention in Different Countries

(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.

(2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.

(3) The provision shall apply to all patents existing at the time when it comes into effect.

(4) Similarly, it shall apply, in the case of the accession of new countries, to patents in existence on either side at the time of accession.

(5) Patents obtained with the benefit of priority shall, in the various countries of the Union, have a duration equal to that which they would have, had they been applied for or granted without the benefit of priority.

Article 4ter Patents: Mention of the Inventor in the Patent

The inventor shall have the right to be mentioned as such in the patent.

Article 4quater Patents: Patentability in Case of Restrictions of Sale by Law

The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.

Article 5 [A. Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses. B. Industrial Designs: Failure to Work; Importation of Articles. C. Marks: Failure to Use; Different Forms; Use by Co-proprietors. D. Patents, Utility Models, Marks, Industrial Designs: Marking]

A. (1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

(5) The foregoing provisions shall be applicable, *mutatis mutandis*, to utility models.

B. The protection of industrial designs shall not, under any circumstance, be subject to any forfeiture, either by reason of failure to work or by reason of the importation of articles corresponding to those which are protected.

C. (1) If, in any country, use of the registered mark is compulsory, the registration may be cancelled only after a reasonable period, and then only if the person concerned does not justify his inaction.

(2) Use of a trademark by the proprietor in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered in one of the countries of the Union shall not entail invalidation of the registration and shall not diminish the protection granted to the mark.

(3) Concurrent use of the same mark on identical or similar goods by industrial or commercial establishments considered as co-proprietors of the mark according to the provisions of the domestic law of the country where protection is claimed shall not prevent registration or diminish in any way the protection granted to the said mark in any country of the Union, provided that such use does not result in misleading the public and is not contrary to the public interest.

D. No indication or mention of the patent, of the utility model, of the registration of the trademark, or of the deposit of the industrial design, shall be required upon the goods as a condition of recognition of the right to protection.

Article 5bis All Industrial Property Rights: Period of Grace for the Payment of Fees for the Maintenance of Rights; Patents: Restoration

(1) A period of grace of not less than six months shall be allowed for the payment of the fees prescribed for the maintenance of industrial property rights, subject, if the domestic legislation so provides, to the payment of a surcharge.

(2) The countries of the Union shall have the right to provide for the restoration of patents which have lapsed by reason of non-payment of fees.

Article 5quater Patents: Importation of Products Manufactured by a Process Patented in the Importing Country

When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country. ...

Article 10bis Unfair Competition

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited:

1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

2. Patent Cooperation Treaty (PCT)

Patent Cooperation Treaty (PCT), Done at Washington on June 19, 1970, amended on September 28, 1979, and modified on February 3, 1984

The Contracting States,

Desiring to make a contribution to the progress of science and technology,

Desiring to perfect the legal protection of inventions,

Desiring to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries,

Desiring to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions,

Desiring to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems, whether national or regional, instituted for the protection of inventions by providing easily accessible information on the availability of technological solutions applicable to their special needs and by facilitating access to the ever expanding volume of modern technology,

Convinced that cooperation among nations will greatly facilitate the attainment of these aims,

Have concluded the present Treaty:

Introductory Provisions

Article 1 Establishment of a Union

(1) The States party to this Treaty (hereinafter called “the Contracting States”) constitute a Union for cooperation in the filing, searching, and examination, of applications for the protection of inventions, and for rendering special technical services. The Union shall be known as the International Patent Cooperation Union.

(2) No provision of this Treaty shall be interpreted as diminishing the rights under the Paris Convention for the Protection of Industrial Property of any national or resident of any country party to that Convention.

Article 2 Definitions

For the purposes of this Treaty and the Regulations and unless expressly stated otherwise:

(i) “application” means an application for the protection of an invention; references to an “application” shall be construed as references to applications for patents for inventions, inventors’ certificates, utility certificates, utility models, patents or certificates of addition, inventors’ certificates of addition, and utility certificates of addition;

(ii) references to a “patent” shall be construed as references to patents for inventions, inventors’ certificates, utility certificates, utility models, patents or certificates of addition, inventors’ certificates of addition, and utility certificates of addition;

(iii) “national patent” means a patent granted by a national authority;

(iv) “regional patent” means a patent granted by a national or an intergovernmental authority having the power to grant patents effective in more than one State;

(v) “regional application” means an application for a regional patent;

(vi) references to a “national application” shall be construed as references to applications for national patents and regional patents, other than applications filed under this Treaty;

(vii) “international application” means an application filed under this Treaty;

(viii) references to an “application” shall be construed as references to international applications and national applications;

(ix) references to a “patent” shall be construed as references to national patents and regional patents;

(x) references to “national law” shall be construed as references to the national law of a Contracting State or, where a regional application or a regional patent is involved, to the treaty providing for the filing of regional applications or the granting of regional patents;

(xi) “priority date,” for the purposes of computing time limits, means:

(a) where the international application contains a priority claim under Article 8, the filing date of the application whose priority is so claimed;

(b) where the international application contains several priority claims under Article 8, the filing date of the earliest application whose priority is so claimed;

(c) where the international application does not contain any priority claim under Article 8, the international filing date of such application;

(xii) “national Office” means the government authority of a Contracting State entrusted with the granting of patents; references to a “national Office” shall be construed as referring also to any intergovernmental authority which several States have entrusted with the task of granting regional patents, provided that at least one of those States is a Contracting State, and provided that the said States have authorized that authority to assume the obligations and exercise the powers which this Treaty and the Regulations provide for in respect of national Offices;

(xiii) “designated Office” means the national Office of or acting for the State designated by the applicant under Chapter I of this Treaty;

(xiv) “elected Office” means the national Office of or acting for the State elected by the applicant under Chapter II of this Treaty;

(xv) “receiving Office” means the national Office or the intergovernmental organization with which the international application has been filed;

(xvi) “Union” means the International Patent Cooperation Union;

(xvii) “Assembly” means the Assembly of the Union;

(xviii) “Organization” means the World Intellectual Property Organization;

(xix) “International Bureau” means the International Bureau of the Organization and, as long as it subsists, the United International Bureaux for the Protection of Intellectual Property (BIRPI);

(xx) “Director General” means the Director General of the Organization and, as long as BIRPI subsists, the Director of BIRPI.

Chapter I: International Application and International Search

Article 3 The International Application

(1) Applications for the protection of inventions in any of the Contracting States may be filed as international applications under this Treaty.

(2) An international application shall contain, as specified in this Treaty and the Regulations, a request, a description, one or more claims, one or more drawings (where required), and an abstract.

(3) The abstract merely serves the purpose of technical information and cannot be taken into account for any other purpose, particularly not for the purpose of interpreting the scope of the protection sought.

(4) The international application shall:

(i) be in a prescribed language;

(ii) comply with the prescribed physical requirements;

(iii) comply with the prescribed requirement of unity of invention;

(iv) be subject to the payment of the prescribed fees.

Article 4 The Request

(1) The request shall contain:

(i) a petition to the effect that the international application be processed according to this Treaty;

(ii) the designation of the Contracting State or States in which protection for the invention is desired on the basis of the international application (“designated States”); if for any designated State a regional patent is available and the applicant wishes to obtain a regional patent rather than a national patent, the request shall so indicate; if, under a treaty concerning a regional patent, the applicant cannot limit his application to certain of the States party to that treaty, designation of one of those States and the indication of the wish to obtain the regional patent shall be treated as designation of all the States party to that treaty; if, under the national law of the designated State, the designation of that State has the effect of an application for a regional patent, the designation of the said State shall be treated as an indication of the wish to obtain the regional patent;

(iii) the name of and other prescribed data concerning the applicant and the agent (if any);

(iv) the title of the invention;

(v) the name of and other prescribed data concerning the inventor where the national law of at least one of the designated States requires that these indications be furnished at the time of filing a national application. Otherwise, the said indications may be furnished either in the request or in separate notices addressed to each designated Office whose national law requires the furnishing of the said indications but allows that they be furnished at a time later than that of the filing of a national application.

(2) Every designation shall be subject to the payment of the prescribed fee within the prescribed time limit.

(3) Unless the applicant asks for any of the other kinds of protection referred to in Article 43, designation shall mean that the desired protection consists of the grant of a patent by or for the designated State. For the purposes of this paragraph, Article 2(ii) shall not apply.

(4) Failure to indicate in the request the name and other prescribed data concerning the inventor shall have no consequence in any designated State whose national law requires the furnishing of the said indications but allows that they be furnished at a time later than that of the filing of a national application. Failure to furnish the said indications in a separate notice shall have no consequence in any designated State whose national law does not require the furnishing of the said indications.

Article 5 The Description

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

Article 6 The Claims

The claim or claims shall define the matter for which protection is sought. Claims shall be clear and concise. They shall be fully supported by the description.

Article 7 The Drawings

(1) Subject to the provisions of paragraph (2)(ii), drawings shall be required when they are necessary for the understanding of the invention.

(2) Where, without being necessary for the understanding of the invention, the nature of the invention admits of illustration by drawings:

(i) the applicant may include such drawings in the international application when filed,

(ii) any designated Office may require that the applicant file such drawings with it within the prescribed time limit.

Article 8 Claiming Priority

(1) The international application may contain a declaration, as prescribed in the Regulations, claiming the priority of one or more earlier applications filed in or for any country party to the Paris Convention for the Protection of Industrial Property.

(2)(a) Subject to the provisions of subparagraph (b), the conditions for, and the effect of, any priority claim declared under paragraph (1) shall be as provided in of the Stockholm Act of the Paris Convention for the Protection of Industrial Property.

(b) The international application for which the priority of one or more earlier applications filed in or for a Contracting State is claimed may contain the designation of that State. Where, in the international application, the priority of one or more national applications filed in or for a designated State is claimed, or where the priority of an international application having designated only one State is claimed, the conditions for, and the effect of, the priority claim in that State shall be governed by the national law of that State.

Article 9 The Applicant

(1) Any resident or national of a Contracting State may file an international application.

(2) The Assembly may decide to allow the residents and the nationals of any country party to the Paris Convention for the Protection of Industrial Property which is not party to this Treaty to file international applications.

(3) The concepts of residence and nationality, and the application of those concepts in cases where there are several applicants or where the applicants are not the same for all the designated States, are defined in the Regulations.

Article 10 The Receiving Office

The international application shall be filed with the prescribed receiving Office, which will check and process it as provided in this Treaty and the Regulations.

Article 11 Filing Date and Effects of the International Application

(1) The receiving Office shall accord as the international filing date the date of receipt of the international application, provided that that Office has found that, at the time of receipt:

(i) the applicant does not obviously lack, for reasons of residence or nationality, the right to file an international application with the receiving Office,

(ii) the international application is in the prescribed language,

(iii) the international application contains at least the following elements:

(a) an indication that it is intended as an international application,

(b) the designation of at least one Contracting State,

(c) the name of the applicant, as prescribed,

(d) a part which on the face of it appears to be a description,

(e) a part which on the face of it appears to be a claim or claims.

(2)(a) If the receiving Office finds that the international application did not, at the time of receipt, fulfill the requirements listed in paragraph (1), it shall, as provided in the Regulations, invite the applicant to file the required correction.

(b) If the applicant complies with the invitation, as provided in the Regulations, the receiving Office shall accord as the international filing date the date of receipt of the required correction.

(3) Subject to Article 64(4), any international application fulfilling the requirements listed in items (i) to (iii) of paragraph (1) and accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State.

(4) Any international application fulfilling the requirements listed in items (i) to (iii) of paragraph (1) shall be equivalent to a regular national filing within the meaning of the Paris Convention for the Protection of Industrial Property.

Article 12 Transmittal of the International Application to the International Bureau and the International Searching Authority

(1) One copy of the international application shall be kept by the receiving Office ("home copy"), one copy ("record copy") shall be transmitted to the International Bureau, and another copy ("search copy") shall be transmitted to the competent International Searching Authority referred to in Article 16, as provided in the Regulations.

(2) The record copy shall be considered the true copy of the international application.

(3) The international application shall be considered withdrawn if the record copy has not been received by the International Bureau within the prescribed time limit.

Article 13 Availability of Copy of the International Application to Designated Offices

(1) Any designated Office may ask the International Bureau to transmit to it a copy of the international application prior to the communication provided for in Article 20, and the International Bureau shall transmit such copy to the designated Office as soon as possible after the expiration of one year from the priority date.

(2)(a) The applicant may, at any time, transmit a copy of his international application to any designated Office.

(b) The applicant may, at any time, ask the International Bureau to transmit a copy of his international application to any designated Office, and the International Bureau shall transmit such copy to the designated Office as soon as possible.

(c) Any national Office may notify the International Bureau that it does not wish to receive copies as provided for in subparagraph (b), in which case that subparagraph shall not be applicable in respect of that Office. ...

Article 14 Certain Defects in the International Application

(1)(a) The receiving Office shall check whether the international application contains any of the following defects, that is to say:

(i)it is not signed as provided in the Regulations;

(ii) it does not contain the prescribed indications concerning the applicant;

(iii) it does not contain a title;

(iv) it does not contain an abstract;

(v) it does not comply to the extent provided in the Regulations with the prescribed physical requirements.

(b) If the receiving Office finds any of the said defects, it shall invite the applicant to correct the international application within the prescribed time limit, failing which that application shall be considered withdrawn and the receiving Office shall so declare.

(2) If the international application refers to drawings which, in fact, are not included in that application, the receiving Office shall notify the applicant accordingly and he may furnish them within the prescribed time limit and, if he does, the international filing date shall be the date on which the drawings are received by the receiving Office. Otherwise, any reference to the said drawings shall be considered non-existent.

(3)(a) If the receiving Office finds that, within the prescribed time limits, the fees prescribed under Article 3(4)(iv) have not been paid, or no fee prescribed under Article 4(2) has been paid in respect of any of the designated States, the international application shall be considered withdrawn and the receiving Office shall so declare.

(b) If the receiving Office finds that the fee prescribed under Article 4(2) has been paid in respect of one or more (but less than all) designated States within the prescribed time limit, the designation of those States in respect of which it has not been paid within the prescribed time limit shall be considered withdrawn and the receiving Office shall so declare.

(4) If, after having accorded an international filing date to the international application, the receiving Office finds, within the prescribed time limit, that any of the requirements listed in items (i) to (iii) of Article 11(1) was not complied with at that date, the said application shall be considered withdrawn and the receiving Office shall so declare.

Article 15 The International Search

(1) Each international application shall be the subject of international search.

(2) The objective of the international search is to discover relevant prior art.

(3) International search shall be made on the basis of the claims, with due regard to the description and the drawings (if any).

(4) The International Searching Authority referred to in Article 16 shall endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentation specified in the Regulations.

(5)(a) If the national law of the Contracting State so permits, the applicant who files a national application with the national Office of or acting for such State may, subject to the conditions provided for in such law, request that a search similar to an international search ("international-type search") be carried out on such application.

(b) If the national law of the Contracting State so permits, the national Office of or acting for such State may subject any national application filed with it to an international-type search.

(c) The international-type search shall be carried out by the International Searching Authority referred to in Article 16 which would be competent for an international search if the national application were an international application and were filed with the Office referred to in subparagraphs (a) and (b). If the national application is in a language which the International Searching Authority considers it is not equipped to handle, the international-type search shall be carried out on a translation prepared by the applicant in a language prescribed for international applications and which the International Searching Authority has undertaken to accept for international applications. The national application and the translation, when required, shall be presented in the form prescribed for international applications.

Article 16 The International Searching Authority

(1) International search shall be carried out by an International Searching Authority, which may be either a national Office or an intergovernmental organization, such as the International Patent Institute, whose tasks include the establishing of documentary search reports on prior art with respect to inventions which are the subject of applications.

(2) If, pending the establishment of a single International Searching Authority, there are several International Searching Authorities, each receiving Office shall, in accordance with the provisions of the applicable agreement referred to in paragraph (3)(b), specify the International Searching Authority or Authorities competent for the searching of international applications filed with such Office.

(3)(a) International Searching Authorities shall be appointed by the Assembly. Any national Office and any intergovernmental organization satisfying the requirements referred to in subparagraph (c) may be appointed as International Searching Authority.

(b) Appointment shall be conditional on the consent of the national Office or intergovernmental organization to be appointed and the conclusion of an agreement, subject to approval by the Assembly, between such Office or organization and the International Bureau. The agreement shall specify the rights and obligations of the parties, in particular, the formal undertaking by the said Office or organization to apply and observe all the common rules of international search.

(c) The Regulations prescribe the minimum requirements, particularly as to manpower and documentation, which any Office or organization must satisfy before it can be appointed and must continue to satisfy while it remains appointed.

(d) Appointment shall be for a fixed period of time and may be extended for further periods.

(e) Before the Assembly makes a decision on the appointment of any national Office or intergovernmental organization, or on the extension of its appointment, or before it allows any such appointment to lapse, the Assembly shall hear the interested Office or organization and seek the advice of the Committee for Technical Cooperation referred to in Article 56 once that Committee has been established.

Article 17 Procedure before the International Searching Authority

(1) Procedure before the International Searching Authority shall be governed by the provisions of this Treaty, the Regulations, and the agreement which the International Bureau shall conclude, subject to this Treaty and the Regulations, with the said Authority.

(2)(a) If the International Searching Authority considers

(i) that the international application relates to a subject matter which the International Searching Authority is not required, under the Regulations, to search, and in the particular case decides not to search, or

(ii) that the description, the claims, or the drawings, fail to comply with the prescribed requirements to such an extent that a meaningful search could not be carried out, the said Authority shall so declare and shall notify the applicant and the International Bureau that no international search report will be established.

(b) If any of the situations referred to in subparagraph (a) is found to exist in connection with certain claims only, the international search report shall so indicate in respect of such claims, whereas, for the other claims, the said report shall be established as provided in Article 18.

(3)(a) If the International Searching Authority considers that the international application does not comply with the requirement of unity of invention as set forth in the Regulations, it shall invite the applicant to pay additional fees. The International Searching Authority shall establish the international search report on those parts of the international application which relate to the invention first mentioned in the claims ("main invention") and, provided the required additional fees have been paid within the prescribed time limit, on those parts of the international application which relate to inventions in respect of which the said fees were paid.

(b) The national law of any designated State may provide that, where the national Office of that State finds the invitation, referred to in subparagraph (a), of the International Searching Authority justified and where the applicant has not paid all additional fees, those parts of the international application which consequently have not been searched shall, as far as effects in that State are concerned, be considered withdrawn unless a special fee is paid by the applicant to the national Office of that State.

Article 18 The International Search Report

(1) The international search report shall be established within the prescribed time limit and in the prescribed form.

(2) The international search report shall, as soon as it has been established, be transmitted by the International Searching Authority to the applicant and the International Bureau.

(3) The international search report or the declaration referred to in Article 17(2)(a) shall be translated as provided in the Regulations. The translations shall be prepared by or under the responsibility of the International Bureau.

Article 19 Amendment of the Claims before the International Bureau

(1) The applicant shall, after having received the international search report, be entitled to one opportunity to amend the claims of the international application by filing amendments with the International Bureau within the prescribed time limit. He may, at the same time, file a brief statement, as provided in the Regulations, explaining the amendments and indicating any impact that such amendments might have on the description and the drawings.

(2) The amendments shall not go beyond the disclosure in the international application as filed.

(3) If the national law of any designated State permits amendments to go beyond the said disclosure, failure to comply with paragraph (2) shall have no consequence in that State.

Article 20 Communication to Designated Offices

(1)(a) The international application, together with the international search report (including any indication referred to in Article 17(2)(b)) or the declaration referred to in Article 17(2)(a), shall be communicated to each designated Office, as provided in the Regulations, unless the designated Office waives such requirement in its entirety or in part.

(b) The communication shall include the translation (as prescribed) of the said report or declaration.

(2) If the claims have been amended by virtue of Article 19(1), the communication shall either contain the full text of the claims both as filed and as amended or shall contain the full

text of the claims as filed and specify the amendments, and shall include the statement, if any, referred to in Article 19(1).

(3) At the request of the designated Office or the applicant, the International Searching Authority shall send to the said Office or the applicant, respectively, copies of the documents cited in the international search report, as provided in the Regulations.

Article 21 International Publication

(1) The International Bureau shall publish international applications.

(2)(a) Subject to the exceptions provided for in subparagraph (b) and in Article 64(3), the international publication of the international application shall be effected promptly after the expiration of 18 months from the priority date of that application.

(b) The applicant may ask the International Bureau to publish his international application any time before the expiration of the time limit referred to in subparagraph (a). The International Bureau shall proceed accordingly, as provided in the Regulations.

(3) The international search report or the declaration referred to in Article 17(2)(a) shall be published as prescribed in the Regulations.

(4) The language and form of the international publication and other details are governed by the Regulations.

(5) There shall be no international publication if the international application is withdrawn or is considered withdrawn before the technical preparations for publication have been completed.

(6) If the international application contains expressions or drawings which, in the opinion of the International Bureau, are contrary to morality or public order, or if, in its opinion, the international application contains disparaging statements as defined in the Regulations, it may omit such expressions, drawings, and statements, from its publications, indicating the place and number of words or drawings omitted, and furnishing, upon request, individual copies of the passages omitted.

Article 59 Disputes

Subject to Article 64(5), any dispute between two or more Contracting States concerning the interpretation or application of this Treaty or the Regulations, not settled by negotiation, may, by any one of the States concerned, be brought before the International Court of Justice by application in conformity with the Statute of the Court, unless the States concerned agree on some other method of settlement. The Contracting State bringing the dispute before the Court shall inform the International Bureau; the International Bureau shall bring the matter to the attention of the other Contracting States.

3. PCT Rules

Regulations Under the Patent Cooperation Treaty as in force from January 1, 1998 (Adopted on June 19, 1970, and amended on April 14, 1978, October 3, 1978, May 1, 1979, June 16, 1980, September 26, 1980, July 3, 1981, September 10, 1982, October 4, 1983, February 3, 1984, September 28, 1984, October 1, 1985, July 12, 1991, October 2, 1991, September 29, 1992, September 29, 1993, October 3, 1995, and October 1, 1997) in excerpts.

Rule 5 The Description

5.1 Manner of the Description

(a) The description shall first state the title of the invention as appearing in the request and shall:

(i) specify the technical field to which the invention relates;

(ii) indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, preferably, cite the documents reflecting such art;

(iii) disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art;

(iv) briefly describe the figures in the drawings, if any;

(v) set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State;

(vi) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used; the term "industry" is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.

(b) The manner and order specified in paragraph (a) shall be followed except when, because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economic presentation.

(c) Subject to the provisions of paragraph (b), each of the parts referred to in paragraph (a) shall preferably be preceded by an appropriate heading as suggested in the Administrative Instructions.

5.2 Nucleotide and/or Amino Acid Sequence Disclosure

Where the international application contains disclosure of a nucleotide and/or amino acid sequence, the description shall contain a listing of the sequence complying with the standard prescribed by the Administrative Instructions.

Rule 13bis Microbiological Inventions

13bis.1 Definition

For the purposes of this Rule, “reference to a deposited microorganism” means particulars given in an international application with respect to the deposit of a microorganism with a depositary institution or to the microorganism so deposited.

13bis.2 References (General)

Any reference to a deposited microorganism shall be made in accordance with this Rule and, if so made, shall be considered as satisfying the requirements of the national law of each designated State.

13bis.3 References: Contents; Failure to Include Reference or Indication

(a) A reference to a deposited microorganism shall indicate,

(i) the name and address of the depositary institution with which the deposit was made;

(ii) the date of deposit of the microorganism with that institution;

(iii) the accession number given to the deposit by that institution; and

(iv) any additional matter of which the International Bureau has been notified pursuant to Rule 13bis.7(a)(i), provided that the requirement to indicate that matter was published in the Gazette in accordance with Rule 13bis.7(c) at least two months before the filing of the international application.

(b) Failure to include a reference to a deposited microorganism or failure to include, in a reference to a deposited microorganism, an indication in accordance with paragraph (a), shall have no consequence in any designated State whose national law does not require such reference or such indication in a national application.

13bis.4 References: Time of Furnishing Indications

If any of the indications referred to in Rule 13bis.3(a) is not included in a reference to a deposited microorganism in the international application as filed but is furnished by the applicant to the International Bureau within 16 months after the priority date, the indication shall be considered by any designated Office to have been furnished in time unless its national law requires the indication to be furnished at an earlier time in the case of a national application and the International Bureau has been notified of such requirement pursuant to Rule 13bis.7(a)(ii), provided that the International Bureau has published such requirement in the Gazette in accordance with Rule 13bis.7(c) at least two months before the filing of the international application. In the event that the applicant makes a request for early publication under Article 21(2)(b), however, any designated Office may consider any indication not furnished by the time such request is made as not having been furnished in time. Irrespective of whether the applicable time limit under the preceding sentences has been observed, the International Bureau shall notify the applicant and the designated Offices of the date on which it has received any indication not included in the international application as filed. The International Bureau shall indicate that date in the international publication of the international application if the indication has been furnished to it before the completion of technical preparations for international publication.

13bis.5 References and Indications for the Purposes of One or More Designated States; Different Deposits for Different Designated States; Deposits with Depositary Institutions Other than Those Notified

(a) A reference to a deposited microorganism shall be considered to be made for the purposes of all designated States, unless it is expressly made for the purposes of certain of the designated States only; the same applies to the indications included in the reference.

(b) References to different deposits of the microorganism may be made for different designated States.

(c) Any designated Office shall be entitled to disregard a deposit made with a depositary institution other than one notified by it under Rule 13bis.7(b).

13bis.6 Furnishing of Samples

(a) Where the international application contains a reference to a deposited microorganism, the applicant shall, upon the request of the International Searching Authority or the International Preliminary Examining Authority, authorize and assure the furnishing of a sample of that microorganism by the depositary institution to the said Authority, provided that the said Authority has notified the International Bureau that it may require the furnishing of samples and that such samples will be used solely for the purposes of international search or international preliminary examination, as the case may be, and such notification has been published in the Gazette.

(b) Pursuant to Articles 23 and 40, no furnishing of samples of the deposited microorganism to which a reference is made in an international application shall, except with the authorization of the applicant, take place before the expiration of the applicable time limits after which national processing may start under the said Articles. However, where the applicant performs the acts referred to in Articles 22 or 39 after international publication but before the expiration of the said time limits, the furnishing of samples of the deposited microorganism may take place, once the said acts have been performed. Notwithstanding the previous provision, the furnishing of samples of the deposited microorganism may take place under the national law applicable for any designated Office as soon as, under that law, the international publication has the effects of the compulsory national publication of an unexamined national application.

Rule 13ter Nucleotide and/or Amino Acid Sequence Listings

13ter.1 Sequence Listing for International Authorities

(a) If the International Searching Authority finds that a nucleotide and/or amino acid sequence listing does not comply with the standard prescribed in the Administrative Instructions under Rule 5.2, and/or is not in a machine readable form provided for in those Instructions, it may invite the applicant, within a time limit fixed in the invitation, as the case may be:

(i) to furnish to it a listing of the sequence complying with the prescribed standard, and/or

(ii) to furnish to it a listing of the sequence in a machine readable form provided for in the Administrative Instructions or, if that Authority is prepared to transcribe the sequence listing into such a form, to pay for the cost of such transcription.

(b) Any sequence listing furnished under paragraph (a) shall be accompanied by a statement to the effect that the listing does not include matter which goes beyond the disclosure in the international application as filed.

(c) If the applicant does not comply with the invitation within the time limit fixed in the invitation, the International Searching Authority shall not be required to search the

international application to the extent that such non-compliance has the result that a meaningful search cannot be carried out.

(d) If the International Searching Authority chooses, under paragraph (a)(ii), to transcribe the sequence listing into a machine readable form, it shall send a copy of such transcription in machine readable form to the applicant.

(e) The International Searching Authority shall, upon request, make available to the International Preliminary Examining Authority a copy of any sequence listing furnished to it, or as transcribed by it, under paragraph (a).

(f) A sequence listing furnished to the International Searching Authority, or as transcribed by it, under paragraph (a) shall not form part of the international application.

13ter.2 Sequence Listing for Designated Office

(a) Once the processing of the international application has started before a designated Office, that Office may require the applicant to furnish to it a copy of any sequence listing furnished to the International Searching Authority, or as transcribed by that Authority, under Rule 13ter.1(a).

(b) If a designated Office finds that a nucleotide and/or amino acid sequence listing does not comply with the standard prescribed in the Administrative Instructions under Rule 5.2, and/or is not in a machine readable form provided for in those Instructions, and/or no listing of the sequence was furnished to the International Searching Authority, or transcribed by that Authority, under Rule 13ter.1(a), that Office may require the applicant:

(i) to furnish to it a listing of the sequence complying with the prescribed standard, and/or

(ii) to furnish to it a listing of the sequence in a machine readable form provided for in the Administrative Instructions or, if that Office is prepared to transcribe the sequence listing into such a form, to pay for the cost of such transcription.

4. Budapest Treaty

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (done at Budapest on April 28, 1977, and amended on September 26, 1980).

Chapter I Substantive Provisions

Article 3 Recognition and Effect of the Deposit of Microorganisms

Article 3

Recognition and Effect of the Deposit of Microorganisms

(1)(a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.

(b) Any Contracting State may require a copy of the receipt of the deposit referred to in subparagraph (a), issued by the international depositary authority.

5. Regulations under the Budapest Treaty

Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (adopted on April 28, 1977, and amended on January 20, 1981).

Rule 6 Making the Original Deposit or New Deposit

6.1 Original Deposit

(a) The microorganism transmitted by the depositor to the international depositary authority shall, except where Rule 6.2 applies, be accompanied by a written statement bearing the signature of the depositor and containing:

(i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;

(ii) the name and address of the depositor;

(iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;

(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.

(b) It is strongly recommended that the written statement referred to in paragraph (a) should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.

6. Agreement on Trade-Related Aspects of Intellectual Property Rights

a. Overview

Part I: General Provisions and Basic Principles

Part II: Standards Concerning the Availability, Scope and Use of Intellectual Property Rights

1. Copyright and Related Rights
2. Trademarks

3. Geographical Indications
4. Industrial Designs
5. Patents
6. Layout-Designs (Topographies) of Integrated Circuits
7. Protection of Undisclosed Information
8. Control of Anti-Competitive Practices in Contractual Licences

Part III: Enforcement of Intellectual Property Rights

1. General Obligations
2. Civil and Administrative Procedures and Remedies
3. Provisional Measures
4. Special Requirements Related to Border Measures
5. Criminal Procedures

Part IV: Acquisition and Maintenance of Intellectual Property Rights and Related Inter-Partes Procedures

Part V: Dispute Prevention and Settlement

Part VI: Transitional Arrangements

Part VII: Institutional Arrangements; Final Provisions

b. Text

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

(d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and

(e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

Part I: General Provisions and Basic Principles

Article 1: Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.[1] In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.[2] Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

Article 2: Intellectual Property Conventions

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[1] When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[2] In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3: National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection[3] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4: Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

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[3] For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

Article 5: Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6: Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7: Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8: Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Part II: Standards Concerning the Availability, Scope and Use of Intellectual Property Rights

Section 1: Copyright and Related Rights

Article 9: Relation to the Berne Convention

1. Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6*bis* of that Convention or of the rights derived therefrom.

2. Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 10: Computer Programs and Compilations of Data

1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).

2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations

shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

Article 11: Rental Rights

In respect of at least computer programs and cinematographic works, a Member shall provide authors and their successors in title the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. A Member shall be excepted from this obligation in respect of cinematographic works unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

Article 12: Term of Protection

Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

Article 13: Limitations and Exceptions

Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

Article 14: Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.

2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.

3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).

4. The provisions of Article 11 in respect of computer programs shall apply *mutatis mutandis* to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such

system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

5. The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, mutatis mutandis, to the rights of performers and producers of phonograms in phonograms.

Section 2: Trademarks

Article 15: Protectable Subject Matter

1. Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

2. Paragraph 1 shall not be understood to prevent a Member from denying registration of a trademark on other grounds, provided that they do not derogate from the provisions of the Paris Convention (1967).

3. Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.

4. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark.

5. Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the registration. In addition, Members may afford an opportunity for the registration of a trademark to be opposed.

Article 16: Rights Conferred

1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

2. Article 6bis of the Paris Convention (1967) shall apply, mutatis mutandis, to services. In determining whether a trademark is well-known, Members shall take account of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark.

3. Article 6bis of the Paris Convention (1967) shall apply, mutatis mutandis, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use.

Article 17: Exceptions

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

Article 18: Term of Protection

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

Article 19: Requirement of Use

1. If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.

2. When subject to the control of its owner, use of a trademark by another person shall be recognized as use of the trademark for the purpose of maintaining the registration.

Article 20: Other Requirements

The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

Article 21: Licensing and Assignment

Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

Section 3: Geographical Indications

Article 22: Protection of Geographical Indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

(a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;

(b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967).

3. A Member shall, ex officio if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.

4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Article 23: Additional Protection for Geographical Indications for Wines and Spirits

1. Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as “kind”, “type”, “style”, “imitation” or the like.[4]

2. The registration of a trademark for wines which contains or consists of a geographical indication identifying wines or for spirits which contains or consists of a geographical indication identifying spirits shall be refused or invalidated, ex officio if a Member’s legislation so permits or at the request of an interested party, with respect to such wines or spirits not having this origin.

3. In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of Article 22. Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.

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[4] Notwithstanding the first sentence of Article 42, Members may, with respect to these obligations, instead provide for enforcement by administrative action.

4. In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

Article 24: International Negotiations; Exceptions

1. Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23. The provisions of paragraphs 4 through 8 below shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.

2. The Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. The Council shall take such action as may be agreed to facilitate the operation and further the objectives of this Section.

3. In implementing this Section, a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement.

4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (a) for at least 10 years preceding 15 April 1994 or (b) in good faith preceding that date.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or
(b) before the geographical indication is protected in its country of origin;
measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO Agreement.

7. A Member may provide that any request made under this Section in connection with the use or registration of a trademark must be presented within five years after the adverse use of

the protected indication has become generally known in that Member or after the date of registration of the trademark in that Member provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Member, provided that the geographical indication is not used or registered in bad faith.

8. The provisions of this Section shall in no way prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.

9. There shall be no obligation under this Agreement to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

Section 4: Industrial Designs

Article 25: Requirements for Protection

1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Member shall ensure that requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members shall be free to meet this obligation through industrial design law or through copyright law.

Article 26: Protection

1. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

2. Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

3. The duration of protection available shall amount to at least 10 years.

Section 5: Patents

Article 27: Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are

new, involve an inventive step and are capable of industrial application.[5] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members 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.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28: Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[6] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29: Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

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[5] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

[6] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30: Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

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[7] "Other use" refers to use other than that allowed under Article 30.

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32: Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33: Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[8]

Article 34: Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

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[8] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Section 6: Layout-Designs (Topographies) of Integrated Circuits

Article 35: Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36: Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:[9] importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

Article 37: Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38: Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the

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[9] The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

Section 7: Protection of Undisclosed Information

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[10] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Section 8: Control of Anti-Competitive Practices in Contractual Licences

Article 40

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

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[10] For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

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

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

Part III: Enforcement of Intellectual Property Rights

Section 1: General Oblgations

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

Section 2: Civil and Administrative Procedures and Remedies

Article 42: Fair and Equitable Procedures

Members shall make available to right holders[11] civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 43: Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.

2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

Article 44: Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

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[11] For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 45: Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 46: Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

Article 47: Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

Article 48: Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

Article 49: Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

Section 3: Provisional Measures

Article 50

1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;

(b) to preserve relevant evidence in regard to the alleged infringement.

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.

4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

Section 4: Special Requirements Related to Border Measures[12]

Article 51: Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures[13] to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods[14] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52: Application

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

Article 53: Security or Equivalent Assurance

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[12] Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

[13] It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

[14] For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

Article 54: Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.

Article 55: Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

Article 56: Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.

Article 57: Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority

to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

Article 58: Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

(a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;

(b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;

(c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

Article 59: Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

Article 60: De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.

Section 5: Criminal Procedures

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

Part IV: Acquisition and Maintenance of Intellectual Property Rights and Related *Inter-Partes* Procedures

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

Part V: Dispute Prevention and Settlement

Article 63: Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64: Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

Part VI: Transitional Arrangements

Article 65: Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66: Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67: Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

Part VII: Institutional Arrangements; Final Provisions

Article 68: Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

Article 69: International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 70: Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this

Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions

of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Article 71: Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

Article 72: Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Article 73: Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

7. European Patent Convention

Excerpts from the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, text as amended by the act revising Article 63 EPC of 17

December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998

Article 52 Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53 Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to “ordre public” or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Article 54 Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.

(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Article 55 Non-prejudicial disclosures

(1) For the application of Article 54 a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:

(a) an evident abuse in relation to the applicant or his legal predecessor, or

(b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.

(2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the period and under the conditions laid down in the Implementing Regulations.

Article 56 Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

Article 57 Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Article 58 Entitlement to file a European patent application

A European patent application may be filed by any natural or legal person, or any body equivalent to a legal person by virtue of the law governing it.

Article 59 Multiple applicants

A European patent application may also be filed either by joint applicants or by two or more applicants designating different Contracting States.

Article 60 Right to a European patent

(1) The right to a European patent shall belong to the inventor or his successor in title. If the inventor is an employee the right to the European patent shall be determined in accordance with the law of the State in which the employee is mainly employed; if the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has his place of business to which the employee is attached.

(2) If two or more persons have made an invention independently of each other, the right to the European patent shall belong to the person whose European patent application has the earliest date of filing; however, this provision shall apply only if this first application has been published under Article 93 and shall only have effect in respect of the Contracting States designated in that application as published.

(3) For the purposes of proceedings before the European Patent Office, the applicant shall be deemed to be entitled to exercise the right to the European patent.

Article 61 European patent applications by persons not having the right to a European patent

(1) If by a final decision it is adjudged that a person referred to in Article 60, paragraph 1, other than the applicant, is entitled to the grant of a European patent, that person may, within a period of three months after the decision has become final, provided that the European patent has not yet been granted, in respect of those Contracting States designated in the European patent application in which the decision has been taken or recognised, or has to be recognised on the basis of the Protocol on Recognition annexed to this Convention:

(a) prosecute the application as his own application in place of the applicant,

(b) file a new European patent application in respect of the same invention, or

(c) request that the application be refused.

(2) The provisions of Article 76, paragraph 1, shall apply *mutatis mutandis* to a new application filed under paragraph 1.

(3) The procedure to be followed in carrying out the provisions of paragraph 1, the special conditions applying to a new application filed under paragraph 1 and the time limit for paying the filing, search and designation fees on it are laid down in the Implementing Regulations.

Article 62 Right of the inventor to be mentioned

The inventor shall have the right, vis-à-vis the applicant for or proprietor of a European patent, to be mentioned as such before the European Patent Office.

Article 63 Term of the European patent

(1) The term of the European patent shall be 20 years as from the date of filing of the application.

(2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents:

(a) in order to take account of a state of war or similar emergency conditions affecting that State;

(b) if the subject-matter of the European patent is a product or a process of manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State.

(3) Paragraph 2 shall apply *mutatis mutandis* to European patents granted jointly for a group of Contracting States in accordance with Article 142.

(4) A Contracting State which makes provision for extension of the term or corresponding protection under paragraph 2(b) may, in accordance with an agreement concluded with the Organisation, entrust to the European Patent Office tasks associated with implementation of the relevant provisions.

Article 64 Rights conferred by a European patent

(1) A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.

(2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

(3) Any infringement of a European patent shall be dealt with by national law.

8. Implementing Regulations to the European Patent Convention

Part II – Implementing Regulations to Part II of the Convention:

Rule 23b General and definitions

(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

(2) “Biotechnological inventions” are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(3) “Biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

(4) “Plant variety” means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

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

(6) “Microbiological process” means any process involving or performed upon or resulting in microbiological material.

Rule 23c Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Rule 23d Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(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.

9. Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

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

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 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) 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;

(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 (6);

(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 (7) 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’,

have adopted this Directive:

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.

Article 4

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 in 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 depository 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	For the Council
The President	The President
J. M. GIL-ROBLES	R. EDLINGER