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Contents

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WIPO Meetings

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I. Committee of Experts on Biotechnological Inventions and Industrial Property

Second Session
(Geneva, February 3 to 7, 1986)

NOTE*

Convened by the Director General of the World Intellectual Property Organization (WIPO) as part of the 1986/87 program of the International (Paris) Union for the Protection of Industrial Property, the Committee of Experts on Biotechnological Inventions and Industrial Property (hereinafter referred to as the "Committee of Experts") held its second session in Geneva from February 3 to 7, 1986. Twenty-nine States, five intergovernmental organizations and 18 non-governmental organizations were represented in the session. The list of participants follows this Note.

The Committee of Experts had been convened in order to examine a report prepared by the International Bureau of WIPO, entitled "Industrial Property Protection of Biotechnological Inventions" (hereinafter referred to as the "WIPO report"), the text of which is reproduced below. The WIPO report examines the existing industrial property protection of the various categories of biotechnological inventions (products, processes and uses in respect of plants, animals, microorganisms and other biological material) and considers possibilities of improving the said protection where it appears to be inadequate.

In a general discussion, delegations expressed their appreciation of the WIPO report, as well as of a preliminary study published by the International Bureau that had been prepared by Dr. Joseph Straus (Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich, Federal Republic of Germany). It was, in particular, stated that biotechnology was a newly emerging, vital and economically important field and that biotechnological inventions deserved to be protected adequately by the industrial property system in order to give sufficient incentive to research and development and to ensure adequate returns on investments.

As regards the parts of the WIPO report describing technical developments and categories of biotechnological inventions (paragraphs 23 to 62) and the present situation of industrial property protection of biotechnological inventions (paragraphs 63 to 157), a number of comments were made in order to amend or complete the information provided. As regards the parts of the WIPO report concerning possibilities of improving industrial property protection of biotechnological inventions (paragraphs 5 to 22), a detailed discussion took place during which the following opinions were expressed.

Concerning the question of whether biotechnological inventions are covered by the concept of invention as developed under national industrial property laws, the Committee of Experts agreed with the conclusions presented in the WIPO report that divergencies still existing between various countries in respect of the interpretation of the concept of invention should be overcome, and that the fact that an alleged invention concerns living matter should not be an obstacle to its being recognized as an invention for purposes of its protection under industrial property laws. As regards the case of isolation of an existing microorganism, it was pointed out that if a process of isolation involving an important technical intervention were specified, the microorganism as obtained by the specific method of isolation could be considered as an invention.

The question of exclusion from patent protection of certain sectors of biotechnology was discussed in detail by the Committee of Experts, which, in this respect, focused almost entirely on the exclusion of plant varieties from such protection, as provided for in a number of national laws and in the European Patent Convention. Taking into account the need for strong protection for biotechnological inventions in order to encourage research, the Delegations of Ireland and Japan and several non-governmental organizations stated that the existing exclusion of certain categories of biotechnological inventions, in particular, plant varieties, from patent protection should no longer be maintained. Reference was also made to the recent decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (*Ex parte Hibberd et al.*), which held that no restriction applies in the United States of America to the patenting of plant varieties. Non-governmental organizations representing the interests of plant breeders, as well as the Office of the International Union for the Protection of New Varieties of Plants (UPOV), defended the existing

* Prepared by the International Bureau.

provision in patent laws excluding the patenting of plant varieties and referred to Article 2 of the International Convention for the Protection of New Varieties of Plants, which obliges member States to grant only one form of protection in respect of the same botanical genus or species. With the exception of the Delegations of Ireland and Japan, all other government delegations which spoke on this matter said that the time was not yet ripe for taking a decision on the question of abolishing the exclusion of plant varieties from patenting; those government delegations drew the same conclusion with respect to the exclusion of animal varieties and essentially biological processes, contained in a number of national industrial property laws and in the European Patent Convention. It was pointed out that extensive studies were required in order to determine whether an effect of the exclusion under consideration was that the protection currently offered was not sufficient, and that it would also have to be studied whether the deletion of those exclusions could have the effect of creating a problem of imbalance in the resulting system of protection between the interests of patent owners and other interests involved, in particular, the interests of the public.

As regards the conditions of patentability and their interpretation, the Committee of Experts agreed that the problem of a grace period for disclosures by the inventor before filing a patent application should be solved in a general manner, covering all categories of inventions, and that special treatment for biotechnological inventions should not be provided for.

As regards the condition of industrial applicability, it was pointed out that, as a general rule, the fulfillment of that condition would have to be shown at the time of filing an application for protection and that, if the applicant subsequently submitted additional information, the general rules on the amendment of applications would apply.

The Committee of Experts also examined, in connection with the condition of sufficient disclosure, whether a deposit of a microorganism as such should be considered a sufficient disclosure enabling an average expert to obtain the said microorganism or whether, for the purposes of a product claim with respect to a microorganism, additional information should have to be given in order to enable an average expert to obtain the deposited microorganism (the so-called condition of ("repeatability").

With respect to the requirement of the deposit of microorganisms and conditions for the release of samples, the Committee of Experts examined the question whether the system of deposit should be available, or be made available, not only to microorganisms in the strict sense, but more generally to material that can replicate itself or that can direct its replication. The question was discussed whether, in the light of recent technical developments, it was necessary to clarify the term "microorganism" as used in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

As regards conditions for release of samples, it was suggested that the International Bureau should include the question of the possible harmonization of those conditions in its future studies.

In conclusion, the Committee of Experts suggested to the International Bureau that it continue its study of industrial property protection of biotechnological inventions, taking into account the views expressed during this session, in preparation for the next session of the Committee of Experts, to be held in 1987.

In preparation for that next session, the International Bureau would carry out a study of the existing situation with respect to the legal protection of biotechnological inventions in each field of biotechnology where different forms of protection may be available (process and product protection in respect of plants, animals and microorganisms, and in respect of other areas of biotechnology). The study should include, for the various areas mentioned above, an analysis of the existing possibilities of protection, or lack of protection, by patents and/or by plant variety rights.

In the framework of the study, a comparative analysis of protection of plant varieties under the UPOV Convention, and any patent protection to be established for that area, would be made, which would examine the conditions for granting either one of the rights mentioned above, as well as their scope and effect of protection. This would include an analysis of questions such as the exhaustion of patent rights and dependence of an invention on another invention.

It was suggested that the International Bureau should request each of the non-governmental organizations that were invited to participate in the work of the Committee of Experts to express its views in order to obtain a clearer picture of the different points of view with respect to the question of industrial property protection of biotechnological inventions.

The study of the International Bureau would, naturally, take into account any further developments in the field of industrial property protection of biotechnological inventions about which it is informed before the next session of the Committee of Experts (new legislation or jurisprudence, or new administrative practices).

With respect to the system of deposit of microorganisms, the Committee of Experts suggested to the International Bureau that the questions raised in the WIPO report, and the comments made by the Committee of Experts, should be submitted to the Assembly of the Budapest Union, which could meet in an extraordinary session during the first half of 1987. The Assembly of the Budapest Union could, in particular, consider how far it would be feasible and desirable to establish clear principles as to what could be deposited as a microorganism. Once the Assembly had reached a conclusion on that question, it would have to be examined whether such a conclusion required an

amendment in the Regulations under the Budapest Treaty or whether an agreed statement of the Assembly would be sufficient in order to ensure the desired clarification.

LIST OF PARTICIPANTS*

I. States

Argentina: N. Fasano. **Austria:** K. Wolf. **Belgium:** A.M. Prieels; J. de Brabandere; B. Remiche. **Brazil:** P. de C. Torres de Carvalho; N. Jessen; P.R. França. **Bulgaria:** O. Delev. **Canada:** J. Keon; J.W. Buchanan; A. McDonough. **Denmark:** L. Østerborg; F. Espenhain; O.P. Callesen. **Finland:** H.I. Lommi. **France:** M. Hiance; D. Darmon. **German Democratic Republic:** S. Schröter. **Germany (Federal Republic of):** E. Steup; B.M. Guenzel. **Hungary:** I. Iványi; E. Parragh. **India:** S.R. Tayal. **Ireland:** M. O'Keeffe. **Italy:** M. Carro Sciamanna. **Japan:** K. Ubukata; T. Miyagi; Y. Masuda; T. Sugie. **Madagascar:** R.G. Razafimahefa. **Netherlands:** M.S.M. Groenendijk; K.A. Fikkert. **Nigeria:** I.P. Ojeogwu. **Norway:** P.T. Lossius; E. Liljegren. **Portugal:** J. Mota Maia. **Saudi Arabia:** A.A. Al-Rasheed; S. Al-Mubarak; A. Omair. **Soviet Union:** Y. Gyrdymov; V. Dementiev. **Spain:** E. Rua Benito; F. Ferrandiz Garcia; J. Elena-Rossello; J.R. Prieto. **Sweden:** C. Holtz; R. Walles. **Switzerland:** J.-L. Comte; A. Rosenkranz; S. Pürro; W. Gfeller. **Thailand:** P. Matangkasombut; K. Phutragool. **United Kingdom:** C. Hoptroff; R. Walker. **United States of America:** L. Schroeder; W. Duffey; P.A. Woodring.

II. Intergovernmental Organizations

United Nations Industrial Development Organization (UNIDO): A. Bromley. **World Health Organization (WHO):** T.S.R. Topping. **Commission of the European Communities (CEC):** A. Brun; A. Saint-Rémy. **European Patent Organisation (EPO):** L. Gruszow; C. Gugerell. **International Union for the Protection of New Varieties of Plants (UPOV):** H. Mast; A. Heitz.

III. International Non-Governmental Organizations

Association of Plant Breeders of the European Economic Community (COMASSO): G.J. Urselmann; J. Winter. **Committee of National Institutes of Patent Agents (CNIPA):** U.M. Kinkeldey. **European Federation of Agents of Industry in Industrial Property (FEMIPI):** E. Thouret-Lemaitre; M. Bellenghi; W. Karau; G. Tasset; M. Björn. **European Federation of Pharmaceutical Industries' Associations (EFPIA):** I. Hjertman; G. Tasset; M. Björn. **International Association of Horticultural Producers (AIPH):** M. Slocock. **International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL):** M. Besson; P. Lange. **International Association for the Protection of Industrial Property (AIPPI):** A. Laird. **International Chamber of Commerce (ICC):** J.M.W. Buraas; K.F. Gross; H. Fritel; W. Smolders; M. Björn. **International Community of Breeders of Asexually Reproduced Ornamental and Fruit Tree Varieties (CIOPORA):** R. Royon. **International Federation of Pharmaceutical Manufacturers Associations (IFPMA):** W.K.M. Arnold; D. Laudien. **International Federation of Industrial Property Attorneys (FICPI):** D.G. Bannerman; W. Dost. **International Federation of Inventors' Associations (IFIA):** K.E. Sundström. **International Federation of the Seed Trade (FIS):** H.H. Leenders. **International Group of National Associations of Agrochemical Manufacturers (GIFAP):** B.M. Roth. **Licensing Executives Society (International) (LES):** C.G. Wickham. **Union of European Practitioners in Industrial Property (UEPIP):** M. de Brabanter. **Union of Industries of the European Community (UNICE):** K.F. Gross. **World Federation for Culture Collections (WFCC):** I.J. Bousfield.

IV. Officers

Chairman: J.-L. Comte (Switzerland). *Vice-Chairmen:* K. Ubukata (Japan); Y. Gyrdymov (Soviet Union). *Secretary:* L. Baeumer (WIPO).

V. International Bureau of WIPO

A. Bogsch *(Director General);* K. Pfanner *(Deputy Director General);* L. Baeumer *(Director, Industrial Property Division);* A. Ilardi *(Senior Legal Officer, Industrial Property Law Section, Industrial Property Division);* J. Straus *(Consultant);* M. Weil-Guthmann *(Consultant).*

* A list containing the titles and functions of the participants may be obtained from the International Bureau of WIPO.

II. Industrial Property Protection of Biotechnological Inventions*

TABLE OF CONTENTS

* Report prepared by the International Bureau.

I. Introduction

1. Within the framework of WIPO's program for the 1984-1985 biennium, the Committee of Experts on Biotechnological Inventions and Industrial Property (hereinafter referred to as the "Committee of Experts") held its first session in November 1984. It discussed a memorandum, prepared by the International Bureau of WIPO, entitled "Industrial Property Protection of Biotechnological Inventions" (document BioT/CE/I/2, hereinafter referred as the "memorandum"), and recommended that WIPO prepare a study as outlined in the memorandum and taking into account the observations made during the session of the Committee of Experts (see document BioT/CE/I/3, paragraph 106).

2. The present report constitutes the study referred to in paragraph 1, above. In addition to the observations made during the first session of the Committee of Experts, it takes into account an analysis of certain basic issues, prepared at the request of the International Bureau of WIPO by Dr. Joseph Straus, Head of Department, Max-Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich, Federal Republic of Germany (document BIG/281, issued in July 1985). Certain parts of this report to some extent use the explanations contained in document BIG/281, which can be consulted for further reference. A glossary of scientific terms used in the report is contained in Annex I.

3. The present report has been prepared in accordance with WIPO's program for the 1986-1987 biennium. It has been submitted to a Committee of Governmental Experts, in which interested non-governmental organizations have also been invited to participate. Although the representatives of such organizations are called observers, they will be given full opportunity to speak during the Committee's meetings.

4. The Committee of Experts is invited to give advice to the International Bureau of WIPO in respect of any question—whether mentioned in the present report or not—considered by it to be relevant to the protection of biotechnological inventions. It is, in particular, invited to express its views on the suggestions made in Part II (Possibilities for Improvement of Industrial Property Protection of Biotechnological Inventions) of this report, including the question of the desirability of revising the Regulations under the Budapest Treaty so as to permit clearly the international deposit under that Treaty of biological material that is not necessarily a microorganism.

II. Possibilities for Improvement of Industrial Property Protection of Biotechnological Inventions

A. General

5. In Part IV of this report, the existing industrial property protection of biotechnological inventions will be examined. In the course of that examination, certain shortcomings in the existing system of industrial property protection will be considered, as well as a diversity of solutions in respect of the questions examined. In the present Part, suggestions are made for improving the existing situation and, at the same time, wherever feasible, for arriving at solutions that could be applied in a great number of countries. The suggestions do not deal with all the shortcomings described in this report; they concentrate on those issues which appear to be the most important ones and in respect of which an improvement appears to be both urgently required and feasible.

6. Since the present report deals with industrial property protection of biotechnological inventions, various possible industrial property titles for the protection of inventions are to be considered. This means that, in addition to patents for inventions, inventors' certificates and utility certificates are to be taken into account. Utility models are to be considered to the extent that they are available for all kinds of inventions and not only for mechanical inventions, as is the case in some countries. Plant variety rights are not considered in all their aspects, since they are not regulated in industrial property laws but in special laws whose execution is entrusted to special authorities distinct from the industrial property office. Nevertheless, plant variety rights are taken into account to some extent in this report because their availability is an important factor in the determination of the availability of industrial property protection for biotechnological inventions.

7. Since the conditions of protection are, basically, the same for all industrial property titles for the protection of inventions, the report does not distinguish between the various industrial property titles of protection. Therefore, the terms "patent" or "patent application" are to be understood as relating also to any other title of protection for an invention that is available under the applicable industrial property law.

B. The Concept of Invention

8. As shown in Part IV (Chapter B, paragraphs 64 to 81), industrial property protection of biotechnological inventions raises important

questions with respect to the concept of invention. Although, particularly in view of recent court decisions in various countries, considerable progress has been made towards achieving a uniform concept of invention, important divergencies still subsist. Because of those divergencies, a biotechnological invention for which a patent has been granted in one country might not be recognized as an invention in other countries. It is, therefore, essential to reach agreement on the concept of invention, and its application, in the area of biotechnology.

9. When examining the various kinds of possible inventions in the field of biotechnology, a distinction is to be made between inventions concerning products, inventions concerning processes, and inventions concerning application of products for a particular use.

10. As regards inventions concerning products (in particular, inventions relating to new plants, animals, microorganisms or biological material, whichever method was used to obtain them), the fact that an alleged invention concerns living matter should not be an obstacle to its being recognized as an invention for purposes of the industrial property law. Thus, it should be recognized that plants, animals and microorganisms could be inventions. However, an alleged invention must "teach" in the sense that it explains how to achieve a certain result; for example, in the case of isolation of an existing microorganism, the invention would consist of the microorganism obtained by a specific method of isolation.

11. In respect of inventions concerning processes, there does not seem to be any specific problem in the field of biotechnology. The biotechnological nature of certain processes should not form an obstacle to the recognition of such processes as inventions under industrial property laws.

12. The same considerations as those presented in the preceding paragraph apply to inventions relating to the application of a particular plant, animal, microorganism or biological material for a particular use.

C. Exclusion from Patentability of Certain Sectors of Biotechnology

13. As explained in Part IV (Chapter C, paragraphs 82 to 119), certain national laws do not permit the patenting of plant varieties, animal varieties and essentially biological processes for the production of plants or animals. As explained in the said Chapter, such an exclusion is no longer justified. All biotechnological inventions should be eligible for patent protection, and patents should be granted therefor, provided that the normal requirements of patentability are fulfilled, namely the requirements of novelty, inventive step, industrial applicability and sufficient disclosure. An inventor who can describe his invention in a manner that constitutes a sufficient disclosure should therefore be able to obtain a patent. As regards plant varieties and animal varieties, however, there may be many cases where an inventor cannot sufficiently describe his invention. It is this inability that should be the reason for not granting a patent; thus, a provision of the law excluding plant varieties and animal varieties from being patented goes too far because it excludes inventions from being patented even if the inventor furnishes a full disclosure.

14. If the above principle is accepted, a particular question arises with respect to inventions which qualify at the same time for the grant of a special plant variety right. Should one and the same invention at the same time be eligible for a patent and for a plant variety right? If the answer to this question is in the affirmative, the consequence would be that the inventor would have, in addition to an exclusive right concerning the distribution of propagation material, an exclusive right concerning the "manufacture" and sale of the plant. Such accumulation of rights does not appear to be harmful *per se*. Similar situations may arise with other intellectual property creations which may enjoy two different kinds of protection (e.g., industrial designs, which may be protected under copyright law and under a special law). In principle, therefore, the availability of patent protection and the availability of special plant variety protection should not be mutually exclusive, and plant breeders should continue to have the possibility of special plant variety protection, which is a suitable system for the protection of living, self-producing matter. Nevertheless, it might be worth studying whether or not there are reasons to limit the choice of the inventor so that, in respect of an invention consisting of a plant variety, he could choose between the two forms of protection, but could not obtain double protection.

D. Conditions of Patentability and Their Interpretation

15. As a general rule, biotechnological inventions should not be subjected to special conditions in respect of the appreciation of their patentability and to special rules as regards the interpretation of those conditions. This means, in particular, that there should not be a special standard of novelty and inventive step in respect of biotechnological inventions. For example, if a need exists in the case of biotechnological inventions to recognize a period of grace for disclosures made by the inventor before filing a patent application, this need should not be understood as being restricted only to biotechnological inventions. A period of grace, therefore, should not be established only for biotechnological inventions but for all kinds of inventions.

16. Likewise, as regards the condition of industrial applicability, no special considerations should apply to biotechnological inventions. The test, therefore, should be whether an invention, at the time of filing the application, could be considered as giving rise to a possible industrial application without requiring that the specific industrial application be described already at that time. Consequently, if proposals made *de lege ferenda* were implemented to the effect that industrial applicability would not be necessary at the time of filing but could be established at some time before the date of the grant of the patent, such a change in the application of the criteria of industrial applicability should not be limited to biotechnological inventions but should apply to all technical fields.

17. As regards the condition of sufficient disclosure, in certain cases it is particularly difficult to describe biotechnological inventions because the particular features of living entities cannot always be described by words in a manner enabling an expert to repeat the invention. For this reason, the system of deposit of microorganisms has been established and adopted by many countries. The possible extension of that system to matters other than microorganisms will be discussed in the following chapter. Insofar as it might not be possible to use the deposit system because the matter to be deposited cannot be accepted for deposit, the disclosure may consist only of a description by words and symbols, possibly supplemented by drawings. If those means do not suffice for making a full disclosure, a patent may not be granted. This rule will have the function of automatically limiting patent protection in the field of biotechnology, a function that is compensated for by the availability of a special system of protection for plant varieties. In this connection, the question arises whether such a special system of protection should be established also for animal varieties (see below, paragraph 22). In respect of microorganisms, however, the possibility of deposit, where permitted, always ensures sufficient disclosure as required by patent laws, which makes a special system of protection unnecessary.

E. Requirement of Deposit of Microorganisms and Condition for Release of Samples

18. Divergencies seem to exist with respect to the possibility of supplementing a written disclosure by reference to the deposit of a microorganism, because not all countries have expressly provided for such a possibility. It should therefore be recommended that countries which have not so far recognized the possibility of deposit should do so and should also become party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the "Budapest Treaty").

19. Recent experience with the deposit system shows that not only living microorganisms are accepted for deposit but also biological material (plasmids, cell lines, seeds, etc.). Such an extension appears to be desirable, provided that each deposit is supplied and maintained in a manner which allows it to be kept for a certain duration (the Budapest Treaty requires a minimum period of 30 years of storage). In this connection, it should be required either that the deposited microorganism be viable (this is the terminology used by the Budapest Treaty), or, alternatively, that it be biologically active. In order to clarify the system of the Budapest Treaty in respect of biological material that does not consist of microorganisms, it would appear to be necessary to amend the Regulations under the Budapest Treaty in order to ensure that biological material that does not consist of microorganisms may

be deposited with an international depositary authority, provided that details of the conditions for storing and testing the biologically active properties of the biological material are indicated by the depositor and that the international depositary authority tests the biologically active properties of the said material; certain provisions of the Regulations, in particular those concerning the scientific description and proposed taxonomic designation, would have to be adapted accordingly. If those amendments were effected, it would not appear to be necessary to revise the Treaty itself.

20. As regards the conditions for the release of samples, certain divergencies exist at present. These conditions are frequently the result of policy decisions taken after intensive discussion with interested circles (see, for example, the so-called "expert solution" adopted under the European Patent Convention). Although a harmonization of those conditions would be desirable, it appears to be difficult to reach a uniform solution within a reasonable period of time. This matter should therefore be reserved for further study, taking into account the practical experience gained with the existing conditions in the coming years.

F. Special Titles of Protection in Respect of Biotechnological Inventions

21. The special system of protection for plant varieties possibly could be further developed. In particular, the possibility of an exclusive right which would not only cover the propagating material but also the plant as such could be examined, taking into account Article 5(4) of the UPOV Convention. This is a matter which should be pursued within the framework of UPOV, however.

22. The question arises whether a special system of protection should be established for animal varieties. There seems to be a difference, in commercial practices, between plant varieties and animal varieties in that, with respect to the former, an important trade in propagating material has given rise to the need for protection, whereas, with respect to the latter, there does not—or not yet—seem to be a need for establishing an exclusive right with respect to the commercialization of propagating material. Thus, at the present stage, patent protection, without the currently existing restriction in some laws, would seem to be fully sufficient. However, it is recommended that this question be reserved for a further study, taking into account future developments in animal breeding as well as economic developments. A possible outcome of such a study could be a recommendation to establish a special system for the protection of animal varieties and a special convention, following the example of the UPOV Convention.

III. General Features of Biotechnology

A. General

23. Biotechnological inventions constitute a category of technology that, although of particular economic importance to all countries, has given rise to considerable difficulties in their legal treatment. The present situation concerning protection of biotechnological inventions is characterized by uncertainties and controversies, which can only be harmful for the creators and users of biotechnological inventions and for the public interest in general.

24. Why did uncertainties and controversies arise? Mainly because of two problems: firstly, it appeared doubtful whether protection should be granted for inventions relating to living matter; traditionally, technology had been understood as an art to cause certain effects in inanimate matter; secondly, because of the unique features of each living entity, it appeared difficult, if not impossible, to describe biotechnological inventions in a manner enabling an expert to repeat the result obtained by the inventor. Because of those problems it was argued, for example, that patent laws were unable to provide adequate protection for new varieties of plants. Thus, when an economic need arose for the protection of plant varieties, a special system of protection, outside the area of patent law, was established in a number of countries and also at the international level. On the other hand, after decades of legal uncertainty, it was only in the late 1960s and in the 1970s, that the highest courts of some countries recognized, under certain conditions, the principle of patent protection for inventions in the field of living matter. In addition, specific legal developments, originating in Europe, led in a number of countries to a situation where plant and animal varieties and essentially biological processes for the production of plants or animals are excluded from patent protection and, on the other hand, microbiological processes and the products thereof are declared as eligible for patent protection.

25. The existence of two different systems of protection, and the provisions explicitly excluding certain inventions from patent protection, while explicitly including others, which all relate to subject matter affected by new technologies in the field of biotechnology, make it necessary to consider the area of biotechnology as a whole before a decision is taken on the extent to which new technology developed in that field qualifies as an "invention." Within this framework it will also be necessary to consider the effect which the remarkable extension of the scientific foundations of biology has had in providing for new, previously unknown, methods for the description of processes in the area of living matter. The fact that microbiological inventions were expressly not excluded from patent protection shows that the legal treatment of biotechnological inventions is less influenced by theoretical principles (e.g., the principle that technology does not comprise inanimate matter) than by economic considerations (the need to grant patent protection to microbiological inventions in order to encourage industry to invest for research in this area). Likewise, the argument that biotechnological inventions cannot be sufficiently described has been overcome by the establishment of a special system of disclosure of living organisms and biological material, providing for deposits of such organisms and material and release of samples to interested parties who have a right to a sample.

B. Subject Matter of Biotechnology

26. Although biotechnology has been called "the last major technological revolution of this century,"[1] it is indeed one of the oldest technologies. "Bios" in ancient Greek means life, and "biotechnology" seems to comprise any technology that uses living entities, in particular animals, plants or microorganisms, or causes organic changes in them. In fact, from the very beginning of civilization, man has deliberately *selected* organisms (animals, plants and microorganisms) that improve agriculture, animal husbandry, baking and brewing. However, the human possibilities of *intervening* in the process of nature, or exploiting it, for a long time remained very limited. Only in the middle of the last century scientific developments started that led first to a better understanding of genetics and to more effective application of traditional genetics and subsequently, in the course of the last decade, to new developments in selecting and manipulating genetic material.

27. Despite the long standing tradition of biotechnological activities, there is so far no generally agreed definition of the term "biotechnology." However, several attempts of a definition recently were made: in its first report, the Office of Technology Assessment of the United States Congress (OTA)[2] defined biotechnology as "the collection of industrial processes that involve the use of biological systems,"[3] and stated that "biotechnology involves the use in industry of living organisms or their components (such as enzymes)."[4] Only three years later, in its second report,[5] OTA offered a much more detailed definition, according to which, "biotechnology includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."[6] In the glossary to the same OTA Report it is furthermore explained that biotechnology includes "commercial techniques that use living organisms, or substances from those organisms, to make or modify a product, and including techniques used for the

[1] See Office of Technology Assessment of the United States Congress (OTA), Commercial Biotechnology, An International Analysis, Washington, D.C., 1984 (OTA report 1984), p. 11.

[2] Impacts of Applied Genetics, Microorganisms, Plants, and Animals, Washington, D.C., 1981 (OTA Report 1981).

[3] OTA Report 1981, Glossary, p. viii.

[4] OTA Report 1981, p. 4.

[5] OTA Report 1984.

[6] OTA Report 1984, p. 3.

improvement of the characteristics of economically important plants and animals and for the development of microorganisms to act on the environment."[7] A more abstract definition can be found in a study prepared under the auspices of the Organisation for Economic Cooperation and Development (OECD) by Bull, Holt and Lilly, in which biotechnology is defined as "The application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services."[8] In this definition, the term "biological agents" refers to a wide range of biological catalysts, particularly to microorganisms, enzymes and animal and plant cells, and the concept of "materials" includes both organic and inorganic materials.[9] Although the authors of the said OECD study admitted that agriculture and traditional crop and animal breeding should not generally be regarded as biotechnology, they emphasized that certain aspects of these activities must be taken into consideration since plants provide raw material for most biotechnological processes and that biotechnology, through the production of microbial pesticides and the use of modern genetic manipulation techniques for the development *in vitro* of animal and crop varieties and improved nitrogen fixing capabilities, would have a profound impact upon agriculture in the future.[10]

28. Taking into account the above proposals for definitions, the following conclusions can be drawn for the purposes of this report.

(a) General agreement exists insofar as the term "biotechnology" is not considered as being limited to living entities, but as including a wide range of biological material, such as animal and plant cells,[11] animal and plant cell lines,[12] enzymes,[13] plasmids[14] and viruses,[15] all of which can have a substantial function in industrial applications similar to the industrial application of microorganisms.

(b) Due to the rapid scientific development in this field, any attempt to define biotechnology in a comprehensive but also, at the same time, precise way must fail. From the legal point of view, such a definition would entail considerable risks.

29. The subject of this study, however, does not depend on a precise definition of biotechnology since, in any case, all technological developments concerning organisms (which include animals, plants and microorganisms) and other biological material are to be covered and since, as will be shown later in this report (see Part III, Chapter D, paragraphs 50 to 62), the distinction between biotechnological inventions and other inventions has no legal consequences because no special treatment of biotechnological inventions will be proposed only on account of their being biotechnological in nature. Therefore, this report will apply an empirical approach, covering everything which generally is considered as biotechnology.

30. Three different categories of biotechnological inventions may be distinguished, namely: inventions relating to an organism or material *per se*, inventions relating to a process for the creation of a living organism or the production of other biological material, and inventions relating to the use of an organism or material. Within those categories, the following subcategories may be distinguished.

(a) Products

(aa) Living entities of natural or artificial origin, such as animals, plants and microorganisms, biological material, such as plasmids, viruses and replicons,[16] and parts thereof, such as organs, tissues, cells and organelles.[17]

(bb) Naturally occurring substances (primary and secondary) from living entities, biological material and parts thereof, according to (aa).

(b) Processes Including Those of Bioconversion,[18] Cultivation, Isolation, Multiplication and Purification

(aa) For the creation of products according to (a).

(bb) For the production of substances through bioconversion using products according to (a) (e.g., enzymatic conversion of sugar to alcohol).

(c) Uses

Of products according to (a) for any purpose (e.g., the use of bacillus thuringiensis as an insecticide, of monoclonal antibodies for analytics or diagnostics, etc.).[19]

31. There are many areas in which inventive work in the field of biotechnology is most active and in which the results of that work seem to have great economic importance. Those areas concern, for example:

pharmaceuticals—e.g., production of regulatory proteins,[20] blood products, vaccines, antibiotics, monoclonal antibodies,[21] DNA hybridization probes;[22]

animal agriculture—e.g., diagnosis, prevention and control of animal diseases, animal nutrition and growth promotion, genetic improvement of animal breeds;

plant agriculture—e.g., improvement of specific plant characteristics, use of microorganisms for crop improvement;

aquaculture—use of marine microorganisms with unusual capabilities, fish culturing, prevention and control of fish diseases;

speciality chemicals and *food additives*—e.g., amino acids,[23] enzymes, single cell proteins, complex lipids,[24] steroids,[25] aromatic specialty chemicals, polysaccharides,[26] biopolymers;[27]

environmental applications—pollution control and toxic waste treatment, microbial mining, microbial enhanced oil recovery;

commodity chemicals and *energy production*—e.g., biomass resources,[28] conversion of biomass to commodity chemicals; bioelectronics—e.g., biosensors,[29] biochips.[30]

32. The present state of development in the aforementioned areas is not uniform. The most outstanding progress has doubtless been achieved in the field of pharmaceuticals: the first therapeutic agent produced by means of recombinant DNA, human insulin, has been on the market since 1983, the same applies to a number of *in vitro* diagnostic products using monoclonal antibodies. In addition, a great number of alpha and beta interferons to treat human viral diseases and

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[7] OTA Report 1984, p. 589. Here OTA also clarifies that it is using the term biotechnology in its report in a sense which only includes the use of novel biological techniques—specifically, recombinant DNA techniques, cell fusion techniques, especially for the production of monoclonal antibodies and new bio processes for commercial production ("new biotechnology") leaving aside the traditional forms, e.g., methods of making bread, beer and wine, etc. ("old biotechnology").

[8] Bull, Holt, Lilly, Biotechnology, International Trends and Perspectives, OECD, Paris, 1982, p. 21.

[9] Bull, Holt, Lilly, *op. cit.*, footnote 8, p. 21.

[10] Bull, Holt, Lilly, *op. cit.*, footnote 8, p. 22.

[11] See glossary (Annex I).

[12] See glossary (Annex I).

[13] See glossary (Annex I).

[14] See glossary (Annex I).

[15] See glossary (Annex I).

[16] See glossary (Annex I).

[17] See glossary (Annex I).

[18] See glossary (Annex I).

[19] It should be noted that in this system of categories, an overlapping of biotechnology and chemical technology is possible: e.g., carrier bound enzymes can be treated as a part of biotechnology (enzyme) or polymer chemistry (carrier), the same applies to synthesized natural substances, such as alcaloids, protcins or nucleic acids.

[20] See glossary (Annex I).

[21] See glossary (Annex I).

[22] See glossary (Annex I).

[23] See glossary (Annex I).

[24] See glossary (Annex I).

[25] See glossary (Annex I).

[26] See glossary (Annex I).

[27] See glossary (Annex I).

[28] See glossary (Annex I).

[29] See glossary (Annex I).

[30] See glossary (Annex I).

cancer, produced by recombinant DNA techniques, are undergoing clinical tests. Remarkable results have also been achieved, e.g., in developing human growth hormones, immunotoxins[31] for the treatment of cancer and "Factor VIII" to treat haemophiliacs.

33. In biotechnological areas other than the area of pharmaceuticals important progress has been made. For example, in the field of animal agriculture, a monoclonal antibody against scours, a potentially lethal form of diarrhea, which kills over one million calves in the United States of America alone every year, has been successfully developed. Moreover, a system of transferring embryos of cattle has been introduced, which seems to be of outstanding importance for animal breeders in developing countries; according to that system, embryos to be transferred result from the artificial insemination of cows with semen from prize bulls; the cows receive hormones so that each one produces up to 10 fertile eggs; the embryos are flushed out with a fluid, transported in flasks filled with liquid nitrogen and impregnated in the wombs of their surrogate mothers; the embryos can pick up from the bloodstream of their surrogate mothers some of the latters' resistance to diseases.

C. Technological Developments

34. When considering technological developments in the field of biotechnology, the most recent technological achievements, commonly labeled "genetic engineering," certainly deserve particular attention. However, the present report does not limit itself to a consideration of the said technologies and generally does not distinguish between the various technologies involved when discussing pertinent questions of protection under industrial property laws or other systems of protection. Indeed, the term "genetic engineering" is not equivalent to "artificial modification of the hereditary material of animals, plants and microorganisms," but is only one possible method, or rather, a bunch of methods for such modifications. Artificial modification of the hereditary material of animals, plants and microorganisms has been successfully applied for a long time in animal and plant breeding, and to a certain extent also in microbiology. The main difference between the so-called traditional methods and those newly emerging consists of the ability of the latter methods to overcome biological barriers previously existing when manipulating hereditary material, e.g., interspecific and intraspecific incompatibilities that constituted a barrier to the "traditional" plant breeding methods. The main limitation to sexual crossing is interspecific and intraspecific incompatibility. Only newly emerging technologies, such as somatic cell hybridization, offer controlled methods of circumventing the sexual barriers. Altogether, it seems preferable not to use the term "genetic engineering" as an all-embracing designation when referring to the new fundamental achievements in biotechnology, but to present the new achievements after having first explained the "traditional" methods.

(a) The Traditional Methods of Breeding Plants and Animals and Treating Microorganisms

(i) Plant Breeding

35. Plant breeding has a long tradition. In the course of domestication of plants by men, many improvements have been made by simple *selection* of variants within a single species, e.g., tomato, rice, maize. A characteristic feature depending on a single continuous mutation has often been directly selected to create a new variety. A further augmentation of genetic diversity produced by gene mutation has been achieved by deliberate hybridization, which will be explained in the following paragraph. Moreover, subsequent gene recombination has enabled selection to be made of new varieties for different purposes and adapted to different conditions. Thanks to this intraspecific variation, known as *Mendelian segregation and recombination*, great advances in the improvement of important crops (e.g., beans, beet, carrots, soya beans and tomatoes) and horticultural plants have been achieved since the beginning of this century. The basis for the genetic improvement of crop plant species by scientific methods was first laid down by Darwin in his writings on the variation of life species (1859) and more specifically Mendel's discovery of the laws of heredity (1865).

36. As knowledge of genetics and plant pathology increased during the first and second decades of this century, a further method, which had its roots in the 19th century, namely the method of *hybridization*, yielded the most important improvements in plant breeding. With this method, repeated cycles of self-fertilization reduce the heterozygosity[32] in a plant so that after numerous generations the breeder has homozygous[33] pure lines that breed true. Cross-fertilization, on the other hand, results in a new mixture of genes or increased genetic variability. Using these two approaches in combination produces a *hybrid*—several lines are inbred for homozygosity and then crossed to produce a parental line of enhanced genetic potential. The effects of hybrid vigor vary and include earlier germination, increased growth rate or size, and greater crop uniformity. However, hybrids are often sterile, which means that propagating material can be obtained only by continuous crossing of the parental lines.

37. Two further plant breeding methods should also be mentioned here: ploidy and so-called backcrossing. *Ploidy*[34] is a method for exchanging or adding genes through altering the number of chromosomes. Since chromosomes are generally inherited in sets, plants whose ploidy is increased usually gain full sets of new chromosomes. Generally, crop improvement due to increased ploidy corresponds to an overall enlargement in plant size, e.g., larger flowers, fruits or seeds. *Backcrossing* stands for a technique capable of improving a commercially superior variety by lifting one or more desirable traits from an inferior one. This can be done by making a series of crosses from the inferior to the superior plant while selecting for the desired traits in each successive generation. Self-fertilizing the last backcrossed generation results in some progeny that are homozygous for the genes being transferred and are identical with the superior variety in all other respects. Single gene resistance to plant pest and disease-causing agents has been successfully transferred by this method.

38. Finally, reference should be made to *mutation breeding*, where the breeder induces changes in a genotype by means other than crossing, e.g., by using X-rays.

39. In addition to the plant breeding techniques mentioned above, attention should be drawn to a method known as *plant tissue culture*, which on the one hand forms a part of already well-established plant breeding techniques, but at the same time serves as a basis for breeding methods which can be considered as a part of genetic engineering. Following the successful propagation, in the 1930s, of plant organs and tissues in culture, the techniques of culture *in vitro* have been extended to many species. Thanks to advances in the knowledge of plant hormones, regeneration of plants from cultured tissue was achieved in the late 1950s. This technique was first applied to the clonal multiplication of plants. The ability to regenerate large numbers of plants from masses of disorganized tissue (Callus) proliferated *in vitro* and from cultured organs and auxillary buds proved more efficient than conventional methods of asexual plant propagation. Subsequently, in 1960, it was demonstrated that single cultured cells plated in an agar medium would divide and form callusses, and an enzymatic procedure for isolating large numbers of protoplasts[35] from higher plant tissues was developed; in 1965, the ability to generate a whole organism from a single plant cell was demonstrated by accomplishing the development of a complete and fertile plant from a single isolated somatic cell; only two years later, haploid[36] plants were obtained from immature pollen (microspores) contained within cultured Datura anthers; in 1971 plants from cultured tobacco protoplasts were regenerated. Moreover, some of the plant tissue culture techniques, such as *in vitro cloning* or asexual propagation, became standard propagation procedure for numerous commercial horticulture operations.

(ii) Animal Breeding

40. In the field of animal breeding developments took place which are similar to those in the field of plant breeding. Until the end of the last century, selection was the only method of improvement of animal varieties. During the first half of the twentieth century, breeding objec-

[31] See glossary (Annex I).

[32] See glossary (Annex I).

[33] See glossary (Annex I).

[34] See glossary (Annex I).

[35] See glossary (Annex I).

[36] See glossary (Annex I).

tives became more complex; farmers and breeders began to look at qualities other than mere external physical attributes. Breeding for multiple purposes led directly to the beginning of the "scientific" era in breeding, for which the scientific basis, however, only developed relatively slowly. The so-called "scientific" era, which started in the 1950s, is characterized by the use of sperm storage, artificial insemination, estrous synchronization,[37] superovulation,[38] embryo recovery, transfer and storage, sex selection and twinning. By combining two or several of the said methods almost total control of the reproductive process of farm animals can be achieved. Moreover, techniques of embryo transfer form also the basis for further breeding techniques, e.g., *in vitro* fertilization, parthenogenesis,[39] production of identical twins, cloning, cell fusion, chimeras and even recombinant DNA technology. However, these techniques do not yet seem to be sufficiently developed for commercial application.

(iii) Industrial Microbiology

41. Applied microbiology has been practiced for thousands of years, for example in fermentation (e.g., the conversion of sugar to alcohol), in the use of yeast in leavened bread and the use of lactic acid bacteria for making cheese. A milestone in microbiology, however, was Pasteur's discovery in the second half of the nineteenth century that fermentation is carried out by living cells. Two other major historical developments were, in the first quarter of the twentieth century, the development of acetone-butanol fermentation with anaerobic bacterium Clostridium acetobutilicum and the discovery that the production of glycerine is promoted by adding sodium sulfite in fermenter. Subsequently, the development of penicillin fermentation marked the beginning of the age of modern industrial microbiology.

42. Among the applications of microbiology, bioconversion is of outstanding importance. *Bioconversions* are reactions in which a compound is converted to a structurally related product by enzymes within a cell; they can be carried out with growing cells, resting vegetative cells, spores or dried cells. A famous example of bioconversion is that of steroids. Thus it became possible to reduce the chemical process converting bile acids to cortisone from 37 to 11 steps, thus decreasing the price from $200 to $6 per gram. Microbial cells can also be used in the area of *sewage treatment*. Such processes can even simultaneously produce energy in the form of methane.

(b) The New Technologies

(i) General

43. In recent years, advanced research in laboratories led to a new, spectacular, method of modifying hereditary material: it has become possible to modify the genes of animals, plants and microorganisms by the introduction of artificially modified hereditary material. One of the bases for this technology was the discovery, made around 1870, that the chief constituents of the cell nucleus were nucleoproteins, a combination of basic proteins and nucleic acid, later established as deoxyribonucleic acid (DNA). About a hundred years later, in 1972, recombinant DNA (rDNA) technology was introduced.

44. DNA is an extremely simple molecule composed of a small sugar molecule, a phosphate group (a phosphorous atom surrounded by four oxygen atoms), and four kinds of simple organic chemicals known as nitrogenous (nitrogen-containing) bases: the phosphates and sugars form two long chains, or backbones, with one nitrogenous base attached to each sugar molecule. The two backbones are held together like the stiles of a ladder by weak attractions between the bases protruding from the sugar molecules. Of the four different nitrogenous bases—adenine, thymine, guanine, and cytosine—attraction exists only between adenine (A) and thymine (T) and between guanine (G) and cytosine (C). Thus, if the sequence of nucleotides on one backbone is: A-T-G-C-T-T-A-A... the other backbone contains the directly opposite complementary sequence: T-A-C-G-A-A-T-T... The complementary pairing between bases running down the center of the long molecule is responsible for holding together the two otherwise independent chains. In the presence of water the two polynucleotide chains do not stretch out to full length, but twisted around each other, forming a *double helix*, which constitutes the hereditary substance of all living matter. By the early 1980s, the process of transcribing DNA's message—carrying the message to the cells' miniature protein factories and building proteins—became clear. Each amino acid in the protein chain is represented by three nucleotides from DNA, those three acting as a word in a DNA sentence that spells out each protein—the genetic code (codon). By means of the genetic code, an entire gene—a linear assemblage of nucleotides—can now be read like a book.

(ii) Recombinant DNA (rDNA) Technology

45. In the early 1960s, scientists for the first time explained how genes from one bacterium move to another. One mechanism accomplishing this interbacterial transfer of genes in nature is *viral transduction*: certain viruses that can infect bacterial cells—bacteriophages—act like hyperdermic needles, injecting their DNA into bacterial hosts. In the host cells they pick up fragments of the bacterial DNA and carry the DNA to other cells in the course of later infection. In another process, known as *transformation*, DNA released by cell death or other natural processes simply enters a new cell from the environment by penetrating the cell wall and membrane. Bacteria also transfer genes directly in a process called *conjugation*, in which one bacterium attaches small projections to the surface of a nearby bacterium. DNA from the donor bacterium is then passed to the recipient through the projections. The ability to form projections and donate genes to neighbors is a genetically controlled trait. The genes controlling this trait, however, are not located in the bacterial chromosomes. Instead, they are located on separate genetic elements called *plasmids*—relatively small molecules of double stranded DNA, arranged as closed circles and existing autonomously within the bacterial cytoplasm (the protoplasm of a cell—the more or less fluid colloidal complex of protein, other organic and inorganic substances, and water—external to the cell's nuclear membrane). Thus, plasmids and phages[40] were identified as the vehicles—or *vectors*—for carrying genes into bacteria. As such, they became tools of genetic engineering, for if specifically selected DNA could be introduced into these vectors, it would then be possible to transfer into bacteria the blueprints for proteins—the building blocks of genetic characteristics. This last step in completing the instruments of genetic engineering became possible after the discovery was made, in 1970, that certain restriction endonucleases, previously described as restriction enzymes, recognized a particular target base sequence in double stranded DNA and broke the polynucleotide chains within the sequence to give rise to discrete DNA fragments of defined length and sequence. By the late 1970s, scores of different restriction enzymes had been isolated from a variety of bacteria, with each enzyme having a unique specificity for one specific nucleotide sequence. These enzymes not only allowed plasmids to be opened up so that new DNA could be inserted, but offered a way of obtaining manageable pieces of DNA as well. With the availability of mechanisms for cutting and joining DNA molecules from different sources, the use of agarose gel electrophoresis to monitor these processes and a means of transforming bacteria with plasmid DNA, the technology of recombinant DNA, commonly known as genetic engineering, was established.

46. The first cloning experiments were reported in 1972. Since then, cloning DNA—i.e., obtaining a large quantity of exact copies of any chosen DNA molecule by inserting it into a host bacterium—became technically relatively simple and widely used. Production of microorganisms with artificially modified hereditary material and of their metabolism products consists mainly of the following process steps:

— making available the desired gene;

— splicing the gene obtained into a vector to form a so-called recombinant vector;

— separating the successfully engineered cells from the unwanted ones;

— culturing (fermenting) the cells thus obtained so that they replicate and produce the desired fermentation product (e.g., the peptide), which then is isolated.

In 1983, for the first time, human insulin produced by rDNA technology reached the market. A number of other products produced by

[37] See glossary (Annex I).

[38] See glossary (Annex I).

[39] See glossary (Annex I).

[40] See glossary (Annex I).

that technology are also already on the market or close to market introduction.

(iii) Somatic Cell Hybridization

47. Yet another possibility of transferring foreign genes into higher plants is what is known as somatic cell hybridization, which uses the rich experience of tissue culture technology. Thanks to the efficient development of enzymatic methods for protoplast[41] isolation in the late 1960s, protoplasts easily became available for fusion studies. In the course of somatic cell hybridization by protoplast fusion, the cells are first isolated from plant tissues, by enzymatically digesting the cell wall in a medium. The protoplasts are then filtered and washed to remove debris and the enzymes. The isolated protoplasts may then be directly cultured by suspension in a growth medium. However, they can also be fused with protoplasts from another species or another genus, which is achieved by adding fusogen (fusion inducing agent) to the medium. In the presence of the fusogen, one cell containing the two nuclei (which may also fuse) and a mixture of the two cytoplasms is formed. Following fusion, the protoplasts are grown in an enriched medium which induces cell wall formation and cell division leading to the development of an aggregate from which callus or cell suspensions can be developed and which can then form a regenerated plant. By using protoplast fusion methods, researchers succeeded in regenerating somatic hybrid plants of potato and tomato, which, however, remained sterile. Commercially more promising, at least for the moment, seems to be the introduction of foreign resistance genes, for example, to make certain plants resistant to disease or herbicides.

48. The potential for improvement of crop plants through rDNA and somatic cell hybridization technologies seems to be vast. Improvements in production of seed proteins, e.g., in the seed protein composition, in nitrogen fixation capabilities, in herbicide, pest and pathogen resistance, in photosynthetic capabilities, in stress tolerance, etc., seem to be possible.

(iv) Monoclonal Antibodies Technology

49. The last technology to be briefly presented here namely the method of producing monoclonal antibodies by using hybridoma technique, is also the newest one. The natural production of antibodies is one aspect of a complex series of events called the immune response in humans and higher animals. When an antigen, usually a protein or carbohydrate, foreign to the body, is introduced, specialized cells called B lymphocytes, present in the spleen lymph nodes and the blood, recognize those substances, and respond by producing antibodies that specifically recognize and bind to those antigens. In 1975, Milstein and Köhler fused myeloma cells[42] with antibody-producing spleen B lymphocytes from mice that had been immunized with sheep red blood cells, and they found that some of the resulting hybrid cells, called hybridomas, secreted large amounts of homogeneous (monoclonal) antibodies directed against sheep red blood cells. The myeloma parent cell conferred on the hybridoma the ability to grow permanently in cell culture and thus to support almost unlimited antibody production, while the B lymphocyte parent contributed the gene's coding for the specific antibody against a sheep red blood cell's antigen. In other words, it became possible to "immortalize" individual antibody-producing cells by fusion with tissue culture-adapted myeloma cells, and to produce large quantities of highly specific monoclonal antibodies against almost any available antigen. A few years later the first products using monoclonal antibodies reached the market, e.g., in the form of *in vitro* diagnostic kits.

D. Categories of Biotechnological Inventions

(a) General

50. Whereas the new technologies present revolutionary features in the field of biotechnology, the other areas of biotechnology (i.e., the traditional methods of plant and animal breeding and traditional industrial microbiology) nevertheless continue to yield new inventions as well. The latter, for the time being and for the foreseeable future, are likely to remain the broad basis of biotechnological activities. The combination of both new and traditional technologies (e.g., rDNA technology or somatic cell hybridization and traditional plant breeding methods) or of different new technologies (e.g., monoclonal antibody technology and rDNA technology) offers vast possibilities for technological development; thus there is a broad range of new technologies being created in this field, each, however, characterized by a different developmental stage.

51. As already indicated,[43] the resulting inventions can be grouped according to the usual distinction made between product inventions, process inventions and application inventions. This distinction does not preclude the combination of several different kinds of claims (product claims, process claims and applications) in one invention, provided that the principle of unity of invention is respected and that the rules of the applicable law concerning the combination of different kinds of claims are complied with.[44]

(b) Inventions Relating to Products (Plants, Animals, Microorganisms and Other Biological Material)

52. The first category of biotechnological inventions (product inventions) concerns "products," that is to say living entities of natural or artificial origin, such as plants, animals and microorganisms, biological material, such as plasmids, viruses and replicons. In addition, parts of plants, etc., such as organs, tissues, cells and organelles, as well as naturally occurring substances (primary and secondary) from living entities (e.g., tobacco leaves, wool), biological material and parts thereof are also included.

53. Plants and animals may be developed either by the traditional methods of plant and animal breeding,[45] by new technologies or by using a combination of the traditional and new technologies.[46] The inventions to be considered here may be either the *plant or animal per se* or the *plant or animal produced by a particular process*. The presentation of an invention as a product that is produced by a particular process may be important for securing industrial property protection, since one of the conditions for granting patent protection for an invention is that it be capable of repeated use merely on the basis of the description, or on the basis of a description in combination with a deposit, and since inventions resulting in new plants or animals *per se* do not always lend themselves to a complete description, but can be described only in combination with the process by which they are produced. Examples are given in Annex II.

54. Not only plants, animals, microorganisms and other biological material and parts thereof as such fall into the product category, but, under certain circumstances, also *products produced by plants*, etc. For example, if a composition for treating human viruses or treating human cancers or tumors were developed using a particular (new or known) polypeptide, the subject of protection would not be the polypeptide as such (which, as in a given case,[47] was a new alpha-type interferon produced by a specific transformed host), but the product developed using the polypeptide.

55. As regards *microorganisms*, a distinction has to be made between the identification and isolation of a microorganism strain that exists in

[41] See glossary (Annex I).

[42] See glossary (Annex I).

[43] See paragraph 29, above.

[44] See, e.g., Rule 13.2 of the Regulations under the Patent Cooperation Treaty (PCT), which reads as follows: "Rule 13.1 shall be construed as permitting, in particular, one of the following three possibilities: (i) in addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process specially adapted for the manufacture of the said product, and the inclusion in the same international application of an independent claim for a use of the said product, or (ii) in addition to an independent claim for a given process, the inclusion in the same international application of an independent claim for an apparatus or means specifically designed for carrying out the said process, or (iii) in addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process specially adapted for the manufacture of the product, and the inclusion in the same international application of an independent claim for an apparatus or means specifically designed for carrying out the process."

[45] See paragraphs 35-40, above.

[46] See paragraphs 45-49, above.

[47] EP patent No. 0032134—August 15, 1984.

nature, and the creation of a new microorganism, in particular by rDNA technology. If a microorganism is only isolated and purified, there arises not only the fundamental question whether the newly isolated microorganism is an invention or a discovery, but also the question whether the specific patentability requirements are met, in particular the requirement of inventive step.[48]

56. In any event, in respect of microorganisms, the same distinction has to be made as for plants and animals, namely between the microorganism *per se*, and the microorganism as produced (or isolated) by means of a particular process.

57. A prominent example of an invention relating to a microorganism *per se* is the invention made by Chakrabarty which concerns a bacterium from a genus pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway;[49]

58. The following examples concern inventions relating to a microorganism as produced (or isolated) by means of a particular process:

— a microorganism transformed by the transfer vector (a recombinant DNA plasmid or bacteriophage) comprising a cDNA sequence comprising coding for the amino acid sequence Pro-Tyr-Arg-Val-Glu-His-Phe...;[50]

— a bacterial cell having ice nuclcation activity as a result of introducing into said cell or a parent of said cell a heterologous DNA sequence derived from *Pseudomonas, Erwinia*, or *Xanthomonas* microorganism encoding for ice nucleation activity or a heterologous DNA sequence encoding for ice nucleation activity and substantially homoduplexing with said DNA derived from said microorganism.[51]

59. With respect to *other biological material*, such as cell lines, enzymes, plasmids, cosmids,[52] etc., various processes for their production may exist, but considerations similar to those concerning microorganisms apply regarding the distinction between products *per se*, and products produced by a particular process.

(c) Processes (Including Those of Bioconversion, Cultivation, Isolation, Multiplication and Purification)

60. The secood category of biotechnological inventions (process inventions) concerns *biotechnological processes* for the creation of plants, animals or microorganisms or parts thereof, for the isolation, purification, cultivation and multiplication of microorganisms or for the production of other biological material or parts thereof. Examples are given in Annex III.

(d) Uses of Plants, Animals, Microorganisms or Other Biological Material

61. The third category of biotechnological inventions (application inventions) consists of uses of a plant, an animal, a microorganism or biological material, e.g.:

— use of the vector according to claim [...] for the transformation and detection of eucaryotic cells capable of expressing the protein which is encoded by the producing DNA, which comprises the carrying out of a culture of eucaryotic cells having deficiency as concerns their endogenous gene of thymidine kinase within a medium in which said deficiency would normally prevent them from growing and in that one produces the cloning of the cells which have grown owing to the incorporation into their genetic patrimony of the said vector.[53]

62. Additional examples would be the industrial use of an existing microorganism or the pharmaceutical application of a microorganism or of a product containing a microorganism or other biological material. It is, however, self-evident that a new use can only constitute an invention eligible for protection where it complies also with other requirements of patentability, e.g., inventive step and industrial applicability.

[48] See below, paragraph 125.

[49] US patent No. 4,259,444—March 31, 1981.

[50] US patent No. 4,322,499—March 30, 1982.

[51] US patent No. 4,464,473—August 7, 1984.

[52] See glossary (Annex I).

[53] EP patent No. 0022685—January 25, 1984.

IV. Industrial Property Protection of Biotechnological Inventions

A. General

63. The examples given in the preceding Part[54] for different categories of biotechnological inventions clearly reveal a high degree of interrelationship, and even interdependency of various fields of biotechnology. Therefore, when considering questions of legal protection, the whole area of biotechnology must be considered.

B. Biotechnology and the Concept of Invention

64. One of the most important problems raised in respect of biotechnological inventions is that of the extent to which the traditional concept of invention, as currently applied for the purposes of industrial property protection, covers those inventions. A distinction will be made between the various biotechnological inventions outlined in Part III, Chapter D, namely:

— plants, animals, microorganisms and other biological material and parts thereof,

— biological processes for the creation and production of plants, animals, microorganisms or other biological material, including those of isolation, purification, cultivation and multiplication,

— uses of plants, animals, microorganisms or other biological material and parts thereof.

65. The concept of invention seems to be of particular importance when considering the first category, that is to say plants, animals or other biological material, in respect of which there has been a considerable restriction of protection. The said restriction is mainly as a result of:

— the distinction made for legal purposes between inventions and discoveries and

— the condition that the invention must be a technical one and the restrictive interpretation of that condition.

(a) Distinction between Inventions and Discoveries

66. When defining what constitutes an invention, for the purposes of industrial property protection, it is usual to distinguish between an invention and a discovery. However, the use of the term "discovery" in different national laws is not uniform. Whereas the patent laws of most countries explicitly exclude "discoveries" from patent protection,[55] the laws of other countries use the terms "invention" and "discovery" synonymously[56] or even provide special regulation for "discoveries."[57]

67. A closer examination of patent office practice and court decisions shows, however, that where the laws exclude "discoveries" from patent protcetion, they use this term in its broadest—and at the same time also the generally accepted—meaning, namely as "the act, process, or an instance of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized."[58] For example, the

[54] Part III, Chapter D, paragraphs 50 to 62.

[55] For example, according to Article 52(2) of the European Patent Convention (EPC), discoveries are not regarded as inventions. In the course of harmonizing their national laws with the EPC, all member countries of the European Patent Organisation (EPO) introduced the same—or substantially the same—provision into their national laws.

[56] 35 USC, paragraph 100(a): the term "inventions" means invention or discovery. In Article 47 of the Spanish Patent Act, scientific discoveries are treated as technical inventions.

[57] For example, the Statute on Discoveries, Inventions and Rationalization Proposals of the Soviet Union stipulates in Section 10(1): "by discovery, in this Statute, is recognized the determination of hitherto unknown objective laws, properties or phenomena of the material world, bringing about fundamental changes in the standard of knowledge." The Statute further determines that it should not apply to geographical, archaeological and palaeontological discoveries of useful mineral deposits and in the field of the social seiences. Finally, specific rights and privileges (e.g., diplomas, rewards, etc.) are provided for the authors of discoveries.

[58] According to the definition in *Webster's Third New International Dictionary*, London, Springfield, Mass., 1963.

Geneva Treaty on the International Recording of Scientific Discoveries, which was adopted on March 3, 1978, but is not yet in force, provides in Article 1(1)(i) that "scientific discovery means the recognition of phenomena, properties or laws of the material universe not hitherto recognized and capable of verification."

68. Where the terms "invention" and "discovery" are used synonymously, as in the law of the United States of America, the term "discovery" does not have the same broad meaning. The courts in the United States of America, as long ago as 1862, clarified the difference between patentable and non-patentable "discoveries" by stating that laws of nature, though they may be discovered, may not be patented as an invention; a discovery may be patented only if the new force or principle brought to light is embodied and set to work and only in connection or combination with the means by which, or the medium through which, it operates.[59] Thus "discoveries" in the common broad meaning of the term are not within patentable subject matter in the law of the United States of America, which therefore does not substantially differ from those laws that explicitly exclude discoveries from patent protection.

69. If discoveries in the broadest sense of that term are to be considered as non-patentable subject matter, this could affect biotechnological inventions in a twofold way. Firstly, a problem arises from the fact that the described new technologies in the field of biotechnology are mostly based on numerous scientific findings which, doubtlessly, satisfy the definition of "scientific discovery" as contained, for example, in the Geneva Treaty on the International Recording of Scientific Discoveries.[60] Secondly, the basic working material of a "biotechnologist" is always some kind of living or biologically active matter—plant, animal, microorganism, plasmid, etc.—and the question arises whether the outcome of his work may still be considered as something discovered or found in nature. It thus becomes important to draw the borderline between discoveries and inventions.

70. In respect of the first problem, that is to say whether inventions can be based on scientific discoveries, a solution emerged for the first time in the French patent law of 1844. Article 30(3) of that law provided that a patent could not be validly granted for principles, methods, systems, discoveries and technical or purely scientific concepts for which no industrial application had been indicated. Thus, it was recognized that a scientific discovery, if combined with an indication of its industrial application, could be considered as an invention. This conclusion, which was adopted also in other countries, is still valid. For example, Article 52(2)(a) of the European Patent Convention, in conjunction with Article 52(3), excludes a discovery from patent protection only to the extent to which it is claimed "as such." The EPO Guidelines for examination (Part C., Chapter IV, 2.1.) state: "If a man finds out a new property of a known material or article, that is mere discovery and unpatentable. If, however, a man puts that property to practical use he has made an invention which may be patentable."

71. In the course of the last few years, patent offices have issued numerous patents for biotechnological inventions which clearly depend on discoveries. Problems that may result from the requirement of industrial application will be examined later.[61]

72. The second question, that is to say the question of the extent to which different products of biotechnology may be considered products of nature, and thus as discoveries, is more difficult, and no uniform answer so far has been given.

73. In the case of products obtained by using the new technologies, e.g., rDNA, somatic cell hybridization, microinjection or hybridoma technology, in particular, the said question does not arise because they are creations of man and do not preexist in nature.[62]

74. Different considerations apply to biotechnological products, whether animals, plants, microorganisms or biological material, which result from conventional breeding or screening techniques, or from uncontrolled events (e.g., mutation). In the United States of America, prior to 1930, plants, even those artificially bred, were considered products of nature for the purposes of the patent law and thus not patentable. The introduction of the Plant Patents Act in 1930 was necessary in order to overcome this barrier. In other countries, the distinction between inventions and discoveries for protecting plants was but a minor concern. With regard to microorganisms and other biological material the fact that they occur in nature has different consequences in various countries. Whereas no protection seems to be available for a microorganism which is simply found in nature in its original form, and therefore treated as a discovery, it is, however, difficult to say precisely how much an inventor has to add to the discovery, e.g., isolating, purifying, screening, in order to obtain protection. In this respect, the Guidelines for examination in the European Patent Office (Chapter IV, 2.1), state:

> "To find a substance freely occurring in nature is (...) mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and if it is 'new' in the absolute sense of having no previously recognized existence, then the substance *per se* may be patentable."

The problem has been solved along similar lines by the Federal Patent Court of the Federal Republic of Germany. In the "lactobacillus bavaricus" case that court upheld a claim to a group of naturally occurring microorganisms. The claim defined the microorganisms as "obtainable" by carrying out certain specified selection steps which resulted in the production of bacteria which predominantly produced the L(+) isomer of lactic acid. Although naturally occurring, the new microorganisms had previously been undiscovered and required human technical intervention to recognize them and produce them in a reproducible manner. The subject matter of the application was, therefore, an invention and not a mere discovery.

75. Thus, at present, the distinction between inventions (and discoveries) for which protection is available and discoveries which cannot be protected still seems a problem for biotechnological products (perhaps less so for more recent technology since it involves a higher degree of human intervention in nature).

(b) Biotechnology as a Technical Field in Which Inventions Can be Made

76. Whereas the borderline between inventions and discoveries concerns all fields of technology, the question whether—and if so, to what extent—hitherto unknown discoveries made in the field of biotechnology may be considered inventions, despite the fact that most of them concern living entities, is a special question in this particular field, and the answer to it again depends on the concept of invention.

77. With the exception of the first patent laws in the England (1624), in the United States of America (1790) and in France (1791), patent laws in most other countries were adopted in the nineteenth century. The common goal of emerging patent legislation was to promote the progress of industry, and therefore the exclusion of scientific findings of no immediate practical use was a generally accepted principle of patent law. The objective of those patent laws was to promote the progress of industry, and this was reflected by the patentability requirement of

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[59] *Morton v. Infirmary*, 5 Blatchf 116, F. Cas No. 9,875 (1862).

[60] Several scientists working in biotechnological fields have been awarded Nobel prizes for their "discoveries," as the awarding Nobel prize committee usually states in the diploma. Some of these scientists are named as inventors in patents of concern for this study.

[61] See below, paragraphs 126 *et seq.*

[62] Nevertheless the decision of the US Supreme Court of June 16, 1980, *Diamond v. Chakrabarty*, 206 USPQ 193 (1980), examined the said question, indicating that applicant's microorganism plainly qualified as patentable subject matter since his claim was not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter, i.e., a product of human ingenuity having a distinctive name, character and use. The Court stated that, since the applicant had produced a new bacterium, with markedly different characteristics from any found in nature and one having the potential for significant utility, his discovery was not nature's handiwork, but his own, and accordingly was patentable subject matter under Section 101.

"industrial applicability." Originally, that requirement was intended to define the area in which inventions can be made. The French patent law of 1844 expressly stated that, subject to specific requirements of patentability, an author of any new discoveries or inventions in all kinds of industry is entitled to an exclusive right.

78. When the German Patent Office started to interpret the requirement of industrial application, it used the criterion of a *teaching of a technical character employing only those physical and chemical means* that were predictable at the time the act was passed.[63] The "technical character," although not a statutory condition, soon became the central criterion for distinguishing patentable inventions from inventions that are not patentable, e.g., from inventions in the field of agriculture, plant and animal breeding, and medical treatment. Nevertheless patents were granted for culturing of yeasts, the preparation of bread and beer, and the production of vinegar (in view of the already established fermentation industry) and for the fermentative production of butyl alcohol and acetone with the aid of bacteria. After the discovery of the antibiotic penicillin, patents were also granted for antibiotics, such as streptomycin, tetracycline, aureomycin, produced, etc., with the aid of known or yet to be discovered microorganisms through fermentative methods. These developments can be considered an exception to the earlier view that inventions belonging to the field of technology encompassed only objects and phenomena of an *inanimate* nature and their utilization and control by *techniques of physics and chemistry*. In 1922, the German Reichsgericht (Supreme Court) decided that the granting of a patent would not be prevented by the fact that the process was applied in the biological field, i.e., that it made use of the live processes of nature instead of chemical processes, thus upholding a patent for a process for the manufacture of curative and immunizing substances for tuberculosis.[64] Subsequently, the German Patent Office allowed claims for agricultural cultivating processes[65] and for plant varieties, but refused claims to animal varieties. In 1969, the Supreme Court of the Federal Republic of Germany decided a case in which the patentability of the breeding of an animal was at issue.[66] This decision generally opened up patent protection for inventions in the whole field of living matter, on the condition, however, that the teaching had to be *repeatable*; e.g., it had to be readily duplicatable by others skilled in the art.

79. In the United States of America, the question of "technical character" or "technical teaching" has never arisen since the basic statutory technique of defining the concept of patentable invention differs from that in continental Europe and Japan. The Patent Act of 1952 expressly itemizes the subject matter eligible for patent protection as: "any new and useful process, machine, manufacture, or composition of matter, or any useful improvement therefor." The doctrine prevailed that a true "product of nature" does not constitute a machine, composition of matter, or manufacture. Nevertheless, the United States Patent and Trademark Office granted as early as 1873 to Louis Pasteur a patent allowing claims "for yeast free from organic germs or disease, as an article of manufacture." Patents were also granted for an antitoxic serum (1877), for a bacterial (1904) and a viral vaccine (1916). Furthermore claims, such as for a "process of and apparatus for treating sewage" (1908) and for a fermentative process to produce butyl alcohol and acetone were affirmed. However, with the exception of claims in respect of the "living organism" plus a carrier, the courts of the United States of America constantly refused claims for product protection in the field of animate matter. In 1980, the Supreme Court, after having reviewed the historical development of statutory and case law, ruled in its well-known decision[67] *Diamond v. Chakrabarty*, concerning a human-made, genetically-engineered bacterium, capable of breaking down multiple components of crude oil, that Chakrabarty's claim was "not to a hitherto unknown natural phenomenon, but to non-naturally occurring manufacture or composition of matter—a product of human ingenuity having distinctive name, character, and use"; the claim was thus to a new bacterium, which has potential for significant utility, with markedly different characteristics from any found in nature, thereby qualifying the bacterium as patentable subject matter; such applicant's discovery that is not nature's handiwork, but his own, "was considered patentable subject matter under Section 101 of the United States patent law. Moreover, the Supreme Court stated that "Congress recognized that relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."

80. The *"Red Dove"* and the *"Chakrabarty"* decisions are, no doubt, milestones in the history of patent protection of biotechnological inventions since they opened up the way for the protection of biological processes and for product claims relating to microorganisms and other biological material.[68]

81. In conclusion, it appears that the limited concept of technical fields no longer constitutes an obstacle to the protection of biotechnological inventions by patents and other industrial property titles.

C. Exclusion from Patentability of Certain Sectors of Biotechnology

82. In respect of certain biotechnological inventions, a number of patent laws contain provisions excluding them from patent protection. Such exclusions are based on policy considerations which deserve careful examination. Whereas in older patent laws of some industrialized countries certain exclusions from patent protection, in particular as regards substances obtained by chemical processes, pharmaceuticals and food products, had been provided for, recent laws in industrialized countries show a clear trend towards abolishing such exclusions. The only exclusions from patenting which were introduced during the last 20 years in industrialized countries concern, without exception, biotechnological inventions, namely plant and animal varieties, and essentially biological processes for the production of plants and animals. Thus, the development of case law, which is characterized by growing recognition of the fact that alleged biotechnological inventions are indeed inventions in the sense of patent laws, is counteracted by statutory provisions excluding certain biotechnological inventions from patenting.

(a) Plant Varieties

(i) General

83. In a number of countries, plant varieties are protected by special legislation which establishes a particular system of protection. In those countries, the laws for the protection of inventions, as a rule, exclude plant varieties from patentability. This is true, e.g., of the European Patent Convention and of the national laws that follow the same approach as the European Patent Convention. The Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents of Invention of 1963, which at present binds nine countries,[69] permits its contracting States in Article 2 not to grant patents for plant or animal varieties or essentially biological processes for the production of plants or animals; the European Patent Convention of 1973, which at present groups 11 countries,[70] made use of that

[63] See Federal Supreme Court decision of March 27, 1969, 1 International Review of Industrial Property and Copyright Law (IIC) 136 (1970) at 137 (*Rote Taube—Red Dove*).

[64] Decision of October 27, 1922, Bl. f. PMZ 1924, 6 (7).

[65] In agricultural cultivating processes, growth, consistency, yield, etc., particularly of plants, are influenced by chemical or physical means, however without changing their hereditary structure.

[66] Decision of March 27, 1969, 1 IIC 136 (1970) (Red Dove).

[67] 206 USPQ 193 (1980).

[68] Similarly, a decision by the Canadian Patent Appeal Board of March 18, 1982, *in re Abitibi*, allowed the claim to a microbial culture system stating: "If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will, and it is useful (e.g., to destroy the spruce bud worm), then it is every bit as much a new tool of man as a microorganism. With still higher life forms it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently" (62 C.P.R. (2 d) 81 (1982) at 90).

[69] France, Germany (Federal Republic of), Ireland, Italy, Liechtenstein, Luxembourg, Sweden, Switzerland, United Kingdom.

[70] Austria, Belgium, France, Germany (Federal Republic of), Italy, Liechtenstein, Luxembourg, Netherlands, Sweden, Switzerland, United Kingdom.

permission and excluded the foregoing from patentability in Article 53(b), and a number of countries party to the European Patent Convention follow the same approach.[71] The WIPO Model Law for Developing Countries on Inventions (1979) contains the same provision, in Section 112(3)(ii), as the European Patent Convention. Recently enacted laws in Cuba, the German Democratic Republic, Mexico, Sri Lanka, Thailand and Yugoslavia have adopted the same provision. The Patent Law of China of March 12, 1984, excludes, in its Article 25(6), animal and plant varieties from patenting but not essentially biological processes. Rule 39.1(ii) of the PCT Regulations under the Patent Cooperation Treaty (PCT) states that no International Searching Authority is required to search an international application if, and to the extent to which, its subject matter is plant or animal varieties or essentially biological processes for the production of plants and animals. Reference should also be made to the Statute on Discoveries, Inventions and Rationalization Proposals of the Soviet Union, as last amended on December 28, 1978,[72] which also contains a special provision, in Section 22, for "new varieties and hybrids of agricultural crops and other cultivated plants," which are not recognized as inventions, and provides special titles of protection for them. Under the Patent Act of the United States of America, special "plant patents" are granted for asexually reproduced varieties (i.e., for varieties reproduced by means other than by seed, e.g., by grafting, budding, cutting, layering, division and the like), whereas special titles of protection are available under the Plant Variety Protection Act for sexually reproduced varieties (i.e., for varieties reproduced by seeds).[73]

(ii) Historical Developments

84. The present state of plant variety protection, and of the corresponding exclusions from patent protection under national laws, is the result of a long historical development.

85. Since the beginning of this century, plant breeders tried to obtain patent protection for new plant breeding methods (= processes) and for new varieties of plants (= products). As outlined above[74] the principal obstacles to be overcome were, on the one hand, the product of nature doctrine in the United States of America and, on the other hand, the narrow interpretation of the "technical" character of an invention in Europe.

86. In attempting to remedy this situation by establishing protection for certain kinds of plants, the "Horticular Patents" Bill was drafted in the USA in 1906, but did not become law. In 1930, the United States Congress enacted the Plant Patents Act to aid a depressed agriculture and to recognize the outstanding achievements of American breeders. However, the protection introduced by this act—plant patents granted by the Patent Office—was limited to asexually reproduced distinct and new varieties, other than tuber-propagated plants (e.g., potatoes). In view of the fact that plants cannot normally be sufficiently disclosed merely by a written description, the requirement of a written description, contained in the patent law, was not maintained as such; instead "a description as complete as is reasonably possible" was required (Sections 4886, 4888). When the 1952 Patents Acts was enacted, the plant patent provisions were incorporated in that Act (35 USC, Sections 161-164). In 1954, Section 161 of the Patents Act was amended, in respect of the kinds of plants eligible for a patent, by adding: "a distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than tuber propagated plants or a plant found in an uncultivated state." The reason for the limitation of the protection granted to asexually reproduced plants in 1930 was apparently the belief that new plant varieties could not be produced by seeds in a reliable way. A second reason for such a limitation might have been the fears of farmers and scientists that protection of sexually reproduced varieties would inhibit free exchange of genetic material and lead to concentration of proprietary control in the seed industry. The exclusion of tuber propagated plants (e.g., potatoes) is related to the fact that in such plants the propagating and usable portions are typically one and the same. The possibility of plant patents for asexually reproduced plant varieties and an exception for tubers, tuberous roots and bulbs has also been adopted in the Republic of Korea (Patent Law, Section 3).

87. At about the same time as the United States of America, some European countries (starting with Czechoslovakia in 1921 and, later on, France, the Netherlands, Austria, Germany (Federal Republic of) and Spain) introduced various kinds of special plant breeders' rights; central registers of seeds and seedlings were introduced. In addition, in Germany, as from the 1930s, and later also in Belgium, France, Hungary, Italy, Japan and Sweden, plants were also admitted to patent protection. In Spain, utility model protection was made available for plants. On the other hand, plant related patent claims were not accepted in Denmark, Switzerland or the United Kingdom.

88. In 1961, the International Convention for the Protection of New Varieties of Plants (UPOV Convention) was concluded in Paris. This Convention has twice been revised, in 1972 and in 1978. At present 17 States are party to it.[75]

89. Subsequent to the adoption of the UPOV Convention, all legislative considerations relating to plant variety protection, at the national and regional levels, have been influenced by the negotiation of the UPOV Convention. With regard to Article 2 of the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions, which permits the contracting States not to grant patents for "plant or animal varieties or essentially biological processes for the production of plants or animals," the interrelationship is evident: the memorandum resulting from the first meeting of the Committee of Experts on Patents of the Council of Europe in November 1960, recommended not to impose a common solution for the highly controversial question of the patentability of new plant varieties, drawing attention to the work for the preparation of a Convention on plant varieties. This recommendation was followed when adopting the Strasbourg Convention. In the preparation of the European Patent Convention, it was decided to make use of the permission provided for in the Strasbourg Convention and to adopt a provision (Article 53(b)) according to which European patents are not to be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals (with the exception of microbiological processes and the products thereof).

(iii) Basic Characteristics of Plant Variety Protection under the UPOV Convention

90. The system of protection as set forth under the UPOV Convention and corresponding national laws was created in order to meet the special needs of plant breeders. It is considered as a well balanced system, taking into account public and private interests. It has some characteristics in common with the patent system, but there are also essential differences of a fundamental and practical nature.

91. The fundamental differences all relate to the targeted subject matter of protection: whereas the protection under the patent system is directed to an *invention*, i.e., "a teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result,"[76] plant variety protection relates to the *product as such*, namely the propagating material of a specific plant variety. The direct consequences of this fundamental difference are threefold: firstly, in order to obtain a plant variety right, no "enabling disclosure" is necessary, i.e., the applicant is not obliged to disclose in detail the process by which the new variety was obtained; although a deposit of propagating material with the examining authority is required for examination purposes, public access to this material is not possible, either before or after the grant of the plant variety right; secondly, no process protection is

[71] Those countries include, in particular, France, Germany (Federal Republic of) and United Kingdom.

[72] English translation published in *Industrial Property Laws and Treaties*, SOVIET UNION — Text 2-003.

[73] For more details, see below, paragraph 86.

[74] See Part IV, Chapter B, paragraphs 64 to 81.

[75] Belgium, Denmark, France, Germany (Federal Republic of), Hungary, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States of America.

[76] This is the definition of invention given by the Supreme Court of the Federal Republic of Germany in the *"Rote Taube"* (red dove) decision. See footnote 89.

provided for under the UPOV Convention; thirdly, plant varieties of natural origin—i.e., discoveries—are eligible for plant variety protection.

92. The differences between patents, on the one hand, and plant variety rights, on the other, are closely related to the specific characteristics of the protected subject matter; they are illustrated by widely differing requirements of protection, and by differences in the scope of protection. According to Article 6 of the UPOV Convention, a new variety must not only be clearly distinguishable from other existing varieties but must also be sufficiently homogeneous and stable in its essential characteristics; novelty of the variety is determined on the basis not of disclosure to the public but on the basis of marketing (with a special grace period provided in Article 6(1)(b), under which the breeder of the new variety is not prejudiced by the fact that, within the four years preceding the filing date, the variety has been entered in trials, or has been submitted for registration or entered in an official register, or by the fact that the variety has been offered for sale or marketed in a country other than that in which the application for protection has been filed).

93. As regards the rights granted to a plant breeder, his prior authorization is required for any production of propagating material of the variety for purposes of commercial marketing, any offering for sale and any marketing of such material, without an exhaustion of rights where such acts are effected by using material acquired with the consent of the owner of the right. The material may be either reproductive or vegetative propagating material. The term "vegetative propagating material" includes whole plants and, as regards ornamental plants, the breeder's right extends to parts thereof normally marketed for purposes other than propagation when they are used commercially as propagating material in the production of ornamental plants or cut flowers (Article 5(1) UPOV Convention), with the possibility for member States of extending the protection, in particular, to the marketed product (see Article 5(4) of the UPOV Convention)—a possibility so far little used. The scope of protection under the UPOV Convention therefore extends to commercial manufacture and marketing of propagating material, at the production stage of the protected variety. Thus, the propagating material may be freely used by competitors in order to create another variety. Plants and parts thereof remain unprotected for any marketing unrelated to propagation purposes. Breeders cannot, therefore, oppose imports of protected varieties from other countries, unless the imported material is offered for sale and marketing as propagating material. Furthermore, according to Article 5(3) of the Convention, utilization of a variety as an initial source of variation for purposes of creating other varieties, or for marketing such varieties, does not require authorization by the breeder, unless the repeated use of the variety is necessary for the commercial production of another variety.

94. Of relevance for this report are also the provisions of the UPOV Convention on the minimum duration of protection, on national treatment and on the right of priority. As regards the duration of plant variety rights, the UPOV Convention (Article 8) requires a minimum of 15 years (18 years for vines, fruit trees and their rootstocks, forest trees and ornamental trees). National treatment is provided for in principle; as an exception, reciprocity may be required by a contracting State in respect of the coverage of plant variety protection in respect of the list of protected genera and species. A right of priority must be recognized in respect of first filings in a contracting State, provided the subsequent filing has been made within 12 months.

95. The interrelationship between plant variety protection and patent protection for the member States of UPOV is regulated by Article 2(1) of the UPOV Convention, which obliges the contracting States to provide only one form of protection (patent protection or *sui generis* protection) for the same botanical genus or species. However, if a State provides for protection by patents, the requirements and effects of such protection must comply with the conditions set forth in the UPOV Convention.[77]

96. Most UPOV member States have established a special *sui generis* system of protection for plant varieties, but some of them protect plant varieties by patents especially adapted for that purpose. In order to enable accession to the UPOV Convention by the United States of America, the lack of protection with regard to sexually reproduced plants in the law of that country was overcome in 1970 by the Plant Variety Protection Act. This Act, which takes into account the UPOV Convention, offers protection for sexually reproduced plants, other than fungi, bacteria or first generation hybrids. At the revision Conference in 1978, the present Article 37 was introduced into the UPOV Convention. According to this Article, a State which before October 31, 1979, already provided protection both in the form of a special title of protection or a patent for the same genus of species, may continue to provide such double protection if it notifies the fact to the Secretary-General of UPOV when depositing its instrument of ratification, acceptance, approval or accession to the 1978 Act. The United States of America, which acceded to the Convention in 1980, has made use of this possibility.

97. In addition, as long as a contracting State has not provided for the protection of a specific genus or species under the conditions set forth in the UPOV Convention, such State is not prevented by the UPOV Convention from granting patents for plants of such non-protected genus or species under the conditions of its national patent law. Such a provision was introduced in the patent law of the Federal Republic of Germany after its accession to the UPOV Convention, and was also maintained after its accession to the European Patent Convention.

(iv) Plant (Variety) Protection under the Patent System

98. The main, and probably the most important, characteristic of plant breeding developments in the last two and a half decades has been the shifting of plant research into the area of molecular biology. In the light of those developments, the fact that Article 2(b) of the Strasbourg Convention and Article 53(b) of the European Patent Convention make an exception from the exclusion from patentability in favor of microbiological processes and the products thereof deserves particular attention because microbiological processes—and possibly also the products thereof—may be used for developing new plants. In order to evaluate the challenges to industrial property protection resulting from the said new techniques, the protection presently available will be briefly examined.

United States of America

99. In the United States of America, the Supreme Court decision in *Diamond v. Chakrabarty*,[78] clarifies that plants are not outside the scope of patentable subject matter and therefore can be patented under Section 101 of the general patent law. However, the Chakrabarty decision did not define the area of application of the Plant Patents Act, the Plant Variety Protection Act, and the general Patent Law.

100. Whereas the patentability of specific vectors for transferring foreign genes into plants cells, and of new artificial genes for valuable plant traits, does not seem to raise problems, difficulties seem to arise in respect of claims relating to cells, where a plant cell contains artificially modified hereditary material. Following the so-called principle of preemption, the United States Patent and Trademark Office distinguishes between various plant cells. If a plant cell is capable of differentiation and useful only for reproductive purposes, it would be considered as no more than an expression of, or tantamount to, the plant itself and may not be protected under the general patent law (35 USC 101) unless the plant itself could not be protected under the Plant Variety Protection Act or by means of a plant patent (35 USC 161). A plant cell which, however, can be used not only in the creation of a particular plant variety but also for other purposes would, according to the same doctrine, be patentable subject matter under the general patent law when defined and claimed as generally useful for plant breeding, not just for breeding a particular variety. The same probably applies also to calluses built up from regenerated cells; if useful only for

[77] See UPOV document CAJ/XV/3 of February 11, 1985, entitled "Interpretation of Article 2(1) and Related Provisions of the Convention" and paragraphs 21 to 26 of document CAJ/XV/8, reporting on the discussion of the said document in UPOV's Administrative and Legal Committee. Attention is also drawn to the Records (UPOV Publication No. 342) of a Symposium held by UPOV in October 1984 on "Industrial Patents and Plant Breeders' Rights—their Proper Fields and Possibilities for their Demarcation."

[78] See paragraph 79 and footnote 62, above.

reproductive purposes, they could be protected under the general patent law only if the plant to be finally regenerated could not be protected under the other, special, titles of protection. Protection under 35 USC 101 would, however, be obtainable, if a callus could be used for other than reproductive purposes, e.g., for the production of perfume. If the callus regenerates into parts of a plant, e.g., into roots or shoots, the same rule seems to remain applicable.

101. The same statement could be made with respect to a plant as such. Under the so-called preemption doctrine, presently applied by the United States Patent and Trademark Office, only tuber propagated plants and first generation hybrids are eligible for protection under the general patent law. The question of whether a plant described as both sexually and asexually reproducible could be protected both under 35 USC 161 and under the Plant Variety Protection Act, has not yet been at issue.

102. The consequences of this practice are manifold, since the protection requirements and the scope of protection differ under the two systems of protection. With regard to the protection requirements, under the general patent law, the patentability requirements of novelty, utility and non-obviousness must be met, and a sufficient disclosure must be furnished, i.e., the application as filed must enable a person skilled in the art to make and use the invention without undue experimentation (35 USC 112). To the extent that the written description is not so enabling, a deposit of plant material in an appropriate depository is required. Under 35 USC 161 a plant patent may be obtained for a "distinct and new variety of plants." These patentability requirements are similar to those of novelty and non-obviousness under the general patent law. The requirement of complete written description is replaced by the requirement of a description "as complete as is reasonably possible" (35 USC 162), and no deposit of the plant is required. The Plant Variety Protection Act requirements are even less stringent and follow the pattern of the UPOV Convention: the description of the plant must be "as adequate or as complete as is reasonably possible," including breeding procedure and genealogy, but not enabling *per se* (7 USC 2422(2)); a deposit is required, but the deposited seeds are not made available to the public without the owner's permission, at least not during the term of the title ("plant variety certificate") granted by the Plant Varieties Office.

103. In respect of claims, the provisions on plant patents permit a single claim to the plant as a whole. Plant variety certificates do not have claims *per se*; each certificate protects a single variety. Under the general patent law, not only plants but also parts thereof, e.g., roots, tubers, leaves, fruits, flowers and seeds, can be claimed. With regard to the scope of protection, a plant patent protects the owner against those reproducing and also against those selling or using plants of the protected variety, but the asexual reproduction is an absolute prerequisite for infringement (i.e., infringement takes place only if the alleged infringer's plant is a direct or indirect asexual reproduction of the patentee's original patented plant).

104. Under the Plant Variety Protection Act, infringement means to perform, without the authority of the certificate owner, in the United States of America, any one of the following acts: "to sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it; import the novel variety into, or export it from, the United States of America; sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or use seed which is marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the novel variety; or dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or perform any of the foregoing acts even in instances in which the novel variety is multiplied other than sexually, except in pursuance of a valid United States of America plant patent; or instigate or actively induce performance of any of the foregoing acts" (7 USC 2001(1)-8, as amended in 1980). According to 7 USC 2401(a), the term "variety" embraces seeds, transplants and plants. The protection conferred by a the plant variety certificate does not, however, prevent farmers from selling surplus seed to other farmers so long as neither the seller nor the buyer are primarily engaged in producing the seed for sale (7 USC 2543), a limitation of the exclusive right which does not exist in respect of plant patents.

105. The broadest scope of protection appears to exist under the general patent law. Enforcement rights under Section 271, 35 USC include rights against any unauthorized making, using or selling, without any limitation as to asexual or sexual reproduction on the part of the infringer; in particular, any commercial use, is an infringement under that Section.

106. In addition, all processes involved, from the development of the DNA transferring vector to the end product—the plant—can be protected in the United States of America by patents. Furthermore, protection under the general patent law does not depend upon the breeding method applied. Plants bred by traditional breeding methods are eligible for protection on the same conditions as those outlined above.

European Patent Convention

107. In respect of the exclusion of plant varieties from patent protection, Article 53 of the European Patent Convention reads as follows: "European patents shall not be granted in respect of (b) plant...varieties or essentially biological processes for the production of plants...; this provision does not apply to microbiological processes or the products thereof." The intended demarcation line between patentable inventions and those excluded from protection, therefore, seems to correspond to the dividing line between biology and microbiology. In fact, the purpose of Article 2(b) of the Strasbourg Convention, which served as a model for Article 53(b), was to remove microbiology from the field of biology. However, the new techniques, particularly those of somatic cell hybridization and rDNA, which were unknown to the authors of the Strasbourg Convention, have in the meantime received vast application in both biology and microbiology so that those two fields have become inseparable. This is demonstrated by the fact that developments starting in the core area of microbiology, where a DNA transferring vector is constructed and a plant cell transformed, now lead to the creation of plants.

108. A good example of the fact that the decisive dividing line cannot be maintained in practice is given by European patent application No. 0122791, which claims, *inter alia*:

— a DNA shuttle vector comprising T-DNA...
— a bacterial strain containing and replicating a DNA vector...
— a method for genetically modifying a plant cell...
— a plant, a plant tissue, or a plant cell produced according to the claimed method.

This example shows that it has become difficult to answer the question of the extent to which the provision in Article 53(b) of the European Patent Convention excludes plants from patent protection. A decision by the Board of Appeal of the European Patent Office, of July 26, 1983,[79] gives valuable guidance for the time being. According to this decision, Article 53(b) differentiates between "plant varieties," e.g., "a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle," on the one hand, and "plants" on the other. Following this decision, Article 53(b) of the European Patent Convention prohibits only the patenting of plants or their propagating material in the genetically fixed form of a plant variety but not the patenting of "innovations which cannot be given the protection afforded to varieties."

109. As far as the transferring vector for carrying foreign DNA into a plant cell is concerned, protection of the process for producing it and the product *per se*—the vector—should cause no problems. The Guidelines for the examination in the European Patent Office explain that the term "microbiological processes" is to be interpreted as covering not only industrial processes using microorganisms, but also processes for producing new microorganisms, e.g., by genetic engineering and that the term "microorganism" also covers plasmids and viruses.[80]

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[79] Official Journal EPO 1984, 112—"Propagating Material/CIBA-GEIGY".

[80] Guidelines for the Examination in the European Office, Chapter IV, 3.5.

110. Following the guiding principles of the decision referred to in paragraph 108 of the Board of Appeal, claims related to a process for transforming plant cells and to the transformed cells *per se* are also likely to be admitted. The same approach is likely to apply to process claims relating to the production of plant tissue by means of genetic engineering, e.g., using the so-called somatic cell hybridization method, and for claims relating to products of such processes, namely the tissue culture itself. Even the next step, the regeneration of tissue culture, using specific enriched media, into parts of the plant, e.g., roots or shoots, might also be covered by the process and product claims under the European Patent Convention.

111. The patentability of a plant itself, according to the Board of Appeal's decision referred to in paragraph 108, depends on whether it can be treated as being genetically fixed, i.e., characterized precisely by the genetically determined peculiarities of their natural phenotype. If this is the case, protection of a plant variety is at issue and the exclusionary provision of Article 43(b) EPC is applicable. Thus, product claims to such a plant, i.e., plant variety, are not allowable. However, if the claimed plant may be assumed to have the features claimed in application No. 0122791 (claims reproduced above, paragraph 108), a product claim seems to be allowable because the plant claimed does not comply with the requirements set forth in the decision by the Board of Appeal. A further question is whether, and if so, to what extent, a plant variety itself can be protected as a direct product of a patentable breeding process, i.e., of a microbiological process on rDNA, of somatic cell hybridization technique or of a non-essentially biological process according to Article 64(2), of the European Patent Convention, which extends the protection conferred by a process patent to the products directly obtained by such process.

(b) Animal Varieties

112. The situation regarding animal varieties differs from that of plant varieties in that there does not seem to be any special system of legislation for the protection of animal varieties. Animal varieties are expressly excluded from patenting under a number of laws, for example, in all patent laws of the member countries of the European Patent Organisation and in China, Cuba, the German Democratic Republic, Mexico, Sri Lanka, Thailand and Yugoslavia. On the other hand, provisions in the Hungarian Law on the Protection of Inventions by Patents (as amended in 1983) concerning the protection of plant varieties, which follow the UPOV Convention, also apply to the protection of animal breeds by patents (Article 71). Whereas the law of the Soviet Union does not recognize animal varieties as inventions, it allows the grant of special types of protection for such varieties.

113. In the United States of America, the situation at present is not entirely clear. However, it is believed that following the rationale of the Supreme Court decision in *Diamond v. Chakrabarty*[81] animals produced by using rDNA technology could constitute patentable subject matter under Section 101, 35 USC. Even if animals were considered to be patentable subject matter, the obstacle of 35 USC 112—enabling disclosure—would remain and could constitute an insurmountable barrier for animal breeders. A similar situation seems to exist in Canada. The Canadian Patent Appeal Board in re Abitibi expressed the view that higher life forms (higher than microorganisms) would qualify as inventions, if the inventor were able to reproduce them at will and consistently. The Board assumed that complex life forms tend to vary more from individual to individual and that therefore such inventions would hardly be able to meet all patentability requirements; however, if it eventually became possible to achieve such a result, and the other requirements of patentability were met, it should not be treated differently.[82]

114. In respect of the methods (processes) involved in animal breeding, no particular problems for their protection seem to exist under the patent law of the United States of America. However, under the European Patent Convention, and the corresponding patent laws of the member States of the European Patent Organisation, the situation seems to be different. Firstly, under Article 53(b) of the European Patent Convention essentially biological processes for the production of animals are excluded from protection; secondly, Article 52(4) states:

> "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application...."

In view of the modern methods of animal breeding, referred to above,[83] this provision of the European Patent Convention and the corresponding national patent laws could constitute a serious obstacle for patenting technical breeding methods recently developed, e.g., various techniques of embryo transfer.

115. With regard to the patentability of microbiological processes relating to animal varieties, e.g., transferring DNA sequences cloned by rDNA technology via microinjection into pronuclei of fertilized animal eggs, the same considerations should apply as for the corresponding processes with regard to plant varieties.[84] It should, furthermore, be mentioned that the patenting of foreign DNA transferring vectors, transformed animal cells, etc., should also be possible under the European Patent Convention.

116. Like plant breeders, animal breeders have for some time been seeking appropriate protection for the results of their work. For example, in the United States of America, in 1928, an attempt was made to introduce protection for animal breeders, within a broader concept—protection by patents to originators of plants and animals; however, this attempt failed and protection was provided for plant breeders only by the Plant Patent Act of 1930. Since then, animal breeding methods have made significant advances. In the 1950s, animal breeding entered the so-called scientific era and is increasingly using the new technologies of rDNA, protoplast fusion, etc. Legal developments, however, at least in the countries of the European Patent Convention went in the opposite direction. Whereas before the introduction of the European Patent Convention animal varieties had been finally considered as being within the concept of invention and therefore patentable, provided they met the same patentability conditions as other inventions, the EPC now excludes them from protection, a situation which creates problems for animal breeders and for progress in animal breeding in general.

(c) Essentially Biological Processes for the Production of Plants or Animals

117. Some laws exclude from patenting "essentially biological processes for the production of plants or animals." This is, in particular, the case under the European Patent Convention (Article 53(b)) and under the patent laws of countries party to this Convention, which followed its approach. However, patent laws of other countries e.g., China, Japan and the United States of America, do not contain such exclusionary provisions.

118. The origin of the exclusionary provision in Article 53(b) of the European Patent Convention is directly connected with Article 2(b) of the Strasbourg Convention.[85] The Guidelines for the examination in the European Patent Office (Part C, Chapter IV, 3.4) interpret the term "essentially biological" as follows:

> "The question whether a process is 'essentially biological' is one of degree depending on the extent to which there is technical intervention by men in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded. To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses, involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth, e.g., a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the

[81] 206 USPQ 193 (1980).

[82] 62 C.P.R. (2d) 81 (1982) at 90—see footnote 68, above.

[83] See paragraph 40, above.

[84] See paragraph 110, above.

[85] See paragraph 83, above.

invention is technical; the same could apply to a method of treating a plant characterized by the application of a growth stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability."

119. The rationale for the exclusion of "essentially biological processes" thus seems to depend upon the role which the "technical intervention" by man assumes in determining or controlling the result it is desired to achieve. Since it is generally assumed that, with the appearance of the new techniques of rDNA, the basic knowledge of plant and animal biology is improving rapidly and constantly, the possibilities of methodically using and controlling natural forces are also improving. The ultimate success also of the new breeding techniques in the field of plant and animal breeding, which routinely apply chemical methods to achieve the results desired and, therefore, do not fall under the "essentially biological..." category will depend on improvements to both the new and the traditional essentially biological processes.

D. The Application of the Conditions of Patentability to Biotechnological Inventions

(a) General

120. Where biotechnological inventions are not excluded from patenting, they may be the subject of applications for the grant of patents (or, where applicable, inventors' certificates). Usually, patent laws require an invention to be new, to comprise an inventive step and to be industrially applicable in order to be patentable. In addition—and this is a condition which is generally implied—inventions must be repeatable since disclosure under the patent system must enable others to repeat the technical solution described in the patent.[86] The question arises whether any specific considerations apply with respect to the conditions of patentability on account of the special nature of biotechnological inventions.

(b) Novelty

121. As regards the condition of novelty, national patent laws usually contain a provision according to which an invention is not new if it has been disclosed to the public, either in writing or orally, by use or otherwise, before the filing date or the priority date. Naturally occurring substances, microorganisms or other biological material therefore raise special problems. On the one hand, an answer is needed to the question of under which conditions they may be treated as new when found in nature; on the other hand, it is to be examined whether, and if so, under what conditions deposits with culture collections can be considered elements of disclosure to the public.

122. With regard to the first question, attention should be drawn to the fact that natural substances, microorganisms and other biological material, e.g., plasmids, appear in nature only in very complex surroundings, which do not allow direct technical use to be made of them. In these surroundings most of them are not recognizable or capable of identification. An antibiotic, appearing in minute quantities in the soil, a bacterium in a complex mixed population, an enzyme in a plant cell or a plasmid in a bacterium may be given as examples. In such inventions, the merit of the invention is to be seen in the first isolation, identification and indication of industrial applicability of such a product, and making that product available to the public. However, there seem to be differences in the application of the novelty requirement in respect of such inventions. In order to find a solution to the problem, it could be argued that the fact that a substance exists in nature should not by itself preclude the novelty of the invention, provided that those skilled in the art are not aware of such existence.

123. The question whether a deposited microorganism or other biological material is included in the state of the art, provided that samples of deposited microorganisms or other biological material are available to the public can normally be answered in the affirmative. It seems, however, that no reliable answer can as yet be given as to the time at which a deposited microorganism is to be treated as having been disclosed (made available) to the public. A possible solution would be to assume that a deposit with a depositary authority would be effective as a reference at least from the date it was listed in the catalogue of the authority or referenced in the literature.

124. A further question in connection with the condition of novelty is the extent to which the specific conditions of biotechnological inventions require the introduction of provisions concerning non-prejudicial disclosures. In view of the fact that most biotechnological inventions are science-based and that scientists are primarily supposed to publish the results of their research as soon as possible and that the possible industrial applicability of such research results is difficult to evaluate even by specialists in the patent field, there appears to be a particular need for a grace period for disclosures made by inventors of biotechnological inventions before a patent application is filed. A closer examination of this question shows, however, that the need for a grace period in the field of biotechnology is not different from the need for a grace period in other science-based technologies. The rapid development of biotechnology during the last few years simply constitutes a particularly valuable proof of such a need. Therefore, a solution should be found on the basis of a general grace period. In this regard, attention is drawn to the fact that the question of a grace period is the subject of a WIPO activity the purpose of which is to achieve international agreement on a general grace period.[87]

(c) Inventive Step

125. As in other technological fields, the patentability requirement of inventive step[88] also constitutes one of the most complex questions in biotechnology. Modern biotechnological inventions, derived straight from the most advanced basic research in molecular genetics, must have caused problems for both the inventors, many of them Nobel prize winners, outstanding professors, etc., involved for the first time in patenting, and the patent offices, which were lacking the necessary expertise to deal with these new kinds of inventions. It seems, however, that apart from the problems usually related to this complex patentability requirement, specific cases of general importance only rarely appear, e.g., problems in connection with non-obviousness of certain characteristics of naturally occurring substances, their production, isolation or use.

(d) Industrial Applicability

126. Following a narrow interpretation of the term "industry," "industrial applicability" has long been a major obstacle to patenting in the area of living matter. However, what first started by the broad definition of the term "industrial" in the Paris Convention for the Protection of Industrial Property in 1883, ultimately had an impact on national patent laws as well; the term "industry" became a comprehensive one, and less stringent. Under Article 57 of the European Patent Convention and Section 116 of the WIPO Model Law for Developing Countries on Inventions, an invention is considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. Although it might be true that Article 57 of the European Patent Convention excludes very few "inventions" from patentability, industrial applicability still presents an important patentability requirement for science based inventions. The same is true for the patentability requirement of utility laid down by the patent laws of some countries, e.g., the United States of America and Japan.

127. Inventions in the field of basic research, i.e., in vast areas of biotechnological research activities, have two specific characteristics: on the one hand, they are based directly on the most recent scientific discoveries and, on the other hand, unlike other inventions, they act as pioneers of new technologies. Two problems relating to the requirement of "industrial applicability" can arise in this connection:

[86] An exception so far exists for plant patents under 35 USC 161-162, see paragraph 102, above.

[87] See WIPO documents HL/CE/I/2 and 5.

[88] Under the European Patent Convention (Article 56) and the corresponding national patent laws, an invention involves inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art; under the patent law of the United States of America, an invention is non-obvious if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matters pertain (35 USC 103).

firstly, "industrial applicability" or "utility" establishes a dividing line between non-patentable discoveries and patentable inventions; secondly, the said requirement determines whether the invention can be used in the laboratory only or also in industry. For example, if a new plasmid is discovered and its properties cleared, the scientist inventor has to find out how a piece of foreign DNA can be introduced into this plasmid and for what purpose the new plasmid could be used (what types of cells could be transformed). Furthermore, the industrial applicability of this new plasmid could depend upon the possibilities that exist in industry to use it.

128. By applying guiding principles which patent law has developed primarily in respect of chemical inventions, most of the possible problems of that kind can also be solved in the field of biotechnology. As in the field of chemistry, however, a liberal approach in interpreting the requirements of "industrial applicability" or "utility" is needed. A possibility that the subject matter of invention can be used in industry in its broadest sense should be sufficient. It should also be sufficient, for instance, that a new plasmid be useful to scientists doing research in a particular field, e.g., in the transformation of plant cells.

129. By applying the requirement of industrial applicability or utility in a liberal way, researchers in the field of biotechnology should as a rule be able to obtain patents for most of the results of their work. The general question raised in legal doctrine, whether patent law should be altered so as to allow the applicant to indicate the industrial applicability of his invention during the examination procedure, both to enable early publication of scientific findings and to obtain patents for them, deserves further examination.

(e) Sufficient Disclosure (Repeatability)

130. Sufficient disclosure of the invention in patent applications is a standard patentability requirement. For example, Article 83 of the European Patent Convention stipulates that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. For biotechnological inventions, however, the condition of sufficient disclosure causes specific problems since living entities are both difficult to describe in writing and self-replicating.

131. Originally, i.e., for as long as the classic fermentation industry had used well-known and easily available microorganisms, the problem of description of microorganisms as such was not even realized. At that time, inventions in the fermentation industry were primarily related to conditions employed in the cultivation of the microbes, such as time, temperature, composition of the nutrient culture, etc., which could all be exactly described. After the discovery of the antibiotic penicillin, however, it became clear that it was possible to produce new or known antibiotics with the aid of known or yet to be discovered microorganisms through fermentation methods. Thus, the choice of the microorganism to be used became the primary significant new element of the invention. Because of the great variability of living matter, however, a sufficient description and classification of microorganisms was impossible. Therefore, in 1949, applications in the United States of America started to refer to deposits of microorganisms in culture collections, although neither the Patent Office nor courts of lower instance had demanded a deposit. In the late fifties and early sixties deposits started to be required. Questions concerning this requirement will be examined in more detail in the following Chapter (E, paragraphs 135 to 157).

132. With regard to higher life forms, e.g., plants and animals, no practice or requirement of deposit exists, at least at present. The deposit of plants according to the plant variety protection laws that follow the UPOV Convention is required only for testing purposes by the plant varieties protection offices. However, Article 5(3) of the UPOV Convention allows the use of protected varieties as an initial source of variation for purposes of creating other varieties. Since the marketing of material other than the reproduction material concerning protected varieties is not covered by the exclusive right of the plant breeder, anybody can obtain material enabling the reproduction of a protected variety, and a deposit is not required for the purpose of ensuring access by the public to the protected variety. Different considerations apply in the context of patent protection where a deposit, complementary to an otherwise insufficient written description, could be a practical way of complying with the patentability requirement of sufficient (enabling) disclosure in the realm of higher organisms. Problems which could and would arise particularly with regard to depositing animals are of a practical nature and not a matter of principle. Technical methods could be applied, similar to those in the field of microorganisms—e.g., the deposit of deep frozen cloned embryos.

133. When courts in Europe opened up the way for patenting living matter, the requirement that a disclosure is sufficient only if it enables a person skilled in the art to repeat the technical solution presented in the invention was particularly emphasized.[89]

134. Notwithstanding the fact that the new biotechnological techniques, such as rDNA, somatic cell hybridization, and microinjection, have opened up new, in some cases even computer aided, ways of written description in all fields of biotechnology, the requirement of sufficient disclosure (repeatability), as practiced under the patent laws of several countries, could continue in future to present a serious obstacle to patenting in this field. This applies both to inventions in the field of microbiology and, in particular, to inventions in the field of higher living organisms, e.g., plants and animals. Therefore, new generally accepted solutions for complying with the requirement of sufficient disclosure are needed. Experience gained with deposits of microorganisms should be taken into account.

E. Special Considerations Concerning Deposits of Microorganisms

(a) Requirement of Deposit

135. To make up for the insufficiency of the description of an invention involving a microorganism to which the public does not have access, the patent procedure of an increasing number of countries requires not only the filing of a written description but also the deposit of a sample microorganism with an authorized depositary authority

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[89] In its *"Rote Taube-Red Dove"* decision of March 27, 1969 (1 IIC 136 (1970) at 141), the Supreme Court of the Federal Republic of Germany ruled, *inter alia:*

"If patent protection is desired, then this teaching must be repeatable, e.g., it must be readily duplicated by others skilled in the art. There is no apparent reason compatible with the principles of patent law that would permit exclusion of the requirement of repeatability for a process for which a patent has been applied merely because the product of the breeding method can propagate itself while maintaining its hereditary characteristics, providing in this way a better guarantee for the advance of general knowledge than would repeatability of a frequently difficult and tedious breeding process. If such process were not repeatable, then the advance of general knowledge in itself would solely rest with the one achieved resulting product."

A similar view has been expressed by the Court of Customs and Patent Appeals in the United States of America in *In re Merat*, F.2d 1390 (CCPA 1975).

In its decision of March 11, 1975, (6 IIC 207 (1975)—"Baker's Yeast") in which a process claim and a product claim related to a deposited microorganism and the production thereof were at issue, the Supreme Court of the Federal Republic of Germany confirmed its general view on patenting living matter by holding that product protection for a new microorganism was allowable only if the inventor showed a reproducible way to produce the new microorganism. Protection for a microorganism *per se* without a teaching to the expert in the art as to how to reproduce the microorganism (apart from propagation of a culture of the same strain) was viewed as so alien to conventional patent law that such protection could not be obtained except by a change in the patent statutes. Despite vigorous criticism in legal writing, this view was later repeatedly confirmed by the Supreme Court (Decision of December 11, 1980, 12 IIC 862 (1981)—"Concentrate of Micro-organism") and also by the Federal Patent Court (Decisions of March 22, 1976, 8 IIC 553 (1977)—"Micro-organisms"; of April 5, 1978, GRUR 1978, 582—"Lactobacillus Bavaricus").

Reference should also be made to the notice issued on December 11, 1981, by the President of the European Patent Office, which reads as follows:

"In the case of microbiological processes, particular regard should be had to the requirement of repeatability referred to in II, 4.11. As for microorganisms deposited under the terms of Rule 28, repeatability is assured by the possibility of taking samples (Rule 28(3)) and there is thus no need to indicate another process for the production of the microorganism" (Official Journal EPO 1/1982, 19).

which maintains a culture collection. The task of the authority is to accept and store deposited microorganism cultures in order that samples may be released to third parties, subject to certain conditions. For obvious reasons, industrial property offices are not equipped to handle microorganisms; their storage and the furnishing of samples requires special expertise and equipment to keep them viable, to protect them from contamination and, for health reasons, to protect the environment from contamination.

136. The procedure in countries that have introduced the possibility of deposit includes the obligation to deposit the microorganism where it proves impossible to describe adequately the invention involving the microorganism. The deposit supplements the description of the microorganism, so that a person skilled in the art is able, on the basis of the description that refers to the deposit, to identify the type of microorganism involved, to procure a specimen of the microorganism and to carry out the invention. In such cases, the description consists of information on the microorganism and on the manner of dealing with it, the necessary information on the deposited culture and also on the deposit as such, which thus becomes an integral part of the description.

137. If the applicant feels that the description is adequate, he can file an application without referring to a deposit. If he has any doubt as to the adequacy of the description, he should make a deposit in order to avoid possible subsequent refusal of the patent application, or possible cancellation of the patent itself. On the other hand, if he considers that the invention involves a microorganism which is well known and available without any particular difficulty (e.g., from a depositary institution with which it has already been deposited), it is sufficient for him to state the scientific name of the microorganism in the description or to indicate the deposit number and the name of the depositary institution with which the deposit was made. Even where a deposit was made, the disclosure may nevertheless be insufficient; the deposit as such is not considered sufficient to ensure repeatability of the invention.

(b) Time of Deposit

138. Where a deposit of a microorganism is required under patent law, the question arises when the deposit has to be made with a depositary institution. Since it is a general principle of patent law that an invention should be repeatable on the basis of the description at the time of filing of the relevant patent application, deposit is considered either as a requirement for granting a filing date for an application or, if a filing date can be granted even without reference to the deposit, lack of deposit on the filing date leads to a refusal of the application because of insufficient disclosure. As the deposit is considered as an integral part of the description, it could be concluded that a sample of the microorganism must be deposited with a depositary institution, at the latest, on the date on which the patent application is filed or, if a priority is claimed, on the priority date.

139. The principle outlined in the preceding paragraph has been adopted by the national laws of a number of countries. In Rule 28 of the Regulations, the *European Patent Convention*, which applies to 11 countries,[90] requires the applicant to make the deposit of a microorganism (which is not available to the public and which cannot be described) with a recognized depositary institution not later than the date of filing of the European patent application. Rule 21(1) of the Decree Relating to the Execution of the Patent Law of *Hungary* requires that a patent application relating to an invention involving a microorganism must be accompanied by a certificate concerning the deposit of the microorganism with the National Microorganism Collection of the National Institute of Public Health. In *Japan*, Rule 27*bis* of the Regulations under the Patent Law, as amended in 1982, provides that a person filing an application for an invention involving a microorganism not readily available to the public must attach to the application a copy of the receipt of the deposit of the relevant microorganism with an institution designated by the Director General of the Patent Office. Instruction 86 of the Instructions for the Drafting of Applications in Respect of Inventions of the *Soviet Union* requires that the description of an invention involving a microorganism must include the deposit number of a culture of the microorganism and the place of the culture collection with which it is deposited. In the *United States of America*, Section 608.01(p) of the Manual of Patent Examining Procedure 1983 provides that the applicant must deposit the microorganism (if previously unknown or unavailable to the public) with a depositary institution on or before the effective filing date of the application.[91] Rule 25 of the Regulations of the Patent Law of the *People's Republic of China* requires the deposit of a microorganism which is not available to the public before the date of filing, or, at the latest, on the date of filing.

(c) Duration of Storage

140. In order to disclose the subject matter of an invention fully, patent laws provide for procedures (publication of the written description and claims, inspection of the Patent Office files) which are intended to disclose the invention publicly so that, subject to any required authorization by the patent owner, anyone interested can utilize the invention. Under those procedures, there is no limitation as to the length of time during which the patent documents are to be kept by the Patent Office and during which the public should have access to the said documents. Since the deposit of a microorganism is part of the description, it could be argued that the deposit needs to be maintained by the depositary institution without any time limit. However, due to the technical complexities involved in the storage of deposited microorganisms, some national laws have introduced provisions limiting the required duration of storage.

141. For example, in *France*, where the deposit of microorganisms is regulated by the combined provisions of Rules 28 and 28*bis* of the Regulations under the European Patent Convention, of Sections 10 and 31 of the Regulations implementing the Patent Law, as amended in 1979, and Rule 9 of the Regulations under the Budapest Treaty, the duration of storage is a minimum 30-year term. In *Japan*, no statutory requirement as to the duration of storage is provided for; however, Rule 27*bis* of the Regulations under the Patent Law, as amended in 1982, refers to the deposit of microorganisms with an international depositary authority as defined in Article 2(viii) of the Budapest Treaty; it is therefore assumed that the provisions of Rule 9(1) of the Regulations under the Budapest Treaty apply, which provide for a minimum 30-year term for storage. In the *Netherlands*, following a court decision of April 3, 1974 (published in the Bulletin of Industrial Property of May 15, 1974), deposited microorganisms must be kept in storage until the expiration of the relevant patent. In *Sweden*, Article 8a of the Patent Act 1983 provides that the microorganism must be "continuously" on deposit. In *Switzerland*, the provisions of Rule 9 of the Regulations under the Budapest Treaty are applied and the duration of storage is a minimum 30-year term. In the *United States of America*, there are no statutory deposit requirements under the patent law; however, in compliance with judicial decisions, Section 608.01(p) of the Manual of Patent Examining Procedure, 1983, provides that the deposit of the microorganism must be made in a depositary institution affording "permanence" of the deposit. The meaning of the term "permanence," however, is not defined.

(d) Conditions for the Release of Samples

142. The purpose of the deposit of microorganisms within the framework of patent procedure is to complement the description of the invention so as to enable a person skilled in the art to carry out the invention. This requires, on the one hand, that the deposit be made, at the latest, at the time of filing the patent application (see paragraphs 138 and 139, above) and that, on the other hand, a sample of the deposited microorganism be available to anyone interested in obtaining one. Various approaches, however, have been adopted in respect of the time when samples of a deposited microorganism are to be made available to requesting parties and in respect of the question of

[90] On October 31, 1985: Austria, Belgium, France, Germany (Federal Republic of), Italy, Liechtenstein, Luxembourg, Netherlands, Sweden, Switzerland, United Kingdom.

[91] The Court of Appeals, Federal Circuit, decided on September 16, 1985 (*in re Lundak*), that, at the filing date, a deposit with a depositary institution which does not furnish samples to the public is sufficient, provided that, prior to granting the patent, the deposit has been effected with a depositary institution which furnishes samples to the public.

whether any restriction may be imposed on the furnishing of such samples.

(i) Time of Availability of Samples

143. As to the time when samples of deposited microorganisms should be available to any requesting party, three main systems are currently applied.[92]

144. In the *United States of America*, according to Section 608.01(p) of the Patent Office Manual of Patent Examining Procedure 1983, the deposited microorganism must be available at the date of the grant of the patent, since at that date the patent description is for the first time made available to the public.[93] It may be concluded from this rule that, where no patent is granted, the availability of the deposited microorganism is not required. The practice applied in the United States of America has the advantage that the availability of the deposited microorganism coincides with the actual grant of the patent, on the basis of which the patent owner can validly enforce his rights in case of infringement.

145. The patent law of *Japan* provides for two publications of the patent application: the first takes place 18 months after the filing date, and the second, which is made for opposition purposes, once the Patent Office has decided to grant the relevant patent. Rule 27*ter* of the Regulations under the Patent Law, as amended in 1982, provides that samples of the deposited microorganisms must be available at the date of the second publication of the patent application.

146. Under Article 93 of the *European Patent Convention*, European patent applications are subject to a dual publication system. The first publication of the patent application takes place 18 months from the filing date or, if a priority is claimed, from the date of priority. The second publication is made upon grant of the European patent. The availability of samples of deposited microorganisms is regulated by Rule 28 of the Regulations under the European Patent Convention, which, after its adoption in 1973, was amended in 1980. However, the amendment does not concern the time of availability which under the old version and the amended version starts from the date of the first publication of the European patent application.

(ii) Restrictions Concerning the Furnishing of Samples

147. Under Rule 28(3), as amended, of the Regulations under the European Patent Convention, a sample of the deposited microorganism can only be issued to the requesting party if the latter undertakes vis-à-vis the applicant or the owner of the patent:

> "(a) not to make the deposited culture or any culture derived therefrom available to any third party before the application has been refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, before the expiry of the patent in the designated State in which it last expires;
>
> (b) to use the deposited culture or any culture derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or up to the date of publication of the mention of the grant of the European patent. This provision shall not apply insofar as the requester is using the culture under a compulsory licence. The term 'compulsory licence' shall be construed as including *ex officio* licences and the right to use patented inventions in the public interest."

Moreover, Rule 28(4) introduces the possibility for the applicant to restrict the availability of the "deposited culture" on the first publication date to an independent expert nominated by the requesting party from a list of experts recognized by the European Patent Office. To make use of this possibility, the applicant must inform the European Patent Office, accordingly, before preparations for publication of the application are completed. The so-called "expert solution" was introduced in the revised Rule 28 to take into account the concern that during the period between the first publication of the European patent application and the grant of the European patent an enforceable patent right does not yet exist and therefore an uncontrolled availability of samples of the deposited microorganism might encourage misuse of the microorganism. This solution was designed to ensure that the released sample of the deposited microorganism is used only for experimental purposes and is not transferred to third parties.

148. Among the countries members of the European Patent Convention, for example, the following restrictions have been adopted: in *France*, Section 31 of the Regulations Implementing the Patent Law, as amended in 1979, provides that the requesting party must undertake vis-à-vis the patent applicant not to communicate the sample of the microorganism to any third party and to use the sample only for experimental purposes. On February 5 and July 20, 1982, respectively, the French Patent Office issued instructions according to which the released sample of the deposited microorganism can only be handled by an "independent expert," as provided for in Rule 28 of the Regulations under the European Patent Convention. In *Germany (Federal Republic of)*, following the decision of the Federal Supreme Court in the *Bäckerhefe* case (1975), requesting parties may be obliged not to pass the released samples to third parties and not to transfer them outside the territory of the jurisdiction of the patent law of the Federal Republic of Germany. In *Italy*, Section 5*bis* of the Regulations under the Patent Law, as amended in 1979, provides that the person requesting a sample of the deposited microorganism must undertake vis-à-vis the patent applicant not to make the sample available to any third party. Moreover, the furnished sample may be used only by a qualified expert, and only for experimental purposes. The expert is liable for any misuse of the released sample. In *Switzerland*, Section 27(6) of the Ordinance Implementing the Federal Law on Patents for Inventions, as amended in 1976, provides that the requesting party must undertake vis-à-vis the patent applicant not to transfer the released sample to third parties. In the *United Kingdom*, Rule 17 of the Regulations under the Patents Act 1977 provides that the requesting party must undertake to use the released sample of the deposited microorganism only for experimental purposes and not to pass the sample to any third party. In other countries, the following restrictions apply: in *China*, according to Rule 26 of the Regulations under the Patent Law, the entity or individual requesting the sample must make an undertaking not to make the microorganism available to any other person and to use the microorganism before the grant of the patent only for experiment purposes. In *Japan*, Section 27*ter* of the Regulations under the Patent Law, as amended in 1982, provides that the furnishing of samples of deposited microorganisms is restricted to cases where the samples are used for experiments or research purposes; moreover, the released sample may not be transferred to third parties. In the *United States of America*, Section 608.01(p) of the Manual for Patent Examining Procedure, 1983, provides that any restriction of public access to samples of deposited microorganisms must be removed from the date of grant of the relevant patent.

149. Thus, it appears that many national laws have adopted the practice of imposing restrictions on the availability of samples of deposited microorganisms and that, notwithstanding certain differences, the said restrictions are similar in scope. With a view to harmonizing the provisions concerning the said restriction, it must be decided to what extent the said restrictions are required, taking into account, on the one hand, the general principle of patent law that the public must have free access to all elements of the disclosure of an invention, and, on the other hand, the particular concerns of patent applicants in respect of microbiological inventions. Without sharing the view that microbiological inventions deserve special treatment within the framework of the patent system, it should be admitted that, due to the fact that they involve living entities that can reproduce themselves, they should be subject to special rules as regards disclosure involving a deposit, in respect of microorganisms not available to the public, and the availability of the deposited microorganism to the public, so that any interested party, after having obtained a sample of the deposited microorganism, can use the invention. The difference between inventions for which a deposit is required and other inventions resides in the fact that use of the former is greatly facilitated to third parties having received a sample of the deposited microorganism. Thus, the restric-

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[92] See R.S. Crespi, Biotechnology and Patents, Past and Future, EIPR, Vol. 3, No. 5, 1981, and Biotechnology and Patents: Outstanding Issues, EIPR, Vol. 5, No. 8, 1983.

[93] See the decision of the Court of Appeals, Federal Circuit (*in re Lundak*) referred to in footnote 91.

tions adopted in various laws referred to above seem in principle to be justified, and, notwithstanding the particular system of each national law—and in particular the existing difference with respect to the time when a patent application is first published—, a harmonization of the relevant provisions seems to be desirable.

(e) Depositary Institutions and the System Established by the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

150. The widespread use of cultures of microorganisms in research, teaching and industry has created a need for the establishment of institutions which are specialized in collecting, propagating, preserving and distributing such material. Their function as depositaries of living organisms has conferred upon them a central position in microbiology, because effective research and teaching demands adequate and reliable sources of properly preserved cultures, contaminant-free and well characterized, to serve as reference material. Moreover, the increased demand for historical information and data on microorganisms has created the need for accessible and up-to-date files on the characteristics of deposited cultures. The depositary institutions which have been established in response to such needs have developed sophisticated systems for storing, retrieving and exchanging information on deposited cultures, which are of primary importance for all those involved in microbiological research.

151. In requiring, under certain circumstances, the deposit of microorganisms, patent procedures have made use of the services offered by existing depositary institutions.

152. A decisive step towards the adaptation of the functions of depositary institutions to the requirements of the patent system has taken place with the adoption in 1977 and entry into force in 1980 of the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the "Budapest Treaty").[94] In essence, the Budapest Treaty has set up a legal mechanism by which the deposit of a microorganism for the purposes of patent procedure with a depositary institution that has acquired the status of "international depositary authority" under the Treaty is recognized for such purposes in all the other contracting States.

153. The Budapest Treaty enumerates the requirements to which depositary institutions have to conform in order to acquire the status of "international depositary authority," and which ensure a uniform treatment of the deposit, storage and availability of samples of microorganisms for the purposes of patent procedure. Under Article 7 of the Budapest Treaty, a depositary institution acquires the status of "international depositary authority" when one of the contracting States provides the Director General of WIPO with assurances that the institution complies and will continue to comply with certain requirements of the Treaty. According to Article 6(2) of the Treaty, the institution, in its capacity of international depositary authority, must:

— have a continuous existence;
— have the necessary staff and facilities to perform its scientific and administrative tasks under the Treaty;
— be impartial and objective;
— be available, for the purposes of deposit, to any depositor under the same conditions;
— accept for deposit any or certain kinds of microorganisms, examine their viability and store them;
— issue a receipt to the depositor, and any required viability statement;
— comply, in respect of the deposited microorganisms, with the requirement of secrecy;
— furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed under the Treaty.

Finally, Article 8 of the Treaty, in conjunction with Rules 4 and 5 of the Regulations, provides uniform measures and a uniform procedure to apply such measures, in case of non-compliance by any international depositary authority with the requirements of Article 6(2).

154. Thirteen depositary institutions[95] have acquired the status of international depositary authority under the Budapest Treaty as of October 31, 1985. Each depositary institution, when it acquired the status of international depositary authority, declared to accept for deposit under Article 6(2)(v) of the Budapest Treaty certain specific kinds of microorganisms. The list of accepted microorganisms may be amended at a later stage. As a result, the kinds of "microorganisms" that the international depositary authorities have declared to accept for deposit under the Budapest Treaty encompass the following:

> bacteria, plasmids, actinomycetes, yeasts, moulds, fungi, bacteriophages, viruses, animal and plant viruses, protozoa, algae, cell lines, hybridomas, oncogenes, phages, plant tissue cultures, seeds.

155. The above list reflects recent research developments in the field of biotechnology; it includes material (e.g., plasmids, hybridomas, seeds) that cannot be considered as living entities but that is used for biotechnological inventions in the same way as microorganisms and that, since it cannot be described in a patent application, is admitted for deposit by depositary authorities. Therefore, the question arises whether the system of deposit under the Budapest Treaty also applies to non-living material. In order to give a tentative answer to this question, two aspects should be distinguished. From the *scientific* point of view, it should be ascertained which are the main characteristics that distinguish non-living material from microorganisms and, from the *legal* point of view, it should be clarified whether under the Budapest Treaty there is any provision that may be construed as preventing its applicability to non-living material.

156. As to the first point, it is generally admitted that *microorganisms* are living organisms of microscopic dimensions. The term microorganism has no taxonomic significance; it relates purely to size. No matter how simple their organization may be, microorganisms are organisms in their own right; they are not merely living entities that have been derived by laboratory techniques from higher (biologically more complex) organisms. Thus, for example, bacteria, yeasts, microfungi, protozoa, microscopic algae are microorganisms. Opinion is divided whether *viruses*, strictly speaking, are microorganisms, although for convenience most microbiologists consider them as such. They are certainly microscopic; the division of opinion, which seems to be more philosophical than scientific, rests on whether they should be regarded as living organisms or merely as biologically active entities. They are not cellular—most consist of genetic material encased in a protein coat—and they cannot reproduce themselves directly. They have to enter (infect) a host cell, and, once inside, their genetic material directs the biosynthetic machinery of the host cell to synthesize more viruses. *Plasmids* are not microorganisms but merely extrachromosomal DNA molecules which often can be transferred from one cell to another. They carry the genes for their own replication, but they can replicate only with a host cell. Plasmids are best regarded as dispensable (from the point of view of the host cell), non-chromosomal pieces of genetic material. *Cell lines* are not microorganisms. They consist of cells originally derived from the tissues of animals or plants. They can reproduce themselves indefinitely *in vitro* when provided with suitable nutrients and environmental conditions and are thus

[94] On April 1, 1986, the following 19 States were party to the Budapest Treaty: Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany (Federal Republic of), Hungary, Italy, Japan, Liechtenstein, Norway, Philippines, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America. Moreover, the European Patent Organisation has obtained a status which in some respects corresponds to the status of a member State.

[95] Agricultural Research Culture Collection (United States of America); American Type Culture Collection (United States of America); Centraalbureau voor Schimmelcultures (Netherlands); Collection nationale de cultures de micro-organismes (France); Culture Centre of Algae and Protozoa (United Kingdom); Culture Collection of the Commonwealth Mycological Institute (United Kingdom); Deutsche Sammlung von Mikroorganismen (Federal Republic of Germany); European Collection of Animal Cell Cultures (United Kingdom); Fermentation Research Institute (Japan); In Vitro International, Inc. (United States of America); National Collection of Industrial Bacteria (United Kingdom); National Collection of Type Cultures (United Kingdom); National Collection of Yeast Cultures (United Kingdom).

living, self-reproducing entities. However, a cell line is not an organism in its own right—it has merely been derived from part of an organism.

157. As regards the second point, it is to be noted that the Budapest Treaty does not contain any definition of the term "microorganism" and that, in connection with Article 2(ii) of the Treaty (definition of "deposit of a microorganism"), the relevant commentary contained in WIPO document DMO/DC/3 indicates that:

> "The term 'microorganism' has various meanings depending on the context in which it is used, including, in particular, 'strain of microorganism' and 'culture of microorganism.' It includes a 'mixture' of microorganisms. Specification of these meanings for the purposes of the Treaty does not seem to be necessary.
>
> As regards the kinds of microorganisms covered, these should be interpreted in the broadest sense, taking into account the purposes of the Treaty; such interpretation need not necessarily correspond to usage in some scientific circles. It includes all microorganisms which can be stored by a depositary institution."

In the light of this commentary, which shows that historically this lack of definition was intended, it appears that any microorganism may be deposited under the Budapest Treaty, provided that it is among the "kinds" expressly accepted for deposit by an international depositary authority under Article 6(2)(v) and provided that it can be stored in conformity with Rule 9 by that authority. This conclusion seems to apply also to non-living material, for example, plasmids and cell lines, which are currently included among the "kinds of microorganisms" accepted for deposit by a number of international depositary authorities (American Type Culture Collection, Collection nationale de cultures de micro-organismes, European Collection of Animal Cell Cultures and In Vitro International, Inc.).

Annex I

Glossary of Scientific Terms

Amino acids—the building blocks of proteins.

Biochip—an electronic device that uses biological molecules as the framework for molecules that act as semiconductors and functions as an integrated circuit.

Bioconversion—a chemical conversion using an enzyme.

Biomass resources—cover all organic matter that grows by the photosynthetic conversion of solar energy.

Biopolymers—naturally occurring macro molecules that include proteins, nucleic acids and polysaccharides.

Biosensor—an electronic device that uses biological molecules to detect specific compounds.

Cell—the smallest structural unit of living matter capable of functioning independently.

Cell lines—cells that acquire the ability to multiply indefinitely *in vitro*.

Cosmid—a DNA cloning vector consisting of plasmid and phage sequences.

DNA—deoxyribonucleic acid, the basic molecular component of the hereditary material.

DNA probe—a sequence of DNA that is used to detect the presence of a particular nucleotide sequence.

Enzymes—proteins that are produced by living cells and that mediate and promote the chemical processes of life without themselves being altered or destroyed.

Estrus (or "heat")—the period during which the female will allow the male to mate with her. The synchronization can be achieved by the use of various drugs.

Haploid—a cell with only one set (half the usual number) of chromosomes.

Heterozygous—when two genes controlling a particular trait are different, the organism is heterozygous for that trait.

Homozygous—when two genes controlling a particular trait are identical for a pair of chromosomes, the organism is said to be homozygous for that trait.

Immunotoxins—are a combination of two molecules—a monoclonal antibody tied to a toxin molecule.

Lipid—a large, varied class of water-insoluble organic molecules; it includes steroids, fatty acids, prostaglandines, terpenes and waxes.

Monoclonal antibodies—homogeneous antibodies derived from a single clone of cells. A clone is a group of genetically identical cells or organisms asexually descended from a common ancestor. All cells in the clone have the same genetic material and are exact copies of the original.

Myeloma—a tumor cell that can also produce antibodies.

Organelle—a specialized part of a cell that conducts certain functions. Examples are nuclei, which contain most of the genetic material (chromosomes), chloroplasts, for conducting the photosynthesis, and mitochondria, for providing energy.

Parthenogenesis (or "virgin birth")—the initiation of development in the absence of sperm.

Phage—any of various specific bacteriolytic viruses normally present in sewage and in body products.

Plasmid—an extra chromosomal (chromosomes are the thread-like components of a cell that are composed of deoxyribonucleic acid—DNA—and a protein), self-replicating, circular segment of DNA.

Ploidy—describes the number of sets of chromosomes present in the organism.

Polysaccharide—a polymer of sugar.

Protoplast—a cell without a wall.

Regulatory proteins—polypeptides consisting of amino acids, e.g., human insulin, interferons, human hormones, etc.

Replicon—a DNA molecule capable of replications, which is a synthesis of new DNA from existing DNA and the formation of new cells by cell division.

Steroids—group of organic compounds, some of which act as hormones to control cell growth and functions in higher animals and humans.

Superovulation—hormonal stimulation of the female resulting in the release from the ovary of a larger number of ova than normal.

Viruses—submicroscopic agents infecting plants, animals and bacteria; they are unable to reproduce themselves outside the tissues of the host.

Annex II

Examples of Biotechnological Processes by which New Plants are Produced

— A cereal produced by a method of producing hybrid seed, comprising growing together in pollinating proximity male pollinator plants which are characterized as recessively-inherited tall plant types having a recessive tall gene, and shorter female plants:[1]

— a gymnosperm clone produced by a process comprising the steps of contacting the terminal portion of a stem of said gymnosperm with about 0.01 to 20 mg of a cytokinin to activate the needle faseicles of said stem; allowing the activated needle fascicles to elongate into shoots; excising the shoots from said stem; and rooting said shoots:[2]

— a first generation semi-dwarf hybrid sunflower plant of reduced internode length, the hybrid sunflower plant having been grown from the seed from the cross-pollination of a pair of parent plants (P_1 and P_2) wherein in at least one parent substantially all pollen is non-functional and at least one parent has gametes with nuclei which carry at least one dominant gene for reduced internode length (Df):[3]

[1] US patent No. 4,351,130—September 28, 1982.

[2] US patent No. 4,377,921—March 29, 1983.

[3] US patent No. 4,378,655—April 5, 1983.

– a plant, a plant tissue, or a plant cell produced according to the method for genetically modifying a plant cell, comprising the steps of: (a) inserting a plant gene comprising a plant promoter and a plant structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the plant promoter being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription; and (b) transferring the T-DNA/plant gene combination into a plant cell.[4]

[4] EP—published patent application, publication No. 0122791—October 24, 1984.

Annex III

Examples of Biotechnological Processes for the Creation of Plants, Animals or Microorganisms or Parts thereof

– A method of producing hybrid seed, comprising: growing together in pollinating proximity male pollinator plants which are characterized as recessively inherited tall plant types having a recessive tall gene, and shorter female plants;[1]

– a process for the *in situ* activation of normally dormant needle fascicles of gymnosperms to produce shoots, comprising the step of contacting the terminal portion of a stem of said gymnosperm with between about 0.01 to 20mg of a cytokinin;[2]

– a method of producing semi-dwarf hybrid sunflower seeds which will produce sunflowers with reduced internode length under normal growing conditions, which comprises: (a) growing a pair of parent plants (P_1 P_2) wherein in at least one parent substantially all pollen is non-functional and at least one parent has gametes with nuclei which carry at least one dominant gene for reduced internode length (Df); (b) cross-pollinating the plants (P_1 P_2) to produce hybrid seeds F_1; (c) harvesting the hybrid seeds;[3]

– a non-agricultural method for production of cocoa cotyledons for food production comprising the steps of: (a) proliferation of immature cotyledonary zygotic cocoa embryos in a basal medium in the presence of a growth enhancer whereby asexually embryos are initiated upon said zygotic embryos; and (b) growing said embryos *in vitro* in a basal medium; and (c) harvesting the cotyledons so produced for food production;[4]

– a method for genetically modifying a plant cell, comprising the steps of: (a) inserting a plant gene comprising a plant promoter and plant structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the plant promoter being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription; and (b) transferring the T-DNA/plant gene combination into a plant cell;[5]

– a method of producing malignant tumor antibodies comprising immunizing an animal with tumor cells, forming fused cell hybrids between antibody producing cells from said animal and myeloma cells, cloning said hybrids and selecting clones which produce antibodies that demonstrate a specificity for said tumor cells;[6]

– process for the production or biotransformation of metabolites by plant cells *in vitro*, which process is characterized in that the cells are cultivated in a non-agitated liquid medium and in the absence of any artificial carrier for including or fixing these cells, the medium circulating on the cells without carrying them away;[7]

– a hybrid vector synthesized from a fragment of mitochondrial DNA, containing a mitochondrial DNA origin of replicating, of acremonium or podospora species.[8]

[1] US patent No. 4,351,130—September 28, 1982 (see also footnote 1, Annex II).

[2] US patent No. 4,377,921—March 29, 1983 (see also footnote 2, Annex II).

[3] US patent No. 4,378,655—April 5, 1983 (see also footnote 3, Annex II).

[4] EP patent No. 0010393—June 6, 1984.

[5] EP published patent application No. 0122791—October 24, 1984.

[6] US patent No. 4,172,124—October 23, 1979.

[7] EP patent No. 0050562—March 28, 1984.

[8] US patent No. 4,492,758—January 8, 1985.

General Studies

The Protection of Trademarks in Bulgaria

I. ESKENAZI*

News from Industrial Property Offices

GUATEMALA

Registrar,
Registry of Industrial Property

We have been informed that Mr. Jorge Rafael Recinos Acevedo has been appointed Registrar, Registry of Industrial Property.

Calendar of Meetings

WIPO Meetings

(Not all WIPO meetings are listed. Dates are subject to possible change.)

1986

July 2 to 4 (Geneva) — Working Group on Links Between the Madrid Agreement and the Proposed (European) Community Trade Mark

September 1 to 5 (Geneva) — Permanent Committee on Patent Information (PCPI) and PCT Committee for Technical Cooperation (PCT/CTC)

September 8 to 10 (Geneva) — WIPO Patent and Trademark Information Fair

September 8 to 12 (Geneva) — Governing Bodies (WIPO Coordination Committee, Executive Committees of the Paris and Berne Unions, Assembly of the Berne Union)

October 13 to 17 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on General Information

October 20 to 22 (Geneva) — Committee of Governmental Experts on Works of Architecture

November 11 to 14 (Geneva) — Committee of Experts on the International Registration of Marks

November 17 to 21 (Geneva) — Paris Union: Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions

November 24 to December 5 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on Search Information

December 8 to 12 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Groups on Special Questions and on Planning

December 16 to 19 (Paris) — Committee of Governmental Experts on Works of Visual Art

UPOV Meetings

1986

July 15 to 18 (Wageningen) — Technical Working Party for Ornamental Plants and Forest Trees, and Subgroup

September 15 to 19 (Wädenswil) — Technical Working Party for Fruit Crops, and Subgroup

November 18 and 19 (Geneva) — Administrative and Legal Committee

November 20 and 21 (Geneva) — Technical Committee

December 1 (Paris) — Consultative Committee

December 2 and 3 (Paris) — Council

Other Meetings Concerned with Industrial Property

1986

September 13 to 17 (Lucerne) — International League for Competition Law: XXIXth Congress

September 23 to 26 (Strasbourg) — Center for the International Study of Industrial Property: Seminar on Licensing and the Transfer of Technology (second module: Strategy and Procedures for the Transfer of Technology)

October 22 to 24 (Mainz) — Pharmaceutical Trade Marks Group: 33rd Conference

December 1 to 5 (Munich) — European Patent Organisation: Administrative Council