LEGAL ASPECTS OF AQUIRING, HOLDING AND UTILIZING PATENTS WITH REFERENCE TO THE ACTIVITIES OF THE INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY

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INTRODUCTION

In its 13th session (Vienna, Austria, 26-28 April 1989) the Preparatory Committee on the Establishment of the International Center for Genetic Engineering and Biotechnology (ICGEB) considered that it would be important for the Center to develop a patent policy as soon as possible. It therefore requested the Director to prepare, in co-operation with the UNIDO Secretariat, a detailed document for its next session on the issues involved both in regard to research in the ICGEB Components and the Collaborative Research Programmed with affiliated centres[1].

In order to comply with the request of the Preparatory Committee, the UNIDO Secretariat asked the authors of the present study to carry out an analysis of the legal aspects of acquiring, holding and utilizing patents with reference to the activities of ICOEB. The study should in particular consider the following aspects;

The legal framework, including the Statutes of the IC6EB, the applicable international conventions and practices in the fields of genetic engineering and biotechnology, including the special system of protection for new varieties of plants.

The legal situation of patents in the above-mentioned fields in Austria, India, and Italy, including an analysis of the advantages and disadvantages of those legal systems to the granting of patents for this particular category of inventions.

A legal analysis of the international agreements concluded on the ICGEB projects between UNIDO and India, and UNIDO and Italy with respect to the question of granting patents.

Licensing in biotechnology and genetic engineering with particular reference to Austria, India, and Italy.

The course of the analysis can be outlined as follows; Before addressing the specific issues connected with the protection of biotechnological inventions, the general characteristics and principles of patent, law have to be presented at first. Thus, the purposes of patent protection, the principle of territoriality, the international patent regime and the different regional and national systems will be summarized (II.) Acquiring and holding patent rights in biotechnological inventions raises numerous specific issues which need to be discussed thoroughly. In this context, the concept of paten table subject matter, the patent ability requirements (novelty, inventive step, industrial applicability and enabling disclosure) and the scope of protection conferred will be analyzed under the patent systems of Austria, India, Italy, Japan and the United States [2] as well as under the European Patent Convention and the

WIPO model law for developing countries (III.). Thereafter, the special protection schemes available for plant varieties will also be reviewed and compared to patent protection (IV.), Furthermore, the treatment of international organizations in patent law requires particular attention. Among the questions arising in this context, the present study will analyze the most important, ones, taking into account, the Statutes of ICGEB and the bilateral international agreements between UNIDO and India and between UNIDO and Italy (V.). International licensing of biotechnological inventions constitutes an extremely vast area which can certainly not be examined in all details in the context of the present analysis. The study will, however, highlight the most important issues to which ICGEB should pay attention when defining and administering a sound licensing policy (VI.). Some conclusions will be presented in the last section (VII.).

INTERNATIONAL, REGIONAL AND NATIONAL REGIMES OF PATENT LAW

General aims of patent law

The granting of patents for new inventions as a way of encouraging innovation is a long-established instrument of promoting technical progress and industrial development [3] Strong support can be found for the assertion that patent law fulfills this task in an efficient manner.[4] Modern patent legislation is based on those four classic objectives justifying patent protection which had been formulated by Fritz Machlup in his well-known historical and economic analysis of the patent systems.[5] According to these widely accepted "patent theories", patents are granted;

- To recognize the intellectual property of the inventor;
- To reward the inventor for his useful services as "teacher of the nation",
- To encourage inventors and industry to invent, invest and innovate; and finally;
- To further the early disclosure and wide dissemination of technical knowledge.

All of these functions serve one superior objective which is to promote technical, economical and social progress. [6]

Whereas in most industrialized countries the importance of patents as an efficient instrument of economic policy is widely recognized:, a more critical view has been prevailing concerning the value of exclusive industrial property rights in third world countries. In fact, since the publication of the UNCTAD study on the "Role of Patent System in the Transfer of Technology to Developing Countries" in 1975 [7], many developing countries have shared the view that patents at best do not hard their economies but most probably have manifold negative economic effects. No attempt for estimating the value of patents for the third world in general will be made here. Attention should, however, be drawn to the complexity of the problem which requires to be considered from many aspects. Any simplicity of argumentation, therefore, tends to be wrong or at least misleading. So, the UNCTAD Study was certainly correct to state that "...patents should be viewed in terms of public interest not only in the theoretical sense but in the practical judgment of what are likely to be the consequences of specific legal provisions for the national economy and its future development. "[8] However, many general conclusions drawn in that Study have obviously failed to get to the bottom of the problems addressed. This is true in particular for the observation that a high proportion of patents granted in developing countries to nationals of developed countries reflects the unequal economic and technological strength of both groups of countries, and for the conclusion that an overwhelming majority of patents granted to foreigners have been used to secure import monopolies. Although both observations were based on correct statistical

data, they failed to notice that these data only slightly deviate from those of many developed countries,

The assumption of the UNCTAD study with regard to the effects of the high proportion of foreign patents in a given developing country, appears to be disproved by the example of South Korea; From 1974 to 1983 the proportion of patents granted to foreigners grew from 30%; to 90% (from 300 to about 2.500 p.a.). But in the same period, a real growth of the gross national product from about 9.000 to, 17.000 billion Won (in constant prices on the basis of 1975) took place. [12] From statistical data collected and prepared by Greif for 30 developing countries, it can even be concluded that the higher the number of patent applications by foreigners, the higher the economic position of a country.[13] Not surprisingly, observers have found "indications that a number of developing countries, particularly those that adopted more defensive strategies on patents, are reassessing the contribution of the patent system to local development, namely the incentives it might provide to secure financing for research development".[14] Having regard to the fact that Mexico was one of the pioneers of those defensive strategies, its revision of patent legislation of 1986 [15] seems to be a proof rather than an indication for the new approach of some developing countries. It goes along the same lines that developing countries, with a weaker technological base, mainly in Africa, and several Asian countries continue to maintain a liberal approach to industrial property protection.

As to the general nature of patent rights, some remarks appear to be necessary in order to avoid misunderstandings: When a patent is granted, the inventor has the right to exclude all others from making, using or selling the invention without his consent for a limited period of time. Consequently, a patent is essentially a "negative" right, i.e., it does not automatically confer a positive right to use the invention, since the patentee has always to
respect the whole legal system. If, e.g., a hazardous drug with potential adverse side effects has been patented, the patentee h-is no right to produce and market the drug until it is approved by the competent administrative authority.

The principle of territoriality

Although most states - with the exception of the socialist countries -have similar patent law structures, there are considerable differences in detail. This means that a particular invention may be patentable under the laws of one country but not under the laws of another country. The legal rights conferred to the patentee are limited to the territory of the country that has granted the patent *(principle of territoriality)*. Consequently, an inventor needs to obtain a patent in each country where he wishes to have protection.[17] The obvious disadvantages of this situation have been the driving force for different attempts at achieving international harmonization of this field of law. In the following, the most important initiatives, which have brought about the current international and regional regime of patent law, will be shortly reviewed before examining the main features of national patent system.

The international regime

The Paris Convention

The Paris Convention (PC) constitutes the ground work of the international patent system. It is a universal treaty establishing certain basic rights for residents and nationals of its member countries for the protection of industrial property rights under the laws of other member countries.
The original Convention was signed in 1883. Eight revision conferences have been held between 1986 and 1967,[19] the ninth is being planned.[20] The PC creates an international union for the protection of industrial property, the so-called Paris Union, of which each contracting country is a member. As a result of the 1967 Stockholm amendment, the administration of the PC was taken over by the World

Intellectual Property Organization (WIPO), a U.N. organization, which was established as successor of the Bureaux Internationaux Reunis pour la Protection de la Propriete Industrielle (BIRPI). As of January 1, 1989, there were 99 member countries,[21] among which Austria, Italy, Japan, and the United States can be found. India, however, has not yet acceded to the PC although it is a member of the WIPO Convention of 1967.[22]

One of the cornerstones of the Convention is the principle of "national treatment" set forth in Art.2, which provides that nationals of any country of the Union are to enjoy in all the other countries of the Union the advantages that the laws of these respective countries grant to their own nationals, provided that the conditions and formalities imposed upon nationals of those countries are complied with. Art.3 extends this principle to nationals of non-member countries who are domiciled or have an establishment in one of the member countries. The purpose of this principle is to eliminate discrimination under national law against foreigners, and to place them on equal footing with nationals of any member country with respect to the acquisition, recognition and enforcement of rights in industrial property under the domestic laws of that country.[23]

From a practical standpoint, the most important right granted by the Convention is the right to priority. This right enables any resident or national of a member country to first file a patent application in any member country and to thereafter file a patent, application for the same invention in any of the other member countries within 12 months of said first filing, with the effect that these subsequently filed applications will enjoy the right of priority of the first filing date, i.e., they will be treated as if they were filed on the first filing date.[24]

In the field of patent law, the PC contains only a small number of! provisions which require member countries to adapt their legislation to certain "substantive international standards" specifically defined by the Convention (cf. Art. 4, 4^{bis}, 4^{ter}, 4^{quater}, 5, 5^{bis}, 5^{ter}, 5^{quater} PC). Thus, e.g., the right of member countries to legislate in the area of compulsory licenses and forfeiture of patent rights is - whilst recognized in principle - restricted to a certain extent, as it can easily be seen by the text of Art. 5a(2), (3), and (4):

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

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

Art. (4) -A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory be non-exclusive and shall not be of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such licence.[25]

Art.19 - PC reserves for the countries of the Union the right to make separately between themselves special agreements for the protection of industrial property, insofar as these agreements do not contravene the provisions of the Convention. Under this provision a number of special multilateral agreements have been concluded, e.g., the Patent Cooperation Treaty, the Budapest Treaty and the European Patent Convention which will be discussed below.

The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) is a worldwide convention which is open to membership to any Paris Convention country. It entered into force in 1978 and, as of January 1989, applies to 41 countries amongst which Austria, Italy, Japan, and the United States can be found.26 The PCT creates an International Patent Cooperation Union with two main purposes, namely (1) cooperation in filing, searching and. examining patent applications and (2) rendering special technical services. 27 For carrying out the former purpose, the PCT provides an essentially procedural system that involves two stages, the "international stage" and the "national stage". The international stage begins when an applicant files his international application in one of the Receiving Offices which retains the "home copy" of the application and forwards the "search copy" to the appropriate International Searching Authority (ISA) and the "record copy" to the International Bureau in Geneva which is part of WIPO. The ISA conducts an international search with respect to the' claimed invention and prepares a search report. Either with or without amendment of the claims by the applicant, the International Bureau publishes the application and search report at the end of 18 months from the effective filing date. The applicant must - before the expiration of 20 months from the effective filing date - supply to each Designated Office a translation (where necessary) of the international application into one of the official languages of the designated state and any required national fee in order to begin the "national" stage. The applicant is then given until the end of the 21st month to make any desired amendments to the application before the national patent office. Thereafter, the application is subjected to the same treatment, by the designated national office as it would apply to any regular national application.[28]

The Budapest Treaty

Under the auspices of WIPO, an international treaty of particular importance to biotechnological inventions was concluded in 1977, namely the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (BT) which entered into force in 1980. The BT is open to membership for any country belonging to the Paris Convention and, as of January 1, 1989, binds 22 States, [29] inter alia Austria, Italy, Japan, and the United States. Article 9 BT contains a special provision under which international patent organizations may file a declaration accepting certain obligations under the Treaty. This possibility has been used in particular by the European Patent Organization.

The objective of the BT is to oblige member states to recognize for their own patent procedures a deposit of microorganisms [30] made in any International Depository Authority, thereby rendering superfluous cost- and time- consuming multiple deposits. Although the BT thus facilitates applications for patent protection of biotechnological inventions abroad, it does not influence the substantive law of the contracting states. Its harmonizing influence on patent laws of the member countries is limited to rather technical provisions regarding the depositing and red positing of microorganisms.

The UPOV-Convention

In 1957, the French Government launched the idea of an international agreement for the protection of plant varieties. After four years of intensive consultations and two diplomatic conferences, the International Convention for the Protection of New Varieties of Plants (UPOV convention) was signed in 1961.

This convention has been revised twice, in 1972 and in .1978; at present 18 States are party to it, inter alia Italy, Japan, and the United States. The protection scheme set up by the UPOV convention and corresponding national laws will be reviewed below (IV.) in more detail.

The European patent system

The European Patent Convention of 1973

Since the international patent system addresses the substantive legal issues only in a rudimentary way, a strong need has been felt for regional patent law harmonization. So far, the most successful and most important of the initiatives made in this respect has been the European Patent Convention (EPC) of 5 October 1973 which entered into force in October 1977 and was ratified by most EC member countries (including Italy) and further European states (Austria, Liechtenstein, Sweden, Switzerland). Patent applications filed with the European Patent Office (EPO) in Munich are dealt with in a uniform application procedure and, if successful, lead to European patents. which are valid in all EPC member states designated by the applicant. Nevertheless., the special legal concept of the EPC must be kept in mind; Although the EPC provides for a system of law for granting European patents, these patents, in each of the Contracting States for which they are granted, have the effect of and are subject to the same conditions as a national patent by that State (Art.1 and 2 EPC). A European patent is granted, defined and revoked in applying rules of the EPC, and to this extent represents a collection of "European" patents. For all other purposes., such as the scope of protection, European patents constitute patents with national effects, subject to national laws, although certain minimum standards are prescribed in Art. 64 (2) and 67 EPC and although Art. 63(1) EPC provides for a common term of the European patent (20 years as from the filing date). This means inter alia that national courts are competent in nullity procedures regarding European patents and that in the course of these procedures they are even not bound by case law of the Board of Appeals of the EPO, which, in final instance, decides on patentability in the framework of the European patent application procedure.

Under the EPC, the application will be carefully examined by the EPO in order to find out whether all the legal requirements for a patent grant are met by the applicant. Although this examination may last several years, the patent application will in any case be published already after the expiry of a period of eighteen months from the date of filing or from the date of priority.[31] Subsequent to the publication of the application, the files relating to it may be inspected on request by any third parties.[32]

The Community Patent Convention of 1975

In contrast to the EPC, the Convention for the European Patent for the Common Market (CPC) - concluded in 1975, but not yet in force - and the 1985 Agreement relating to Community patents make an attempt to achieve an even higher degree of harmonization; A Community patent will have the same legal effects in the whole EC-territory. Nullity proceedings will have to take place at a specifically established European court. It. is difficult; however", to predict the entry into force of the CPC, but. a date prior to 1993 would be highly unlikely. Furthermore,, the CPC may well come into force for less than all member States of the Community.

National patent systems

General

Since a truly international regime of patent law is still lacking, the principle of territoriality prevails up to this day and national patent laws still play a predominant role. In this respect, one also has to bear in mind that, notwithstanding the great success of the EPC,, the national route has. remained equally open in Europe. Consequently, an inventor who wishes protection for his invention, e.g., in Austria or in Italy, may also file an application with the national patent offices. As to their substantive patent law., the EPC member states have harmonized their legislation to a wide extent.[33] This has happened, however, on a largely voluntary, unilateral, uncoordinated basis since it results from the

design of the EPC that the Contracting States are not obliged to automatic ally align their national patent laws with the EPC.

The national patent laws of those countries on which the present study is specifically focusing (i.e. Austria, India, Italy, Japan, and the- United States) will now briefly be reviewed. Attention has to be drawn to the fact that, in this part of the present study, only the general features of the respective national patent system will be outlined.[34] A short comment on the USIPO model law for developing countries also seems to be appropriate.

The Austrian patent system

Austria ratified the European Patent Convention in 1979 [35] and subsequently adapted its national patent law of 1970 to that Convention by means of the Patent Law Amendment Act (Patentrechtsnovelle) 1984.[36] A further amendment Act of 1986 strengthened the protection for certain biotechnological inventions.[37] The application procedure differs in Austria from that under the EPC; There is no automatic laying open of the application after 18 months of the filing date. Only when the Patent Office considers that the application has been made in proper form and that the grant of the patent is not precluded, it shall order the application to be published. [38] Then the application will be laid open for public inspection for a period of four months.[39]
The legal effects of the patent begin to operate provisionally in the applicant's favour on the day of publication. [40] As to the duration of protection, no complete harmonization with the EPC has been achieved. An Austrian patent lasts 18 years from the day of publication of the application with only the maximum duration of the patent limited to 2'0 years from the filing date.

The Indian patent system

The history of Indian patent law can be traced back to the early date of 1856. When gaining independence In 1947, India, however, felt that the Patents and Designs Act of 1911 was not fulfilling its objective. After intensive work of several co sun it tees and a detailed report submitted by Justice Ayyangar, a new patent law was enacted in 1970. [42] The Indian Patents Act of 1970, which is currently in force, provides for an examination of the patent application as to substance. It envisages the possibility of a worldwide search and gives power to conduct such a search. In India, the normal patent term is 14 years from the date of filing, with the exception that. any patent for the process of manufacturing substances used or capable of being used as food, medicine or drug has only a duration of 7 years from the filing .,date of 5 years from the date of sealing of the patent, whichever is shorter.

The Italian patent system

In 1979, the Italian patent law was brought in line with the EFC and the CPC. The amending law No. 338-1979 revised most sections of the Patent Act and its implementing regulations. [44] Some minor changes have been made since then. [45] In contrast to the patent systems of most other industrialized countries, the Italian granting procedure has been and is still characterized by the absence of a prior examination for novelty and inventive step.[46] Only in certain exceptional cases, in which novelty is obviously lacking, the Patent Office refuses the grant of the patent. [47] Also in Italy - like under the EPC -, the patent application is laid open after a period of 18 months from the filing date or the priority date.[48] The protection of the applicant during the patent granting procedure differs to some extent from that under the EPC. [49] Italian patents have a term of 20 years as from the date of filing.[50]

The Japanese patent system

The first Japanese patent law was enacted in 1885. Currently in force is the Law No. 121 of 1959, which has been amended on several occasions.[51] In Japan, the patent term is 15 years from the date of publication of the patent application, provided, however, that such term does not exceed 20 years from the filing of the patent application. An extension of the normal patent period is possible if the patentee could not work the invention for two years or more because of the necessity to comply with official safety review procedures.[52] The Japanese Patent Office examines the claimed invention as to substance (novelty, non-obviousness, etc.). After 18 months from the filing date, the application will be laid open for public inspection (Art. 65^{bis}). [53]

The U. S. patent system

The U.S. Constitution authorizes Congress to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries,[54]

Accordingly, since 1790, the U.S. Congress has enacted a number of Patent Acts. Currently in force is the U.S. patent Act of 1952, which ahs been amended several times. The normal life of a U.S. patent is 17 years from the date of the patent grant. Under the Patent Term Restoration Act of 1984., however, this term can be extended for certain groups of inventions (in particular pharmaceutical products) provided that -they could not be marketed because of safety review. The U.S. patent law adheres to the first-to-invent concept and differs thereby from nearly all other patent systems which adhere to the first-to-file principle. There is no laying open of unexamined patent applications, since U.S. patent law allows public access to the information contained in the patent application only if and when a patent is granted.[55]

The WIPO model Law for the developing countries

It. would be clearly beyond the scope of the present study to give a| survey of the different national patent laws in developing countries in general. Attention should be only drawn to the Model Law for Developing Countries which was elaborated and published under the auspices of WIPO in 1979. In its preamble, it sets out its purpose, i.e. to create a legal regime to favour the inventive spirit of nationals and to facilitate acquisition and assimilation of foreign technologies.[56] A large number of developing countries have shaped their patent legislation in a way that corresponds to the WIPO model law. In addition, mention shall be made of the Agreement on the Creation of an Industrial Property Organization for English-Speaking Africa (ESARIPO) adopted at Lusaka, Zambia, in 1976,[57] and of the OAPI Uniform Law (1977 Bangui test), prepared with the assistance of WIPO.

The GATT-TRIP negotiations

Whereas the worldwide international regime of patent law is based on the principle of national treatment and establishes only rather low substantive standards, an attempt to change this situation is presently made by means of bilateral and multilateral trade negotiations. In particular, attention should be drawn to the negotiations of the GATT Uruguay Round in the context of which the United States have tabled a specific initiative concerning intellectual property rights. The U.S. GATT initiative refers to the earlier GATT project of negotiating an international anti-counterfeiting code, but aims at broadening the GATT competence to "trade-related aspects of intellectual property" (= TRIP). Its purpose is to conclude a GATT-treaty establishing high standards of protection for different categories of intellectual property, enabling the owners to effectively enforce their intellectual property rights and providing the contracting parties with operative dispute settlement procedures. The U.S. proposal has found support among several GATT member states and within industry circles. It has been inserted into the declaration of Punta del

Este and reiterated in the GATT declaration of April 1989. There can be no doubt that the GATT-TRIP-negotiations might also have a great influence on the international protection of biotechnological inventions.[58]

COMPARATIVE ANALYSIS OF PATENT LAW IN THE FIELD OF GENETIC ENGI-NEERING AND BIOTECHNOLOGY

General

The rapid development of modern biotechnology has raised numerous questions in the field of industrial property law. In order to analyse and improve the current state of patent law vis-a-vis biotechnological inventions, several in-depth studies have been completed ,1 both in the national and in the international context.[59] Furthermore, legislative action has been taken or is currently under consideration. The recently published EC Proposal for a Council Directive on the Legal Protection of Biotechnological Invention[60] can probably be considered to be the most important of these initiatives. The proposed Directive is intended to harmonize possible solutions in the construction of ambiguous legal provisions and to strengthen patent protection. It covers microbiological achievements and plant biotechnology as well as the results of modern animal breeding techniques.

The legal issues involved in the patenting of biotechnological inventions will be now closely examined. In this respect, the following basic questions have to be answered;

- To what extent do research results in biotechnology constitute patent-' able subject matter in the different patent systems? (B)
- How can the general conditions of patentability be fulfilled in the context of biotechnological inventions? (C)
- What is the scope of protection of a patent granted for a biotechnological invention? (D)

Patentable subject matter

General

The success of any patent, application filed by IC6EB or UNIDO primarily depends on the question whether it concerns "patentable subject matter". In this respect, it has to be noted that patent law is based on a certain concept of what constitutes an invention. In some patent systems this concept has been worked out by case law without an explicit legislative guidance, in other patent systems the concept of invention is reflected by a number of general exclusionary provisions. Furthermore, specific exclusionary provisions, which have a direct impact on the patentability of the results of biotechnological research and development, exist in most countries. Both groups of exclusions will be summarily reviewed in the following.

General exclusions

Three general exclusions merit special attention in the field of biotechnology, namely

- the distinction between discoveries and inventions
- the requirement that the invention must be a technical one, and
- the exclusion of inventions for reasons of morality and order public.

a) Distinction between discoveries and inventions

Most patent laws draw a strict demarcation line between discoveries and inventions and exclude the patentability for applications concerned with mere discoveries.[61] This holds true for the EPC,[62]

Austria,[63] India,[64], Italy,[65] and the WIPO model law.[66] Even in countries like the United States that use the terms "invention" and "discovery" synonymously, a closer examination reveals that under the so-called "natural phenomena doctrine" a similar demarcation line exists.[67] The patentability of biotechnology research results is affected by this dichotomy in a twofold way:

To a large extent, the work of ICGEB will be based on scientific findings. Consequently,, the question arises how far the research esults have to be developed in order to be accepted as inventions and hence to be patentable. It seems, however, that no general answer can be given to this question, since an analysis of the concrete case is nearly always a prerequisite. It must, however, be kept in mind that., in numerous countries,, the statutory exception is shaped in a narrow form excluding only " dicoveries as. Such.", and that current patent practice takes due regard to this legislative intent. Reference should be made, e.g., to the EPO Examination Guidelines (Part C, Chapter IV, 2.1) which 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."

In the course of the last few years, patent offices have issued numerous patents for biotechnological inventions which were clearly based on discoveries. Statistics have revealed that genetic engineering has taken patent protection far into the field of fundamental scientific research and that, in a given period, 20% of all the relavent U.S. patent applications fell within this area. This development appears to be rather encouraging for an active patent policy of ICGEB.[69]

The second issue raised by the distinction discovery/invention concerns the fact that the basic working material of a "biotechnologist" is always some kind of living or biologically active matter. It therefore has to be questioned whether the outcome of his work may still be considered as something discovered or found in nature. The discovery/invention dichotomy thus appears in the form of the so-called "product of nature doctrine". Although the exact boundaries of this doctrine had always remained quite unclear, it had a strong influence especially on U.S., case law, but has actually retreated to a considerable extent.[70] Nevertheless, the EPO Guidelines can again be cited as an example:

"To find a substance freely occuring 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 paten tale. Moreover, if the substance can be proerl 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."

b) Technical character of invention

Historically, a major obstacle against the patenting of biological inventions was formed by the argument that innovative achievements in the field of living matter do not constitute "inventions" since they are not deemed to be within the ambit of 'technology". So in the beginning of this century, patent offices and courts in various countries, especially in the Federal Republic of Germany, had taken the view that the term "invention"
referred to the field of technology and encompassed only objects and phenomena of an inanimate nature and their utilization and control by techniques of physics and chemistry.[71] Although this view continues to be advocated sporadically, it has already been rejected in explicit terms by a number of well-known court decisions. In this respect, mention should especially be made of the "Red Dove" decision of the German Federal Supreme Court[72] and the "Chakrabarty" decision of the US Supreme Court,[73] both. decisions being regarded as milestones in the history of patent protection of biotechnological inventions.

It thus appears that the originally limited concept of invention has been broadened by the development of modern patent law. In most countries, therefore, no valid argument against the patentability of biotechnological inventions can be made by pointing to an alleged "lack of technical character" of living matter in general.[74]

c) Safety aspects and issues of morality

Patent law contains a safeguard against the patenting of inventions the publication or exploitation of which would be contrary to ordre public or morality. This is a valid principle under all patent systems have reviewed. [75] There can be no doubt that certain application of modern genetic engineering may lead to safety concerns and ethical objections. In order to decide to which extent inventions are excluded from patentability because of these concerns, one must bear in mind that, under most patent, laws, the term "ordre public" only compromises the most fundamental principles of the respective legal order. The exclusionary provision therefore does not apply for the sole reason that the exploitation of the invention is prohibited or restricted by law or regulation.[76]

In certain cases, however, hazardous inventions in the field of genetic engineering might be even contrary to the public order. Public health is, e.g., expressly mentioned in Indian and Japanese patent laws.[77] It is a rather open question to which extent patent offices should take account of possible safety issues. Under current patent practice, however, only little weight is given to safety considerations. As to the question whether a pharamaceutical product with potential adverse side effects fulfils the utility requirement, U.S. Courts have held that Congress delegated to agencies other than the PTO the responsibility to determine whether an invention is safe enough for human consumption.[78] Certainly, only a single case analysis will reveal whether a given patent application constitutes such an extreme case that it risks to be refused because of inherent dangers.

Some inventions in the field of genetic engineering will be excluded from patentability due to ethical considerations. This holds true, e.g., to methods referring to the cloning of human beings, to the production of human/non human chimeras, etc. In addition, it has been suggested in literature that patents on human genes, cell lines, hybridomas, etc. should be excluded for moral reasons. [79] In this last respect, however, the current patent practice, under which patents on human genes and human cell lines have already been granted, appears to be very liberal. It has furthermore been asserted that ethical reasons would forbid patents on animals, whereas this argument does not appear to be well founded in law, it might nevertheless influence the patent practice in some countries.[80]

Specific exclusions in the field of biotechnology

In most patent laws, a whole series of special exclusionary provisions exists, having a direct impact on the patentability of biotechnological inventions. Consequently, certain sectors of innovative activity in this field cannot be protected at all while those areas which are not specifically excluded have to be considered as patentable in principle. Although this heterogenous "piece-meal approach" and the unclear legal situation resulting from it have severely been criticized since several years, a patent practitioner has to carefully take into account all these exceptions and the different possibilities of construing them when deciding today whether and where to apply for a patent. In legal doctrine, most commentators plead for observing the following guidelines; As a general rule, exclusionary provisions have to be construed narrowly. In addition, due attention has to be paid to the protection needs of modern biotechnology. To what extent national patent offices and courts will follow these guidelines has, however, still to be seen.

a. Animal varieties

Whereas, under U.S. and Japanese patent law, new animal varieties are considered to constitute patentable subject matter, [81] in numerous patent systems [82] (e.g. EPC [83], Austrian [84] and Italian[85] patent law as well as the WIPO Model Law [86]) explicit provisions can be found according to which no patent, shall be granted for animal varieties.[87] Under Indian law, the patentability of animals, appears very doubtful although no explicit exclusionary provision exists in this respect. On the one hand, certain exceptions contained in 3(h) (agricultural methods), 3(I) (treatment of animals) as well as 5(a) (food products) Patent Act should be taken into account. On the other hand, it could be observed that Indian commentators,, who recently interpreted the national patent law with regard to the protection of biotechnological inventions, did not suggest that animal varieties would be patentable.[88]

The ambit of the exclusionary provisions concerning animal varieties is not clearly defined. Practically, no case law exists. Certainly, not all inventions in the field of animal genetic engineering are excluded, but only a part of them. It is, however, extremely difficult to draw an exact demarcation line. The legal problems are caused, at least in part, by the lack of a scientifically accepted definition of the term "animal variety".

A very controversial issue is the problem whether the exclusion of animal varieties means that animals in general are not patentable subject matter, or whether it only means, in contrast, that animals in form of a variety. can not be patented. Although the second alternative seems preferable,[89] the EPO has in a very recent decision refused to take this view and to grant a patent for certain transgenic animals.[90] Whether this decision which appears to implicitly conflict with a recent appeal decision in the field of plant breeding [91] will be upheld by the Board of Appeals of the EPO, is an open question.

Animal parts that do not suffice to establish a variety should equally be patentable. This is certainly valid for genome sections like genes, promoters, enhancer sequences, transposons, plasmids, and chromosomes. Somatic cell lines should also be patentable, at least if they have been derived from sexually reproducing animals for which no cloning system currently exists. Patent applications for animal sperm and non-fertilized egg cells would constitute a borderline case. It has also been argued that the breeder of a new animal variety might successfully claim new products derived from these animals., e.g. lamb meat of high nutritional value or mink furs of a certain colour.

In all those cases in which - according to the foregoing analysis - the subject matter of a patent application has to be considered as an animal variety, these applications are in principle embraced by the exclusionary provision of Art. 53(b) EPC. But, as it is explicitly stated in phrase 2, this provision does not apply to the products of microbiological processes. It has therefore been argued that animal varieties produced by genetic engineering techniques might be regarded as patentable. Since, in modern animal genome technology, single genes are frequently cloned and multiplied in microorganisms, recombined with a vector (transposon, plasmid, virus) and microinjected into animal embryonic cells or otherwise transferred to host animals, it has been suggested that the resulting animals and their offspring constitute the products of a microbiological process and that,, consequently., the new animal variety is patentable [92] However, legal uncertainties also remain to this extent, since it is extremely difficult to draw an exact borderline between microbiology and "macrobiology".[93]

b. Plant varieties

As it will be shown in more detail below, [94] a number of countries have established a particular protection system for plant varieties outside the general regime of patent law. The majority of these countries expressly exclude plant varieties from patentability.[95] Several other patent systems, which do not even foresee a special protection scheme, also exclude plant varieties. Thus. plant varieties are not considered patentable subject matter in numerous patent systems,[96] i.e. Austria,[97] EPC [98] and the WIPO model law.[99] An analogous situation exists in Italy. It is true that Art. 13 (2) Italian Patent Law, which is

the national parallel to Art. 53 (b) EPC, does not specifically exclude plant varieties from patentability. But the decree No. 74 of 12 August 1975 submits plant patents to a specific protection scheme which corresponds to that of UPOV.[100] In India and in Japan, the law is not completely clear. The national patent laws of both countries do not explicitly provide for the exclusion of plant varieties. Under Indian law,, however, the patentability of plants appears very doubtful. On the one hand, the exceptions contained in 3(h) (agricultural and horticultural methods), in 3(I) (treatment of plants) as well as in 5(a) Patents Act (food products) should be taken into account. On the other hand, Indian commentators, who recently interpreted the national patent law with regard to the protection of biotechnological inventions, did not suggest that plant varieties would be patentable.[101] Concerning the Japanese law, one has to bear in mind that, in June 1985, an agreement was reached between the Japanese Ministry of Agriculture and Fisheries and the Ministry of International Trade and Industry whereby plant varieties per se are to be protected exclusively under the Seed and Seedlings Law, while processes. for developing these varieties can be patented.[102] In sharp contrast to this, plant varieties can be protected in the United States under special protection schemes (Plant Patent Act and Plant variety Protection Act) as well as under the general patent statute.[103]

The question how to construe the exclusionary provisions directed plant varieties raises issues similar to those already discussed above.[104] Under the practice of the EPO, a narrow interpretation prevails: In its decision "Propagation Material/CIBA-GEIGY", the Technical Board of Appeal stated that a distinction has to be made between plants and plant varieties in the framework of Art. 53(b) EPC and that this provision prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety. Consequently,, the Board allowed a claim for propagating material for cultivated plants, characterized in that it is treated with a certain chemical substance.[105] A further step was taken by the Lubrizol. decision;[106] Starting from the assumption that the term "plant variety" means a multiplicity of plants which are largely the same in their characteristics (i.e. 'homogeneity') and remain the same within specific tolerances after every propagation or after every propagation cycle (i.e. 'stability'), the Board concluded that only possession of both these criteria., homogeneity and stability, would be a prerequisite for a "plant variety". Since the claimed hybrid seeds or plants, considered as a whole generation population, were not stable, the Board did not regard them as a "variety" and, consequently, granted the patent.

c. Microorganisms

In most countries, microorganisms are not excluded from patentability by explicit legal provisions[107] and can therefore in principle be protected by means of product claims. Under the EPC, this standpoint can be supported by two main arguments; Since microorganisms are not to be classified as plants or animals, but constitute a third group of living entities, they do not fall into the ambit of Art. 53(b) EPC, first phase. Furthermore, Art. 53 (b) EPC, second phrase, expressly states that the exclusion does not apply to the products of microbiological processes.

Microorganisms can be regarded, in view of the microbiological reproduction process itself, as such products.[108] Accordingly, a revision of the EPO examination guidelines took place in 1981.[109] This point of view also seems to be shared by most Italian commentators.[110] In Austria, the Board of Appeal of the Austrian Patent Office rendered a final decision on 7 March 1985, whereby it rejected the patentability of microorganisms.[111] This decision prompted the Austrian legislator to introduce patent protection for microorganisms per se by an Amendment Act of 1986. Section 2 of the Patent Law was amended to expressly state that the patentability exclusion does not extend to "microorganisms as such", thereby going beyond the language of Art. 53 (b) EPC.[112] It seems tha:t in all those countries which have followed the example of Art. 53 (b) EPC [113] the better arguments speak in favour of admitting patents on microorganisms per se.

In countries which neither have an explicit exclusionary provision nor a legal text shaped in the form of Art. 53 (b) EPC microorganisms are generally patentable. This holds true, e.g., in the United States, where the Supreme Court, in its famous Chakrabarty decision,[114] rejected the contrary position of the PTO, and in Japan where, according to the examination standards for microorganisms issued in 1979 by the Patent Office, patents for organisms themselves arc available.[115]

In India, however, the legal situation is rather uncertain; On the one hand, Indian commentators apparently hesitate to affirm the patentability of microorganisms and restrict themselves to the statement that "inventions relating to the processes for the production of substances by bio-conversion involving the role of microorganisms would be patentable.[116]

d. Essentially biological processes for the production of plants or animals

Numerous patent systems exclude from patenting "essentially biological processes for the production of plants or animals.[117] In particular, this holds true for the EPC and the patent, laws of most EPC member countries, e.g., for Austrian[118] and Italian[119] patent law. Art. 112(3) (ii) WIPO Model Law also contains such an exception. Under Indian patent law, an even broader range of innovative activity in biotechnology is considered not to be patentable subject matter since "methods of agriculture or horticulture" and "processes for the treatment of plants, to render them free of disease or to increase their economic value or that of their products" are excluded by 3(h) and (I) Patents Act. However, patent laws of other countries, e.g., Japan and the United States, do not contain similar exclusionary provisions.

In the recent past, this type of exclusionary provision has been increasingly criticized for not being clear at all and for drawing a completely arbitrary demarcation line between patentable and non-patentable subject matter. [120] According to most commentators, the term "essentially biological" should be construed as "essentially natural and uncontrollable" or "essentially without human intervention".[121]This view is also espoused by the Examination Guidelines of the EPO according to which

> "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."

In the field of plant breeding inventions, the very recent Lubrizol decision of the Technical Board of Appeal of the EPO took a somewhat modified position;

According to it, the "necessity for human intervention alone is not yet a sufficient criterion" since something "beyond a trivial level" has to be contributed. These dicta indicate that the EPO attempts to narrow the exclusionary provision by regarding it simply as a mere concretization of the patentability criterion of inventive step. A further argument could be advanced to support the patentability of processes employed in modern genetics:

Since the exclusionary provision does not apply to microbiological processes, one might assert that numerous methods in genetic engineering have a microbiological character. This argument has already been presented in the parallel context of the exclusion of animal varieties.[122]

e. Therapeutic methods and pharmaceutical products

A great part of the achievements of modern biotechnology concerns the field of medicine and pharmacy. In this respect, it has to be kept in mind that several patent laws explicitly exclude inventions in, this are from patentability. So, in many countries, including India, [123] protection is not available for pharmaceutical products. In contrast to that, the large majority of industrialized countries does not

exclude such inventions from patentability. This holds true, e.g., for the EPC,[124] Austria,[125] Italy,[126] Japan and the United States.

On the other hand, the EPC {Art. 52(4)} and several national patent systems [127] exclude from patentability "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body". Such a provision can be found, e.g., in the WIPO Model Law[128] as well as in Italian [129] and Austrian national patent laws,[130] in the latter country, however, restricted to methods concerning the human body.

In all these patent systems, it is explicitly made clear that the exclusion, does not apply to products used in processes for diagnosis or therapy. For instance regulatory proteins such as human insulin, interferon's, growth hormones or monoclonal antibodies, which may be used in therapy and diagnostic methods, fall not under the exclusion.[131]

A similar exclusionary provision also exists in Japanese patent law, [132] whereas i the United States patents are available for therapeutic and diagnostic methods.[133] Indian patent law contains an even broader exception in its 3(I), according to which is excluded:

"any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.[134]

f. Other exclusions relevant to biotechnology and genetic engineering

Attention should be given to further exclusions contained in some national patent laws, which might have an impact on the protection of research results of ICGEB; According to a recent WIPO survey, food products are excluded by the patent laws of 35 countries, chemical products by 22 countries,, pharmaceutical processes by 10 countries, food processes by 9 countries, substances obtained by microbiological processes by 7 countries, cosmetics by 2 countries, and fertilizers by 2 countries. These exclusions, however, do not have any relevance in the countries specifically reviewed in the present study (EPC, Austria, Italy, Japan, United States), with the exception of India where no patent protection is available for food products, for chemical products and - as it has already been mentioned - for methods of agriculture or horticulture.[135]

Conditions of patenting

General

Usually, patent laws require an invention to be new, to comprise an inventive step and to be industrially applicable in order to be patentable. Furthermore, the patent application has to sufficiently disclose the claimed subject matter (requirement of reproducibility). Considering the activities of IC6EB, the traditional patentability requirements have to be analysed with regard to research results in biotechnology, although, in this respect, insurmountable difficulties do not exist in general,

The requirement of novelty

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 filing date or the priority date.[136] A detailed analysis of this patentability requirement is beyond the scope of the present study. Attention shall only be drawn to two specific issues, i.e.:

- Are products found in and isolated from nature lacking novelty?
- What are the effects of a publication before patent application?

a. Products found in and isolated from nature

The objection that microorganisms or other biological material isolated form nature are not new has rather frequently been raised in patent law history. The view prevailing today does not consider, however, this objection as well-founded. The simple fact that the product for which patent protection is sought existed before in a naturally occurring mixture does not have the consequence that the invention had already been made available to the public. only if information was previously made available concerning the existence of the particular mixture, its use or even its content, the question of novelty must be examined in the light of such information. If the said information already provided the concept of the particular product as a separate entity and enabled a person skilled in the art to produce it in such a form, the product may be considered not to be new. However, in the absence of such specific information, and on the basis of the fact that the product isolated or synthetized is physically different from the mixture available to the public prior to the invention, novelty should be admitted as a matter of principle.[137]

b. Negative effects of publication before patent application

Researchers should furthermore be reminded that, under several patent systems, especially under the EPC, in Austria and in Italy, the novelty requirement is absolute and does not grant a general grace period. From this it follows that also previous publications and communications of the inventor himself destroy the novelty of a subsequent patent application in these countries, a consequence frequently overlooked by researchers working in the public sector. In contrast to that, other patent systems contain a novelty grace period of 6 or 12 months. Thus, according to 31(d5 Indian Patents Act, an invention shall not be deemed to have been anticipated by reason only of

"the description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such a society, if the application for the patent is made ... not later than six months after ... reading or the publication of the paper."

The Japanese patent law equally recognizes a 6-months grace period [138] whereas in the United States this period lasts one year.[139] Currently, attempts are made for the introduction of a grace period on the international level. But for the time being, every researcher should be aware that a scientific publication before patent application will result in the loss of patent rights in numerous countries.

The requirement of inventive step

Under the EPC and the corresponding national patent laws (e.g., Austrian and Italian patent law), 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.[140] A similar definition is used in the Indian[141] and in the Japanese[142] patent law as well as in the WIPO model law. [143] Under the U.S. patent, law 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 natters pertain.[144]

As in other technological fields, the patentability requirement of inventive step (or of non-obviousness) also constitutes one of the most complex questions in biotechnology. So far, case law provides only little guidance in this respect. Nevertheless,, some of the problems which have shown up so far will be briefly reviewed in the following; Under the EPC, a recent decision of 27 January 1988, addressed, inter aria, the issue of inventive step relating to recombinant plasmids. The Technical Board of Appeal held the invention of the applicant non-obvious and set the contrary decision of the Examining Division aside. According to the view of the Board, the non-obviousness of the plasmids also imparted

an inventive step to the other claimed subject matters relating to their preparation and to their use for making polypeptides and immunogenic substances.[145] In the United States, the CAFC has issued two important rulings concerning the criterion of inventive step in biotechno1ogica1 cases. In Hybritech, Inc. v. Monoclonal Antibodies, Inc.[146] the Court for the Federal Circuit reversed a lower court decision and upheld the validity of claims drawn to methods to conduct standard immunoassays using monoclonal antibodies of defined specificities instead of polyclonal preparations.

In re 0' Farrell[147] the patentability of claims to a recombinant expression system was held to have been properly denied.[148] The CAFC upheld the decision of the PTO finding obvious claims to a DMA capable of expression in bacteria comprising a heterologous gene in reading frame with a homologous upstream sequence encoding part of an en does no us protein. It is interesting to note that the cited reference, which destroyed the nonobviousness of the claimed invention, was an article published more than a year earlier by more or less the same inventive entity.[149] Most commentators agree that is very difficult to deduce clear guide lines from the actual case law. Some attempts at providing a more systematic and detailed analysis have, however, already been undertaken.[150]

The requirement of industrial applicability

Patent applications must generally meet the requirement of "industria1 applicability"[151] or, as in India[152] and in the United States,[153] the similar requirement of "utility". 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 of 1883, ultimately had an impact on national patent laws as well; the term "industry" became a comprehensive one, and less stringent. Under the patent system of the EPC,[154] Austria,[155] Italy[156] and under the WIP0 model law[157] an invention is considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. This principle also prevails in Japan and - for the patentability requirement of utility - in the United States.[158] Commentators of Indian patent law equally refer to broad definitions.[159]

Nevertheless, industrial applicability (or utility) still presents a sensitive patentability requirement for science based inventions: Inventions resulting from basic research in biotechnology, on the one hand, are frequently based directly on the most recent scientific discoveries and, on the other hand, can act as pioneers of new technologies. Two problems might arise in this respect. Firstly, the requirement of industrial applicability or of utility establishes a dividing line between non-patent-able discoveries and pa ten table inventions; secondly, the said requirement determines whether the invention can be used in research laboratories only or also in industry. For example, when a new plasmid is discovered and its properties are cleared, the scientist inventor has to find out how a piece of foreign DMA can be introduced into this plasmid and for what purposes the new plasmid could be used, e.g. what types of cells could be transformed etc. Furthermore, the industrial applicability of this new plasmid might depend upon the possibilities that exist in industry to use it.[160] while a liberal approach in interpreting the requirements of industrial applicability and utility might be desirable[161] it must be kept in mind that in some countries diverging case law exists. According to the U.S. Supreme Court, a chemical process is not useful merely because it produces the intended product, for which no use is known, or because the produced compound belongs to a classe of compounds which is the subject of serious investigations.[162]

The requirement of enabling disclosure

Since the British Judge Bu1ler, in 1785, stated in re Ark-Wright that an inventor who applies for a pa tent

"...must disclose his secret and specify his invention in such way that others may be taught by him to do the thing for which the patent is granted,"[163]

sufficient disclosure of the invention in patent applications has become a standard patentability requirement.[164] For biotechnological inventions, however, the condition of sufficient disclosure causes specific problems since living entities are difficult to describe in writing. In the last decades, patent law has developed a new solution to overcome these problems, i.e. the deposit of biological material. Already in the late fifties and early sixties, patent office practice, in the United States and in Europe, started to require deposits of microorganisms in culture collections when the written description itself did not suffice to reproduce the invention. This practice was later confirmed by several decisions of national courts, especially in the Federal Republic of Germany and in the United States. Today, the deposit of microorganisms has become a generally accepted additional form of invention disclosure in many patent systems. This holds true, e.g., for the EPC,[165] the Austrian,[166] Italian,[167] Indian,[168] Japanese[169] and U.S. patent law.[170] It is furthermore witnessed by the conclusion of the Budapest Treaty which, as it has already pointed out,[171] makes multiple deposits superfluous, but does not harmonize, however, the substantive patent law provisions of the different countries. There are considerable differences concerning the details of a correct deposit which can not totally be reviewed in the context of the present study.[172] Only some crucial issues will be highlighted in the following.

The deposit practice has evolved in the area of microbiological inventions, with regard to higher life forms, e.g., plants and animals, up to now only very little case law exists. It is true that, according to current practice, provisions of patent laws, regulations and treaties which refer to the deposit of "microorganisms", are interpreted in a very broad manner,, even without., paying much attention to the scientific use of this term.[173] Nevertheless, the question whether a deposit of seeds, of animal sperm, embryos, etc. will be considered by national patent offices as fulfilling the disclosure requirement remains open.[174]

In almost all countries, a deposit is only required when the written disclosure given in the patent application does not suffice to enable the person skilled in the art to obtain the biological material.[175] The great majority of patent systems considers a deposit sufficient not only for the purpose of proc ess claims, but also for the purpose of product claims directed to the deposited material itself. In these countries, there is no need to indicate another process for the production of the microorganism.[176]

In most patent systems, the deposit of the biological material most be made at the very latest at the filing or priority date.[177] In the United States, this requirement has been relaxed by a recent ruling of the CAFC,[178] according to which the deposit can be made until the patent is granted. As to the place of deposit, the member countries of the Budapest Treaty are obliged to recognize a deposit in any international depositary authority. Some patent systems also accept deposits in other culture collections. According to the B T , a period of storage is provided for which alsts at least 5 years after the most recent request for furnishing a sample, but in any case at least 30 years after the date of deposit. Most patent systems therefore, require this period of storage as a minimum condition.

The Budapest Treaty has left the crucial question of access to samples by third parties to be dealt with by the national laws of the individual member countries. In this respect, a great divergence exists; Under the EPC, the deposited culture has to be available upon request to any person from the date of publication of the patent application, i.e. 18 months after the filing or priority date. Such availability shall be effected by the issue of a sample of the microorganism to the person making the request. During the time between publication of the application and grant or refusal of the patent, the applicant can, however, restrict this access so that a sample will be issued only to an independent expert.[179] In Austria, the situation is similar, but no "expert option" exists[180] The interval between publication of an Austrian patent application and the grant or refusal to the patent is, however, considered usually substantially

shorter than in the case of European patent applications.[181] In Italy, the legislator has chosen a system more favorable to the applicants The latter can restrict the availability of the deposited microorganism to an independent expert during the whole life time of the granted patent.[182] In the United States, there is no need to make the microorganism available deducing the patent application procedure. Only in the case that the patent is granted, an unrestricted furnishing of samples must be secured by the applicant.[183] Details of the deposit requirements under current Indian practice can not be given with certitude, in view of the scarcity of legal comments on this subject.

The content of the right conferred

General

As a general principle,, the owner of a patent has the exclusive right to the exploitation of the patented invention. According to the WIPO model law, exploitation means, for a product patent, the making, importing, offering for sale, selling and using of the product, or the stocking of the product for the purposes of offering for sale, selling or using; for a process patent, exploitation means the use of the process, or the doing, in respect of a product directly obtained by means of the process, of any of the acts referred to above in connection with a product patent ("extension of process patent protection to products").[184] The patent systems of Austria, India, Italy, Japan, and the United States contain similar provisions,[185] with slight differences, however. E.g., in the United States, only very recently the patent law has been amended in order to give the owners of patented processes the right to exclude imports of products made by that process,[186] but even today this right is limited in various ways. In India, the extension of process patents to products directly obtained is not explicitly provided for in the Patents Act 1970.[187] On the international level, attention has to be paid to Art. 5^{quater} Paris Convention. This provision stipulates that, where the law of a member State confers rights with respect to a product (manufactured by a patented process, that State is obliged to grant to the owner of the patent the same rights if such a product is imported into it as those it grants in the case where such a product is manufactured on its territory.

Extension of biotechnological process protection to products directly obtained

Biotechno1ogica1 inventions raise some specific issues in those patent systems which provide for an extension of process patents to products. If, e.g., the subject matter of a process patent is a new method for the production of living matter containing specific genetic information, the question arises whether only the products initially obtained by the process should be considered to be "directly obtained" or also the subsequent generations obtained there from which still carry the same genetic information.[188]

An even more specific issue arises when the patented process is a plant or animal breeding method, namely the question whether the extension to the products directly obtained there from is affected by the explicit exclusion of plant or animal varieties exclusion of plant or animal varieties from patentability.[189] Both these questions are explicitly addressed and answered in favour of the patentee by the proposed EC directive,[190] but, as to the present situation, legal uncertainty still reigns.

Implications of the exhaustion doctrine

In most patent systems, the so-called principle of exhaustion is generally recognized, either by explicit statutory provision or by case law and legal doctrine. What is meant by this principle can be illustrated, e.g., by Art. 1(2) Italian Patent Law, which reads as follows:

"This exclusive right shall extend also to trade in the product covered by the invention, but shall

be exhausted after that. product has been put on the market in the territory of Italy by the proprietor of the patent, or with his consent."[191]

Diverging opinions have been expressed as to the question how the principle of exhaustion applies to those; patented products which are capable of' self-replication, e.g., microorganisms or plants. Under certain circumstances, the act of replication can be considered as a mere use of the sold product (in this case the principle of exhaustion applies), whereas under other circumstances the act of replication has to be properly characterized as the manufacture of the patented product (in that case, the exhaustion doctrine should not be applied). Drawing an exact borderline, between these cases is, however, an extremely difficult task.[192]

Exemptions for scientific research

Most patent laws limit the rights of the patent holder to acts done for industrial or commercial purposes. Acts done only for scientific research or for experimental use remain free. Provisions of this type are in particular contained in the patent statutes of Italy,[193] India[194], Japan,[195] and the United States[196] as well as in the WIPO model law[197]. How far this exemption reaches, is, however, to always very clear.[198]

Since the research undertaken by ICGEB will take place mainly in Trieste and New Delhi, the relevant provisions of Italian and Indian patent law will be cited in full length. Art. l(3)(a) Italian Patent Law reads as follows:

> " The exclusive right conferred by the patent right shall, regardless of the subject matter of the invention, not extend to:
> acts done privately and for non-commercial purposes, or for experimental purposes.[199]

47 (3) Indian Patent Law reads as follows:

"The grant of a patent under this Act shall be subject to the condition that any machine, apparatus or other article in respect of which the patent is granted or any article made by the process in respect of which the patent is granted, may used, and any process in respect of which the patent may be used, by any person, for the purpose merely of experiment or research includinq the impartion of instructions to pupils."[200]

THE SPECIAL PROTECTION SCHEME FOR PLANT VARIETIES

General

A specific protection scheme for plant varieties has been established in the 18 member countries of the UPOV convention,[201] among which Italy, Netherlands, and the United States, but loping country, can be found. Also in some countries which have not acceded to the UPOV convention, special titles for plant varieties are available.[202] On the other hand, in numerous other states, especially in developing countries (e.g. India), [203] no particular protection system for plant varieties exists. In order to illustrate the general features of plant variety protection schemes, the UPOV convention and the Italian national legislation will be reviewed in the following (B.). Concerning the national protection schemes existing in Japan and the United States, some additional remarks should suffice (C.). Finally, a comparison of plant breeders' rights systems and patent laws will be roads (D.).

The protection scheme provided by UPOV and Italian plant variety patent law

According to Art. 2(1) UPOV convention, national legislators may recognize the "breeders' right" either by the grant of patents or of special titles of protection. But this freedom of choice is only a

very limited one, since even a legislator who opts for the first alternative roust accommodate his national patent law in this particular area to the provisions of the UPOV convention. National legislation in Italy is very illustrative in this respect; whereas Italy has - in contrast to other UPOV member countries - opted for "plant variety patents" as the national form of protection of the "breeders' right", it enacted a specific decree (Decree No. 1975-974 of 12 August 1975, as am ended in 1985) which brought the requirements for and the scope to protection in line with the UPOV system.[204] Art.2 (1) UPOV convention also contains the so-called "prohibition of double protection"; A member State whose national law admits protection under both forms of protection (patent and special title of protection) amy provide only one of them for one and the same botanical genus or species. In order to open the way for the accession of the United States, the 1978 revision of the UPOV convention inserted an exception to this principle in Art. 37 according to which any member State may provide for different types of protection for one and the same genus or species if such multiple protection was provided for prior to the end of the signature period for the 1978 Act (= 31 October, 1979). The United States has used this provision by making a respective notification to the Secretary-General of UPOV.

To be eligible for plant variety protection, a variety must be distinct, homogeneous , stable, new and designated by a denomination; Art. 6(l)(a) UPOV convention and Art. l(2)(c) Italian Decree No. 974-1975, as amended, require that the new variety must be clearly distinguishable by one or more important characteristics from any other known variety. According to Art. 6(l)(c) UPOV convention and Art. 1 (2)(a) Italian Decree, the new variety must be sufficiently homogenous, having regard to the particular features of its sexual reproduction or vegetative propagation,, Art. 6(l)(d) UPOV convention and Art. (2)(b) Italian Decree stipulate that the variety must be stable in its essential characteristics, i.e., it must. remain true to its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or mu1ti1ication , at the end of each cycle. According to the novelty requirement contained in Art. 6 (1) (b) UPOV convention, the variety must not have been offered for sale or marketed, with the agreement of the breeder, in the territory of the State where the application is filed. However, a grace period of one year can be provided by national legislation in this respect. Italy, e.g., has opted for the latter alternative.[205] Concerning the marketing of the variety in other States, a grace period of 4 years (or even of 6 years in the cases of vines, forest trees, fruit trees and ornamental trees) is established by Art. 6(l)(b)(ii)f UPOV convention and Art. 1(3) Italian Decree, Art. ,13 UPOV convention and Art. 5 Italian Decree require that the new variety be given a denomination by which it is to be identified. The varietal name cannot consist solely of figures, i.e., of a numerical designation, except where this is an established practice.

Art. 7(1) UPOV convention and Art. 8 Italian Decree require examination of the variety prior to the granting of protection, to ensure that the criteria of distinctness, uniformity and stability are met. This examination can be carried out by the member state in which the application has been filed, or in other member states specifically authorized to conduct examination of specified plant materials. Centralization of examination has evolved, primarily for reasons of cost.

In principle, the UPOV convention applies to all botanical genera and species (Art. 4). But the contracting States are allowed to limit protection to only a minimal number of genera or species of plants, i.e., States must - after eight years of membership - protect at least 24.[206] Most UPOV member countries have enacted particular decrees in which all the taxa for which protection is available are specifically enumerated.[207] Although these national lists have gradually been extended in the course of the years, extensive areas of plant agriculture are still not covered by UPOV-type plant breeders' rights in the member countries of UPOV.

In defining the scope of protection mandated by UPOV, Art. 5 provides that the prior authorization of the breeder is required for

- the production for purposes of commercial marketing
- the offering for sale
- the marketing

of the reproductive or vegetative propagating material, as such, of the variety.[208] The right of the breeder shall extend to ornamental plants or parts thereof normally marketed for purposes other than propagation when they are used corn mere tally as propagating material in the production of ornamental plants or cut flowers. Protection under Art. 5 thus does not cover plant material produced or sold other than as a reproductive or propagating material. Pursuant to Art. 5(4) UP0V convention, a member state may, however, extend the rights conf (erred under its national protection to the marketed product. The Italian legislator has made use of this right in 1975 in the area of ornamental plants. According to Art. 4(2) Italian Decree, the exclusive right granted to the breeder is extended to the production, marketing and importation of the products of the variety in cases when its predominant use occurs through the sale of plants, parts of plants or flowers to be used for ornamental purposes. In a recent judgement[209], the Tribunal of San Reno made clear that Italian plant variety patents on ornamental plants include the exclusive rights on the flowers, regardless of whether such flowers are sold for ornamental purposes or as reproduction materials.

An important restriction of the exclusive right is contained in Art. 5(3) UPOV convention, the so-called "breeder's exemption"; Authorization by the breeder is not required for the utilization of the variety as an initial source of variation for the purpose of creating other varieties or for the amrketing of such varieties. The authorization is only required, when the repented use of the variety is necessary for the commercial production of another variety. In its Art. 4(3), (4) and (5), the Italian Decree contains a similarly shaped, but more detailed exemption.

The UPOV convention sets forth a minimum duration of the breeders' right; 15 years, computed from the date of issue of the title of protection. Foe vines, forest trees, fruit trees and ornamental trees, the period of protection may not be less than 18 years (Art. 8). In Italy, the legislator has adopted the 15-year duration, but has considerably extended the protection for plants with a woody stem, namely to a period of 30 years (Art. 7 Italian Decree).

Plant variety protection laws in further countries

In Japan, specific protection for plant varieties is provided for in the Seeds and Seedlings Law of 1947, which, as amended in 1982, formed the basis for accession to the UPOV convention in 1982. Protection is available for those varieties which fall under the list of genera and species which is gradually extended by specific decrees. In the United States, the Hubbard decision made clear, in 1985, that general patent law is generally open for the protection of plants. Besides that, special protection is provided f or by two different schemes; The Plant Patent Act (PPA) of 1930 was introduced to protect asexually reproduced plant varieties. It embraces all species with the exception of tuber propagated plants (i.e., Irish potatoes and Jerusalem artichokes). The Plant Variety Protection Act (PVPA) of 1970 introduced protection for sexually reproduced plant varieties. The PVPA is more similar to the UPOV scheme than the PPA, but it nevertheless contains some provisions which resemble those of general patent law.

Comparative analysis of patent law and paint variety protection law

As to the comparison of patent law and plant variety protection law, the present study will limit itself to some general remarks: the UPOV system has been conceived and established when the current progress in plant genetic engineering was not foreseeable. Modern biotechnology rendered the interface between plant breeders' rights and patents extremely unclear and triggered a great amount of discussions

about the value of the UF'OV system. On the one hand,, it has been argued that applying for plant variety certificates would lead to a considerably lower level of protection than that provided by patents in other areas of technology. In particular, the fact that most variety protection laws do not extend protection to: the marketed product other than propagating material is viewed as a negative aspect and compared to the different situation prevailing in patent law. The so-called breeders' exemption is criticized because it goes much further than the research exempting in patent law, thereby p raven ting the breeder of the protected variety from invoking his exclusionary right against a "cosmetic breeder" who has introduced minor genetic changes in a protected variety and then markets the resulting "derived" variety. Some commentators, furthermore,, point to the burden of long-lasting field tests required for the official examination to distinctness, homogeneity and stability. In addition, the progress achieved by inventions in plant biotechnology can frequently be used for generating a multitude of a new varieties, whereas, under plant variety protection laws, the right is always granted for a single variety. Furthermore, Art. 2(1) UPOV convention, which prohibits double protection, is considered to be an anomaly in the context of an international convention for the protection of intellectual property.

On the other hand, the proponents of the UP0V system still believe that the special protection scheme is well-tailored to the needs of plant breeders, at least of those breeders who work with traditional methods. They do not want to question the whole system. It can be observed, however, that even the advocates of the UPOV system are beginning to recognize several severe shortcomings of the UPOV system and are trying to make a number of adjustments. A mayor revision of the UPOV convention is currently in preparation,[210] which aims at introducing, inter alias, the following changes:

- a limited concept of dependency
- extension of the protection to the marketed product, and
- opening of the system to all plant species and genera.

INTERNATIONAL ORGANIZATION AND PATENT LAW

General

Certain specific issues are raised by the acquiring, holding and licensing of industrial property rights when international organizations are concerned. There is, however, an almost complete lack of court decisions and authoritative legal opinion in this respect. Consequently, the following analysis has to be considered as a preliminary one.

Legal capacity of ICGEB for acquiring and holding patents

No reasonable doubt should exist as to the legal capacity of the future ICGEB to acquire, hold, transfer and license industrial property rights. It is a well recognized principle in international law that any international organization must possess some form of personality in domestic law.[211] Like many other treaties, which establish an international organization, the Statutes of ICGEB also contain explicit provisions in this respect. Art 13 (1) Statutes reads as follows:

> "The Centre shall have juridical personality. It shall be fully empowered to discharge its functions and achieve its objectives, including the followings:
>
> (b) to award contracts;
> (c) to acquire and dispose of movable and immovable property;
> (d) to initiate legal proceedings."

Furthermore, explicit provisions regarding industrial property rights are contained in Art. 14 (2) and (3) ICGEB Statutes which reads as follows:

> "(2) All rights, including title, copyright and patent rights, relating to any work produced or

developed by the Center shall be vested in the Center.

(3) It shall be the policy of this Center to obtain patents or interest in patents on results of genetic engineering and biotechnology developed through projects of the Center"

Like numerous other international organizations which regularly acquire parents,[212] ICGEB also has the legal capacity to act in this way. Only in those - largely hypothetical - cases in which the specific activity would have absolutely nothing to do with the purpose of ICGEB, the legal capacity to acquire a patent in this respect might be doubtful. [213]

The immunities and privileges of ICGEB in relation to procedures

The impact of immunities and privileges on patent proceedings is a complex issue that merits careful analysis. Like other international organizations, ICGEB will enjoy a number of immunities and privileges. Explicit provisions are contained in the Statutes, in particular in Art. 13 (2), (3) and (4). Similar immunities and privileges are enjoyed by UNIDO, insofar as the latter organization currently still acts on behalf of ICGEB. Particular attention has to be given to the

"immunity of the ICGEB from every form of legal process" and on the "immunity of the property and assets of ICGEB from search, requisition, confiscation, expropriation and any other form of interference, whether by executive, administrative, judicial or legislative actions."

The question arises which consequences these immunities will have on patent proceedings started by ICGEB or started by administrative authorities or third parties against ICGEB. [214]

So far, the problem mentioned above has received only little attention. In; a resolution of 1969, the Council of Europe recognized that the question of immunity from legal process has to be answered in different way depending on the aspect of patent law concerned.[215] Nevertheless, the following tentative guidelines might be given; In the context of "normal" patent application procedures, international organizations may acquire patent rights under the same conditions as all other applicants. The respective national or regional patent law will be applied without right by the Italian Patent Office, it must follow the rules laid down in Italian Patent Office, it must follow the rules laid down in Italian patent law. There is no necessity to interpret this implicit acceptance of national patent law as a "waiver of immunity" by ICGEB.[216] According to one commentator (Dr. Kunz-Hallstein), a similar legal standpoint should be taken as to those proceedings which might result in the revocation of the patent or in the declaration of its nullity, notwithstanding the immunity of the international organization from legal process and of its property from any form of interference. Dr. Kunz- Hallstein underpins his stood as a continuation of the application procedure.[217] On the other hand, he suggests that the immunity of the international organization must be observed in the case of the granting of a compulsory license. Furthermore, if an international organization infringes the patent of a third party in the course of its activities, it generally enjoys immunity from any national infringement proceedings. Dr. Kunz-Hallstein points out, however, that in the latter case the international organization is obliged to offer and cooperate in an arbitration proceeding, according to general principles of international law.[218]

International Organization and the Paris Convention

Attention should be given to the question whether ICOEB will be entitled to claim the benefits provided for an international conventions in the field if industrial property, e.g., whether it can claim national treatment and priority rights under the Paris Convention, whereas it is well settled that the benefits provided by the PC can also be invoked by legal entities (corporations, etc.), by State enterprises, by other bodies of public status and even by the States themselves,[219] the legal position of international organizations is somewhat doubtful.

During the preparations of the Lisbon revision conference of the PC, Dag Hammarskjold , Secretary-General of the United Nations, addressed this issue in a letter of 18 August, 1958, which reads in its pertinent part:

"Le comite, administratif de coordination a estime, par ai1leurs, qu'il pourrait y avoir interet a examiner la possibilité d'assurer en termes express 1'application des dispositions de la Convention en matière de brevets, aux Nations Unies, aux institutions spécialises et Aa 1'Agence internationale de 1'energie atonique.

Le bénéfice des dispositions de la Convention est accorde aux ressortissants de chacun des pays de 1'Union. L'Organisation des Na lions Unies, les institutions spécial i. ses et 1'Agence Internationale de 1'energie atomique ne sauraient, toutefois, en raison précisément de leur statues international, 'e'être considères comme "ressortissants" des Etats de leur siège, ni se reclasser de cette quille. Dans certains cas, il serait cependant désirable que ces organisations internatioles puissent exercer leur droits en mitée de brevets en leur nom propre, sans qu'il leur soit nécessaires. Aussi, pourrait-il être extrêmement souhaitable que la Convention leur reconnaisse une position semblable a`celle qui, dans des circonstances analogues, leur a été accordée dans le cadre de la Convention universelle sur les droits d'auteur."

The International Bureau therefore proposed to introduce a corresponding provision into the PC, thereby explicitly granting the advantage of the Convention to the United Nations and its specialized agencies. The proposal was, however, removed from the conference program, apparently because the member States taking part id the revision conference did not consider such a provision to benecessary.[220] Consequently, the problem has been left unresolved; On the other hand, some legal commentators suggest that international organizations are not entitled to the benefits of the Paris Convention.[221] On the other hand, international patent practice has not yet given rise to any dispute in this respect. In his profound analysis of this issue. Dr. Kunz-Hallstein did not succeed in finding a single case in which an international organization, which applied for patents, was denied the benefits of national treatment or of priority. Therefore, a good argument can be made that current international practice clearly speaks in favor of the position that international organizations are generally entitled to the benefits of the Paris Convention.

An additional problem, however, is caused by the fact that the seat of 1C GEE is Trieste as well as New Delhi, the letter-being in a country which is not a member of the Paris Convention. But it appears that the fact that the headquarters of ICGEB are partly located in Italy will be sufficient to entitle it to the benefits of the Convention ,1 since Art. 3 PC reads as follows:

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

Inventions of staff members, consultants, affiliated centres and other research units

According to Art. 14 (2) ICGEB Statutes, all rights, including titles, copyright and patent rights, relating to any work produced or developed by the Centre shall be vested in the Centre. With regard to this provision, the analysis will focus on the following questions:

- Do staff members of ICGEB have any rights to patents concerning the inventions developed by them?
- Are staff members entitled to financial compensation for inventions developed by them?
- What is the impact of Art. 14 (2) ICGEB on the rights concerning inventions developed by consultants, affiliated centres and other research units.

According to the prevailing legal doctrine and the case law developed by the Administrative Tribunal of the International Labour Organization (ILO-Tribunal), international organizations are free to determine that exclusive rights on inventions developed by a staff member as part of his official duties shall be the property of the organization.[222] The organizations have also full discretion as to how they should use or dispose of the exclusive rights, inside as well as outside the member countries.[223] This point of view can be supported by the following arguments; It has been recognized in international organization and its staff members. IN order to guarantee the fulfillment of their functions, international organizations are authorized to regulate this relationship in an autonomous way. Since the question whether the employer or the employee is entitled to any rights resulting from the work of the latter is more closely related to the field of labour law than to that of patent law,[224] ICGEB can freely determine that it be entitled to claim all patent rights concerning inventions developed by staff members as part of their official duties.

The discretion of ICGEB in the area of employees' inventions also extends to the question whether staff members are entitled to any compensation for the invention they have developed. This standpoint has in particular been adopted by the ILO-Tribunal in its decision "In re Mashing".[225] Thus, ICGEB is not obliged legally to provide for any compensation at all. National provisions which foresee such a compensation under certain conditions (e.g., Art 23-26 Italian patent law[226] are not applicable to the relationship ICGEB/staff member. Consequently, if the future Staff regulations of ICGEB[227] will not contain any more detailed provisions in respect of inventions developed by staff members in the course of their official duties, no compensation right will exist. This situation would correspond to that of most international organizations since staff regulations very seldom contain provisions in favour of the inventor.[228] On the other hand, it might be a sound policy for the Centre to establish - and lay down in the ICGEB staff rules - a compensation system in order to further the creative activities of its personnel, since national legislators had good reasons to provide for similar schemes in their domestic, laws.[229] In this context. Art. 8 (6) ICGEB Statutes should be taken into account which reads as follows:

"The paramount consideration in the employment of the scientific and technical staff and in determining the conditions of service shall be the necessity of securing the highest standards of efficiency, competence and integrity."

The fact that not only industry, but also academic research facilities in a number of countries provide employed researcher-investors with a financial return of their inventions, could make it difficult to attract eminent scientists to ICGEB if the Centre follows a policy too restrictive in this respect.

Further legal issues are raised by inventions developed by independent consultants and experts or by affiliated centres, if the respective research work has been fully or partly financed by ICGEB. According to its Statutes, the Centre shall, e.g., conclude agreements for special relationships with Affiliated Centres and Networks which may include financial aspects. The Centre may contribute to the financing of Affiliated Centres and Nestworks.[230] Common research projects partly or fully financed by ICGEB will certainly be undertaken in the near future. In this respect. Art. 14 (3) Statutes again comes into play according to which the Centre shall obtain patents or interests in patents on results developed through projects of the Centre. In a similar way,, UNIDO has inserted a clause 8 in its "General Conditions of 'Special Service Agreement - Expert on Mission'", which reads as follows:

"The title rights, copyrights, and all other rights of whatsoever nature in any material produced under the provisions of this agreement shall be vested exclusively in UNIDO."

However, rights to inventions made by consultants or by other persons who are not subject to internal service regulations of ICGEB or UNIDO can not be determined to originally be vested in ICGEB or in UNIDO, but can only be transferred by contract. Certainly, the Centre may insert clauses in its General Conditions of Contracts which explicitly provide for an assignment of rights. But insofar as no

such clause is inserted or accepted by the other party, national contract law will apply. In this case, the rules of private international law will presumably point out Italian or Indian law as the proper law of contract if no choice of law clause provides otherwise. In addition, the Centre has to take into consideration that the freedom of the other party to transfer the rights might be restricted by national law as to some extent.[231]

LICENSING ISSUES

General aspects of licensing

There are three principal legal methods that can be used to bring about a commercial transfer and acquisition of techno1ogy: sale or assignment., licensing and know-how agreements. When all the exclusive rights conferred by the grant of a patent are transferred, without any restriction in time or other condition, by the owner of the patented invention to another person or legal entity, it is said that an "assignment" has taken place. The concept 0f assignment is recognized in the laws of many countries.[232] when an assignment takes place, the transferor - the so-called "assignor" - no longer has any rights in respect of the patented invention. The transferee - the so-called "assignee" -becomes the new owner of the patented invention and is entitled to exercise all the exclusive rights conferred by the grant of the pa tent.[233] The second legal method is through a license, that is the giving by the owner of a patented invention to another person or legal entity of the permission to perform, in the country and f0r a limited period of time, one or more of the invention patented in that country. The legal document evidencing the permission given is usually referred to as a "license contract" since the license is normally granted subject to certain conditions, e.g. payment of royalties or field-of-use restrictions (i.e. that the invention will be used by the licensee only for the manufacture of products destined for a specific use).[234] The third of the three principal legal methods for the transfer and acquisition of technology concerns know-how. Know-how is an amount of information, e.g., developed in the course of research and development activities or through experience in the application of industrial and business techniques. In a know-how contract, the recipient usually commits himself not to disclose the know-how to third persons.

There are further legal methods for the transfer of technology (sale of goods and equipment,, consultancy arrangements, turn-key projects, joint venture agreements), which will not be discussed in detail, however, in the context of the present study. Attention shall only be drawn to the fact that in biotechnology the sale of valuable microorganisms or other biological material has a particular importance since biological material may - under certain circumstances - represent a "whole mini-factory".

A clear answer can be provided to the question on which of the three principal legal instruments mentioned above ICGEB should generally rely: Assignments of exclusively rights would result in the complete loss of any lega l title to the invention and, consequently, counteract the policy expressed in Art. 14 (2) Statutes according to which patent rights relating to the work of ICGEB should be vested in the Centre. The assignment of patents will. only play a role as to those exclusive rights which UNIDO might acquire during the interim period and which it might later transfer to ICGEB. This transfer is foreseen in Art. I (6) of the Agreement between the Government of India and UNIDO on Basic Terms and Conditions Concerning UNIDO Projects Envisaged by the Interim Programs for ICGEB, which reads as follows:

"Patent rights, copyright rights and other similar proprietary rights to any discoveries or work resulting from UNIDO's projects under this Agreement in India, as well as licenses acquired for the purpose of the projects, shall belong to the UNIDO unless and until ownership thereof is transferred to the International Centre for Genetic Engineering and Biotechnology on terms and conditions to be mutually agreed upon between the Centre and UNIDO. If, notwithstanding the foregoing, for any reasons transfer of ownership

has not taken placed before the end of calendar year 1989, ownership shall remain with UNIDO which shall hold or transfer such rights for the purpose of promoting biotechnology research and its application in India and other developing countries. "

A similar provision is contained in Art. I (7) of the Agreement between the Government of Italy an d UNIDO on Basic Terms and Conditions Governing UNIDO Projects Envisaged by the Interim Programs for ICGEB.

Know-how agreement would presuppose that the propriety rights of ICGEB be largely based on trade secrets. This, however, would contradict the general policy of ICGEB to publish research results in order to disseminate technological information.[235]

License contracts thus appear to be the legal instrument on which IC6EB should rely in general. In the following, the present study will make an attempt to analyze Art.. 14 (4) Statutes, which provides for access to intellectual property rights in favour of certain States (B.). Some general remarks concerning the licensing to industry (C.) and the drafting of license agreements will also be made (D.).

Access to patents of ICGEB to be granted to States

Art. 14 (4) ICGEB Statutes reads as follows:

> "Access to intellectual property rights concerning the results emanating from the research work of the Centre shall be granted to members and to developing countries that are not Members of the Centre in accordance with applicable international conventions. In formulating rules reg1ating access to intellectual property the Board shall not establish criteria prejudicial to any Member or any group of Members."

The legal meaning of the first phrase is certainly not unambiguous,, since the reference to applicable international conventions appears to be somewhat vague and since the manner in which the "access to intellectual property rights" has to be granted is not defined at all. It can therefore only be suggested that, in order to comply with Art. 14 (4), first phrase. Statutes, it would suffice to grant non-exclusive licenses to Member states and developing countries, these licenses being limited to the patent rights valid in the territory of the respective State. No other legal obligation seems to result from this provision. This point of view is supported by the following observations;

The beneficiaries of Art. 14 (4) are the States, not private persons or other legal entities. Certainly, sound patent policy should also imply the possibility of licenses to private entities, e.g., in order to enlarge the financial returns of an invention, in order to make technology transfer- more efficient or in order to cooperate closely with industry.[236] But it does not seem that a legal obligation exists to this respect. Furthermore, Art. 14 (4) does not require that the access be granted in the form of an exclusive license, although it might of course be very reasonable in a certain situation to grant an exclusive license to a State, e.g., if this State intends to transfer the right to a private enterprise which would otherwise not be willing to make the necessary investments for exploiting the invention.[237] Art. 14 (4) does not explicitly state that the access has to be granted gratuitously. Thus it seems possible that the license grant is made under the conditions of the payment of royalties. Further more. Art, 14 (4) only seems to require that the access is granted as to those patents which are valid in the territory of the respective State. This means that, e.g., no obligation of ICBEB exists to grant a (non-exclusive) license to the Italian government concerning the patent rights hold by ICGEB in India or in Japan.

The second phrase of Art. 14 (4) prohibits discrimination among the member states. This provision will be of particular importance in, all those situations in which no direct legal obligation of ICGEB can be deduced from Art. 14 (4), first phrase. If, e.g., ICGEB owns patents in a State which is neither member of ICGEB nor a developing country, there will be no obligation of ICGEB to grant a

licence to any State at all. But if, in such a situation, ICGEB intends to grant licenses, it is not allowed to establish general rules or a general practice which would discriminate against any member State or any group of member States

Licensing of industry

Whereas States are entitled to rely upon Art. 14 (4) ICGEB Statutes in order to obtain access to patents held by the Centre, there is no explicit provision governing the licensing of exclusive rights to; private persons and industrial entities. Reference can only be made to some general principles pronounced in the Statutes which might provide some guidelines in this respect. Particular attention should be given to Art. 14 (5) which reads as follows:

"The Centre shall use its patent and other rights, and any financial or other benefits associated herewith, to promote, for peaceful purposes, the development, production and wide application of biotechnology, predominantly in the interest of developing countries."

In addition, Art. 3 (j) Statutes recognizes that a function of ICGEB should be to

"maintain close contacts with industry".

A sound licensing policy should therefore encourage a widespread development and marketing of inventions resulting from ICGEB research. If well adapted to the mutual needs,, licensing contracts are a very useful tool to bring about an efficient transfer of technology. It should be recognized that furtherance of the widespread use of an invention may require various forms of agreements, including the granting of exclusive licenses in certain situations. Since products based on biotechnology inventions often require expensive regulatory approvals, it might be difficult to find a licensee willing to make the necessary investment without .an exclusive position.[238]

Issues to be addressed in licensing contracts

The diversity of factual situations, which might comprise licensing to States as well as licensing to private corporations of different types and different sizes, makes it impossible to work out a model contract that could be used under all circumstances. Consequently, the present study restricts itself to enumerate some of the major issues that should be explicitly addressed in a licensing contract;

- scope of license (license category, subject matter and field of use,, license exclusions, new inventiontransfers)
- financial terms (lump sum payments, royalties., etc.)
- risk allocation (third-party risks, patent infringement)
- tangible property issues
- choice of applicable law
- dispute settlement (e.g., arbitration).

Attention has also to be given to possible restrictions contained in national transfer of technology laws and in national (or regional) antitrust laws. One more point should be mentioned; A specia1 to r of biotechnology licensing are materials transfer agreements.[239] These agreements are essentially research-purposes-on1y licenses which frequently grant the licensor some kind of right to intellectual property created through use of the licensed material. Sometimes such materials transfer agreements are concluded in an early stage of negotiations in order to give some protection to the licensor during the period in which the future licensee uses the opportunity to examine the biological material.

CONCLUSIONS

According to Art. 14 ICGEB, the Centre shall take out patents. With good reasons., trade secrets are not mentioned in this provision, since relying upon the secrecy of scientific information would counteract the general policy of ICGEB to disseminate knowledge and to publish its research results.

The present study has addressed the most important patent law aspects that should be taken into account when elaborating a patent policy lot ICOEB. It has been shown that despite certain harmonization on the regional level and despite several international treaties, the principle of territoriality still prevails. This means that successful patent applications of ICGEB, e.g., in India or in Italy would lead only to patent protection in these two countries. Adequate international protection of major inventions necessarily requires to go through multiple national (or regional) patent application procedures. It has been analyzed in detail what kind of obstacles in the field of biotechnological inventions have to be overcome in Austria., India and Italy as well as in the patent systems of other economically important countries (EPC, Japan, United States), whereas, in this area, only few general exceptions to patent ability exist in Japan and the United States,, the situation differs under the EPC, under Austrian and Italian Patent Law as well as under the WIP0 Model Law. All the latter patent systems contain several exclusionary provisions, thereby causing certain problems for biotechnological inventors. The Indian patent system equally stipulates numerous exceptions which appear even to be much broader in scope.

The special protection scheme for plant varieties has been discussed and compared to the principles prevailing in general patent law. Mention has been made of major shortcomings of the UPOV system and the corresponding national laws, which, to a certain extent,, will be addressed by the ongoing revision of the UPOV convention.

An important issue concerns the question in which countries patent protection should be sought. No general guidelines can be given, however, in this respect. Certainly, seeking worldwide protection is, if possible at all, a very expensive patent policy in view of the fees of patent offices [240] and patent attorneys. Thus, going for worldwide protection appears to be a completely exceptional case even for major multinational corporations. Consequently, a reasonable selection of countries where to apply will have to be made in each case. This choice should certainly be influenced ;by the character and the possible applications of the invention. A major scientific breakthrough with numerous industrial applications merits wider protection than a smaller development useful only in a very restricted field. Also other considerations might play a decisive role in limiting the choice where to apply; Mew transgenic plants of a certain species which can be grown only in a very limited geographical area would be an example. The choice will be furthermore influenced by the general patent policy of ICGEB: If the intellectual property rights shall serve as a source of financial benefits or if they shall improve the bargaining position of ICGEB or its licensees vis-a-vis multinational corporations,[241] ICGEB should apply for patents in major industrialized countries. However, patents in developing countries are also needed, if one of the goals of ICGEB's patent policy is to strengthen the biotechnological capacity in those countries, by giving, e.g., an exclusive legal position to a medium-sized enterprise in a developing country, in order to protect it, for a limited time, against the competition of major foreign corporations.

To start with the filing of a PCT application will generally be the best method for ICGEB when seeking international protection of its inventions. In countries which are not F'CT member states but which have acceded to the Paris Convention, ICGEB might benefit from a priority right if the national patent authority, adopts the position that international organizations are also entitled to priority rights under the Convention. There is, however, some legal incertitude in this respect. A national patent authority, which shares the contrary view, might therefore refuse a patent application of ICGEB as lacking novelty, if the Centre, e.g., has at first filed an application in a member country of the PC, then

published its research in a scientific journal, and only thereafter filed the patent application in the respective country. The safest way to proceed would thus be to delay the publication of the research results till patent applications have been filed in all those PCT non member states where protection is intended to be sought. It has to be kept in mind that the positive impact of novelty grace periods foreseen in some national patent laws is restricted to the patentability of the pre-published invention in the respective national system.

No general answer can be provided to the crucial question at which stage of the research process steps for securing patent rights should be taken. In this respect, each single case has to be carefully analysed by an experienced patent counsel.

The position of international organizations raises specific questions in national and internationa1 patent law, which have been addressed and briefly discussed in the course of the present study. A particular issue concerns the inventions of employees in the context of the work of the Centre. In general, ICGEB has full discretion to freely regulate this issue, insofar as its staff members are concerned. Nevertheless, it might be good policy to provide for a system of compensation, especially if very valuable inventions have been developed. Rules governing these questions could be included in the staff regulations of ICGEB.

When patent rights have been acquired, the question of licensing arises. From a merely legal perspective, IC6EB is only obliged to grant non-exclusive licenses to member States and to developing countries with regard to those patent rights which are held by ICGEB in the respective country. Discrimination is generally prohibited. Apart from these obligations, ICGEB has broad freedom to develop and define an own patent policy. Some general suggestions have been made in this respect.

Finally, it is worth considering whether ICGEB should make an attempt to become an International Depositary Authority under the Budapest Treaty. On the one hand, activities of ICGEB in this area might presumably require supplementary facilities and personnel. On the other hand, the Centre could become a "treasure-house" of genetic resources with particular importance for developing countries.

LEGAL ASPECTS OF ACQUIRING, HOLDING AND UTILIZING PATENTS WITH REFERENCE TO THE ACTIVITIES OF THE: INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (ICGEB)

addendum to the Document of August 1989

I.

1) As regards the legal personality and capacity required for acquiring, holding and utilizing patents, reference is made to Article 13 (I) of the Statutes. There is no doubt, that the Organization is furnished with the necessary legal personality and capacity in order to be able to fulfill the aforementioned functions.

2) It is, however, necessary to distinguish between the question of the legal personality and capacity of the Organization and its eligibility for the benefits of national treatment and priority under the Paris Convention. As expressed under marginal note 89 of the Study, the international patent practice of the past has not given rise to any dispute in parallel cases in this respect. Inquiries with the European Patent Office did also not reveal many a problems as yet. As far as the right of priority under the European Patent Convention and the Indian Patent Act of 1970 is concerned,, the following should be added:

3) According to Article 87 (1) EPC

> "A person who has duly filed in or for any State party" to the Paris Convention for the Protection of Industrial Property, an application for a patent or for the registration of a utility model or for a utility certificate or for an inventor's certificate, or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of 12 months from the date of filing of the first application."

In order words, since "a person" (in the German EPC text: "jedermann"; in French "celui qui") is all encompassing, there can be no doubt that the only precondition for claiming the right of priority under the EPC for ICGEB, is, to file the patent application first in |a State party to the Paris Convention. Moreover, Article 87 (5)' EPC, stipulates that even in the case of first filing in a State which is not party to the Paris Convention the right of priority can be claimed, provided that the State fulfills certain requirements and is notified as such by the Administrative Council of EPO. As yet, however, no such notification has been made by the Administrative Council (Cf. Singer/Singer, Europäisches Patentübereinkommen, Kommentar, Cologne etc, 19i89, p. 317). Thus. first filling in India does not meet the Article 87 (5) EPC requirement.

4) As indicated in marginal note 90 of the Study and indicated above., India is not a member of the Paris Convention. The Indian Patent Act of A 970, however, in Sections 133 et seq. provides for a special treatment of so-called "Convention Countries". According to Sec. 133 (1) - "Notification as to Convention Countries" the Central Government may, by notification in the Official Gazette, declare countries to be a Convention Country for the purpose of the; Patent Act if such countries afford to applicants for patents in India or to citizens in respect of the grant of patents and the protection of patent rights. As regards the priority right. Sec. 135 (1) reads as follows:

> "Convention applications - without prejudice to the provisions contained in s. 6, where a person has made an application for a patent in respect of an invention in a Convention Country (hereinafter referred to as the "basic application"), and that person or the legal representative or assignee of that person makes an application under this Act for a patent within 12 months after the date on which the basic application was made, the priority date of a claim of the

complete specification, being a claim based on matter disclosed in the basic application, is the date of making of the basic application."

According to information available "six or so mainly Commonwealth Countries already enjoy this privilege." (Cf. San gal, Paris Convention and the Indian Patent System: Legal Perspectives, in: Sanga1/Singh, op. cit. pp. 33 et ses. (at. p. 46)). It is further reported, that countries like Japan, USA and the Federal Republic of Germany are not treated as "Convention Countries" (Bhatnagar, Paris Convention and India, in: Sangal/Singh, op.cit. pp. 85 et seq. (at p. 87)). If patent protection is desired and in principle also available in India, in order to secure all rights of ICGEB also in this country, it appears necessary to file the first patent application in at least one State member of .the Paris Convention and in India at the same (or about the same)|time. since ICGEB will not enjoy the priority right in India for patent applications first filed abroad (except in those six Commonwealth Countries) only by filing simultaneous applications (advisably, but not necessarily on the same day), negative effects of interfering intermediate applications filed in India, or interfering publications in India or elsewhere can be avoided.

II.

5) The Rule implemented in Article 14 (I) of the Statutes is contradictory only at first sight. Quite apart from the fact that results of research activities can be published also via patents, a Research Centre of the dimension of ICGEB will always need clear patent policy and its Director will have to control all permissions concerning the publication of research results. The Director, however, could well share this competency with heads of departments etc. It will be up to the patent policy laid down in writing to designate the competent persons in charge of control and to provide the necessary instruments of communication. The necessity to obtain permissions to publish research results should be implemented in the labor contracts of all employees of the Centre.

6) Although scientists are, as a rule, not enthusiastic when faced with internal control of planned publications, they did already in the past develop a sound relationship also to the problem of patenting. This is clearly revealed by the empirical study on "The Significance of the Novelty Grace Period for Non-Industrial Research in the Countries of the European Economic Community" prepared by J. Straus (Commission of the European Communities, Luxembourg 1988, QFA EUR 1127.1 EN – copy attached).

7) The admonition made in marginal note 107 of the Study should also be read together with the information about the Regulation of the Priority Right under the EF'C. In view of the clear wording of Article 87 (1) EPC, there is no doubt that the Centre will enjoy such priority right in all cases in which the first application is filed in or for any State party to the Paris Convention.

III.

8) with reference to the so-called Materials Transfer Agreements, attention should be drawn to the fact that scientific research using patented products and processes is in general permitted by patent law (cf. Study, marginal notes 70-71). One could raise the question, however, whether ICGEB should nevertheless restrain from using such patented methods since the commercial application of possible improvements of already protected products and processes might fall under the scope of the patent of the third party. Although this argument may have some merits in certain cases, its value should not be overestimated and it should not influence the general research policy too much;

First, ICGEB will be free to claim exclusionary rights for new and inventive improvements of already patented subject matter. Second, the third party will presumably not own patents in all those countries

in which a future commercial application of the improvement might take place. Industrial entities based in developed countries usually do not apply for patents in a great n u m b e r of developing countries. Apart from that, provisions excluding certain biological inventions from the field of patentable subject matter exist in numerous developing countries and make patents of third parties (and also of ICGEB) insofar impossible. Third, even in the case in which the commercial application of ICGEB improvements would interfere with patent rights of third parties in a specific country, an agreement may be reached between ICGEB and the patentee which benefits both sides, e.g. by cross-licensing provisions.

9) A somewhat different situation arises when ICGEB, before starting its own research, has entered into a "Biological Materials Transfer Agreement" in order to gain access to scientifically important or promising material. In that case, certain restrictive provisions which are quite usual in this field might prevent ICGEB from applying for patents of possible improvements and from commercially exploiting these improvements even in those countries in which the transferor has no exclusive right. One may therefore raise the question whether, as a matter of policy, ICGEB should enter into such agreements at all since,, inter alias, the principle that ICGEB has to take out patents for results of its research, could not be adhered to. It seems that a flexible attitude is needed in this respect; Certainly, in the framework of negotiations with a potential transferor of biological material, ICGEB should try to avoid clauses which restrain its freedom of acquiring exclusive rights and of commercializing possible research results. Since cooperation with a prestigious scientif ic center, in part located in an interesting geographic area (climate and soil characteristics) and having a special relationship with a number of developing countries, may give rise to research opportunities of great valued for the third party, ICGEB appears to have a bargaining position allowing for negotiating out more favorable contracting terms. If, however, the material to be transferred is of extreme importance for the research of ICGEB, the Center may be well advised to accept certain restrictive terms. The principle that ICOEB should take out own patents does certainly not forbid such a flexible negotiating strategy.

10) When biological material is transferred from ICGEB to other research institutions or private companies, material transfer agreements should be concluded in which the issue of intellectual property as well as other issues of disposing of the material transferred have to be addressed (Cf. Study, marginal, no. 102). The details of such agreements can vary, depending on the importance of the transferred material,, the general relationship of ICGEB with the other party 'and other policy considerations. In particular, a flexible strategy might have to be followed vis-à-vis exclusive rights on biological material and products which have been derived from the transferred material. Under normal circumstances, however, the material agreement should include the following obligations of the transferee;

- to use the biological material only for experimental research purpose.
- not to use the biological material for commercial purposes without first obtaining a license from ICGEB,
- not to transfer the biological material to others (except to employees, agents and consults who are bound to it by corresponding obligations)
- to indemnify the ICGEB against any claims, costs or other liabilities which may arise as a result of the transferee's use of the biological material.

In the annex; some examples of materials transfer agreements and/or licence agreements in the field of biotechnology (reproduced from Brinton, Biotechnology, Licensing, 16 AIPLA Q.J. 3.79 et seq., and Rowland, Legal Implications of Letter Licenses from Biotechnology, 1 High Technology L.J. 99 et seq.) are given in order to provide ICGEB with some guidance for the drafting of corresponding agreements.

FOOT NOTES

1) Doc. ICGEB/Prep.Comm./13/14, p.7 Cf. also Art.6(2)(e) ICGEB Statutes.

2) Whereas the inclusion of Austrian, Indian, and Italian patent law into the scope of this analysis follows from the fact that these States are the seat countries of UNIDO and ICGEB, attention has also to be paid to the patent systems of Japan and the United States since the possibility of acquiring patents in major Industrial 1ized countries should be considered when defining the patent policy of ICOEB.

3) Cf. for details Beier/Crespi/Straus, Biotechnology and Patent Protection; An International Review, Paris; OECD-Publication, 1985, p. 15,

4) Cf. Beier., The Significance of the Patent System for Technical, Economic, and Social Progress, 11 IIC 563 et seq. (1980), with numerous references. Nevertheless this basic assertion is still disputed. Foran economic analysis of the patent law see, e.g., Firestone., Economic Implications of Patents,, Ottawa 1971, Silberston, The Economic Importance of Patents, 1987, Taylor/Silberston, The Economic Impact of the Patent System, Cambridge 1973.

5) Machlup, An Economic Review of the Patent System, Study No. 15, Sub-Committee on Patents, Trade Marks, and Copyright of the Committee of the Judiciary, US Senate, 85th Congress, Second Session, Washington, D . C . 1958 = Die wirtschaftlichen Grundlagen des Patentrechts , 1962 = GRUR Int. 1961. 373-393. 473-482. 524-53.

6) Cf. also Beier/Crespi /Straus „ loe. cit. (supra note 3); Ullrich, The Importance of Industrial Property Law and Other Legal Measures in the Promotion of Technological Innovation, Ind. Prop. 1989, 102 et seq.

7) Doc. CD/B/AC.11/19/Rev 1, jointly prepared by the United Nations Department of Economic and Social Affairs, the UNCTAD Secretariat and the International Bureau of WIPO.

8) See the general summary of the UNCTAD study at pp.63 et seq.

9) Op. cit., p.52.

10) Op. cit., p.64

11) Statistics show that not only in developing countries around 80%; of the patents are granted to foreigners but that in some developed countries, such as Australia, Belgium, Canada and Denmark, the quota is even higher than 90% (the average for industrial countries, excluding the United States and Japan, comes close to 80%). Moreover, the degree of non working patents of approximately 50% is more or less the same in developing and in developed countries. C f . for details Greif, Patents and Economic Growth, 18 II C 199 et seq. (1987), at p.206.

12) According to Greif, loc. cit (supra note II), at p. 211.

13) C f . Greif, loc. cit. (supra note 11), at p. 211 et seq, figure 2.

14) UNCTAD Trade and Development Report, 1987, p.108

15) Cf. PYRangeł-OrtizPY, Mexican Patent Legislation after the Revision of 1986, Patent World, September 1987, p. 49 seq.

16) Cf. UMCTAD Trade and Development Report, 1987, p.108. When discussing the problem of industrial property protection in the field of biotechnology in developing countries, each country must weigh the benefits and possible draw-backs of introducing provisions that protect inventions in this field (e.g., microbiological processes and products, plant and animal varieties, etc.)in the context of it own specific history, social-economic conditions, and, last but not least, wealth

of natural resources.

17) C F . also Saliwanchik, Patenting Biotechno1ogica1 Inventions: A Guide for Scientists, Madison, Wisconsin 3.988, p.9

18) For details cf. Beier, One Hundred Years of International Coo 9 Cooperation - The Role of the Paris Convention in the Past, Present, and Future, 15 IIC 1 et seq. (1984)

19) Rome 1886, Madrid 1890, Brussels 1897 and 1900, Washington 1911, The Haque 1925. London 1934,, Lisbon 1958 and Stockholm 1967.

20) For details of the initiatives concerning the revision of the PC, cf. Kunz-Hallstein, Die Genfer Konferenz zum Revision der Pariser Verbandsübreinkunft zum Schutze des gewerblichen Eigentums, BRUR Int. 1981, 137 et. seq; irf., Verschärfter Ausübungszwang für Patente? GRUR Int. 1981, 347 et seq.

21) A list of the PC member countries can be found in Ind. Prop. 1989, 6 et seq.

22) Cf. Ind. Prop. 1989, 3 et seq.

23) Ct- Bent/Schwaab/Conlin/Jeffery, Intellectual Property Rights in Biotechnology Worldwide, New York 1987, p.401.

24) For details cf. Bodenhausen, Guide to the Application of the Paris convention for the Protection of Industrial Property as Revised in Stockho1m in 1967, Geneva 1968, p . 35 et seq.Yieczorek, Die Unionsprioritat im Patentrecht, Cologne/etc.1975.

25) For a commentary on this provision, cf., e.g., Bodenhausen, loc. cit. (supra note 24), at. p.67 et seq..

26) The following countries have acceded to the PCT; Australia,, Austria, Barbados, Belgium, Benin, Brazil, Bulgaria, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Democratic People's Republic of Korea, Denmark, Finland, France, Gabon, Germany (Federal Republic of), Hungary, Italy, Japan, Liechtenstein, Luxembourg, Madagascar, Malawi. Mali, Mauritania, Monaco, Netherlands, Norway, Republic of Korea, Romania, Senegal, Soviet Union, Sri Lanka, Sudan, Sweden, Switzerland, Togo, United Kingdom, United States of America. Cf. Ind. Prop. 1989, 14.

27) Cf. Art. 1(1) PCT.

28) Cf. Bent et al.. loc.cit, (supra note 23), at p.421et seq.

29) As of January 1, 1989, the following countries had acceded to the Budapest Treaty; Australia, Austria, Belgium, Bulgaria, Denmark, Finland, France, (3 s r »i a n y (Federal Republic of), Hungary, Italy, Japan, Liechtenstein, Netherlands, Norway, Philippines, Republic of Korea, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America. Cf. Ind. Prop. 1989, 16. In addition, the German Democratic Republic and Czechoslovakia deposited their instruments of accession in April respectively May 1989. Cf. Ind. Prop. 1989, 215.

30) Concerning the deposit requirements in substantive patent in law, cf. infra, marg. nos. 62-66

31) Cf. Art. 93(1) EPC

32) See for a critical analysis of "early publication system" Beier. Die Rechtsbehe1fe des Pa tentanme1ders und seiner Wettbewerber im Vergleich, GRUR Int. 1989, 1 et seq., at p.11 et seg., Straus/Moufang, Patent- und eigentumrechtliche Aspekte der Hinteregung und Freigabe von biologischem Material für Patentierungszwecke, Baden-Baden 1989 (in pres).

33) A further international treaty, i.e., the Strasbourg Convention on Unification of certain Points of

Substantive Law on Patents for Invention (concluded in 1963), served as an additional vehicle for the European harmonization process.

34) For more details cf. infra, especially under III.

35) Cfr. Marterer, The Patentability of Micro-organisms per se, 18 IIC 666 (1987).

36) Cf. Marterer, loc cit. (supra note 35), at p.666. For a translation into English see Industry Property Laws and Treaties (ed.: WIPO), Austria - Text 2-001.

37) Cfr. Marterer, loc.cit. (supra note 35), at p.668,, referring to BGB1. No. 382/1986. Cf. also infra, at marg. no.47.

38) 101 (1) Austrian Patent Law; cf. also Graser, Erfindungs- und Lizenzrecht - Einführung in das Österreichische Patentrecht, Vienna 1987, p.28

39) 101 (3) Austrian Patent Law.

40) 101 (2) Austrian Patent Law.

41) 28 Austrian Patent Law; cf. also Leberl/Marterer. The 1984 Law Amending the Austrian Patent Law, Ind. Prop. 1986, 126 et seq., at,p.129; for further details of Austrian patent law in general 1, reference is made to standard legal literature. Cf. e.g., Friedl/Schönherr/Thaler, Patent- and Markenrecht, 1979, Schönherr (Ergänzungsband), Patentrecht, 1984; Freibel/Pullitzer, österreichisches Patentrecht, 2nd ed. 1970; Gräser, loc. cit. (supra note 38); Hermann/Schmidt, österreichisches Patentgesetz, 1978; Schönherr, Gewerblicher Rechtsschutz und Urheberrecht, Grundriss , Allgemeiner Tei1, 1982; Schönherr/Thaler, Entescheidungen zum Patentgesetz, 1980.

42) For details cf. Bhatnagar, The Role of Patents in Research and Development in India, Ind. Prop. 1985, 167 et seq.; id.. R&D in Developing countries. Patent World, March 1989, p.35.

43) 53 Indian Patents Act; for further details of Indian patent law in general, reference is made to standard legal literature. Cf. e.g. Narayanan, Patent Law, 2nd ed., Calcutta 1985; Swaminathan, Patent Protection in India for Newer Areas of High Technology, Intell. Prop. Asia & Pac., March -June 1988, p. 51 et seq.; Indian Patent System and Paris Conventions Legal Perspectives (ed.: Sangal/Singh), Delhi 1987.

44) For details c f. Ubertazzi/Vohland, The New Italian Patent Act, 11 IIC 441 et seg., at p. 442 (1980). For an English translation of the current Italian patent law see Industrial Property Laws and Treaties (ed.; WIPO), ITALY - Text 2-001.

45) Cf. Mayer, Änderung des italienischen Patent- und Mustergesetzes, Mitt. 1987, 149 et seq.; Rossoni, The"Innovations"Introduced into the Italian Patent System by Law N o.6 0 of February 14, 1987, Ind.Prop. 1987, 402 et seq.

46) Cf. Ubertazzi/Vohland, loc.cit. (supra note 44), at p. 453.

47) Cf. Scheer, International Patent-, Muster- und Warenzeichenrecht, 44th ed. 1985, p. 246.

48) Art. 4(2) Italian Patent Law.

49) For details cf. Ubertazzi/Vohland loc.cit. (supra note 44), at p. 455.

50) Art. 4(4) Italian Patent Law. For further details of Italian patent law in general, reference is made to standard legal literature. Cf., e.g., Fiammenghi, I brevetti - guida pratica alla nuova legistazione, 3rd ed., Rome 1984; Floridia, I brevetti per invenzione e per modello - Codice delta riforma nazionale, Milano 1980; Giabrocono/Andreolini, Brevetti e proprieta industriale, 19S7; Jacobacchi, Italian Patent Law, Milano 1985; Marchetti/Ubertazzi, Commentario breve alla legislazione sulla proprieta industriale e Intellettua1e, 1987; Sena, I diritti sulle invenzioni e sui

modelli industriali, 2nd ed., Milano 1984.

51) For a translation to the Japanese patent taw cf. Industrial Property Laws and Treaties (ed.; WIPO), JAPAN, Text 2-001.

52) Cf. 66 Japanese Patent Law.

53) For further details of Japanese patent law in general, reference is made to standard legal literature. Cf., e.g., Doi, The Intellectual Property Law of Japan, 1980; Esaki , Änderungen des japanischen Patent-, Muster- und Warenzeichenrechts, GRUR Int. 1976, 100 et seq.; Kukimoto, Summary of Japanese Patent Law, 1971; Rahn, The Role of Industrial Property on Economic Developments The Japanese Experience, 14 IIC 449 et seq. (1983); Sekine/Kakinuki, Recent Developments in Japanese Patent Law, 11 El PR 235 et seq. (1989); The 1987 Revision of the Patent Law and Utility Model Law in Japan, Patents & Licensing, June 1987, p. 7 et seq.

54) U.S. Constitution Art. I, 8, cl.8.

55) For further details of U.S. patent law in general, reference is made to standard legal literature. Cf., e.g., Chisum, Patents - A Treatise on the Law of Patentability, Validity and Infringement, Looseleaf, Vol. 1-7, New York 1978 ff.; Lipscomb, Walker on Patents Vol. 1-6, 10, Rochester/San Francisco, since 1984.

56) Cf. also Bertone, The WIPO Model Law for Developing Countries on Inventions and Know-How, Patent world, January 1987, p. 42 et seq.

57) For details cf. Mills, The First Years of ESARIPO, Ind.Prop.i984,, 180 et seq.; id. Patents and the Exploitation of Technology Transferred to Developing Countries (in Particular, Those of Africa), Ind. Prop,. 1985, 120 et seq.

58) Cf. for details Fuller, Intellectual Property Rights Associated with Biotechno1ogy - An International Trade Perspective, 16 AIPLA Q.J. 529 et seq. (1988/89).

59) Cf. Beier/Crespi/Straus loc, ciit. ; Bent et al. ; Cooper. Biotechnology and the Law., New York (Loose Leaf); Moufang, Genetische Erfindungen im gewerblichen Rechtsschutz, Cologne/etc. 1988. Further references. should be made to the work of the committee of Experts on Biotechnological Inventions established by WlPO, particularly to WIPO Doc. BIG/281 'Industrial Property protection of Biotechnological Inventions: An Analysis of Certain Basic Issues - Prepared by J. Straus" = Straus, Gewerblicher Rechtsschutz für Biotechnologische Erfindungen, Cologne/etc. 1987

60) Cf. Official Journal of the European Communities of 13 January 1989, C 10/03; ORUR Int. 1989. 52 et seq. = 20 IIC 55 et seq. (1989).

61) The Geneva Treaty on the International Registration of Scientific Discoveries which was adopted on March 3, 1978, but is not yet in force, does not appear to be a useful instrument for improving the protect ton of scientific achievements, neither in the international nor in the national 'context. For Details Cf. Beier/Straus, Der Schutz wissenschaftlicher Forschungsergebnisse, Weinheim/etc. 1982, p.74 et seq.

62) Cf. Art.52 (2) EPC: "The following in particular shall not be regarded as inventions within the meaning of paragraph 1:(a) discoveries, scientific theories and mathematical methods;..."

63) Cf. 1(2) No. 1 Austrian Patent Law.

64) Cf. 3(c), and (d) Indian Patent Law.; for details cf. Narayana, Patent law, p. 33 et seq., p. 38 et seq.

65) Cf. Art. 12(25 (a) Italian Patent Law.

66) Cf. Art. 112 (3)(i) WIPO model law

67) For details see WIP0 Doc. Biot/CE /11/2 , p . 27 e t seq.; Moufang loc.cit. (supra note 59), p. 159 et seq.

68) CF. Beier/Straus. Genetic Engineering and Industrial Property, I n d . Prop. 1968, 447 e t seq., at p. 458 with further references.

69) Problems that may result from the requirement of industrial application will be discussed later.

70) Cf. WIPO Doc. Biot./CE/IV/2, p. 21.

71) For details cf. Moufang, loc.cit. (supra note 59), at p. 81 et seq.; Straus, loc.cit. (supra note 59), at p. 51 et seq.

72) Decision of March 27, 1969, 1 IIC 136 (1970).

73) Decision of June 16, 1980,, 206 USPQ 193 (1980).

74) Cf. Straus, loc. cit. (supra note 59), at p. 58; WIPO Doc. BioT/CE/IV/2, p. 20; Narayanan, p. 25.

75) Cf. Art.,53 (a) EPC: 2 No. 1 Austrian Patent Law; Art. 13(1) Italian Patent Law. A similar wording can be found in 3 9 B 0 Indian Patent Law, in 32; (ii) Japanese Patent Law and - with certain modifications - also in Art. 117 WIPO model law for developing countries. In the United States, no explicit statutory provision exists. But the patentability requirement of utility will not be considered as fulfilled if! the invention claimed is frivolous or injurious to the morals, or the health., or the good order of society. Cf. for details Grimaldi, Comment - Utility and the New Legislation, 52 JPOS 683 et seq., at p. 685 (l970).

76) Cf. the axplicit provisions in Art. 53 (a) EPC; 2 No.1 Austrian Patent Law;; Art. 13 (1) Italian Patent Law; Art. 117 Model Law. Cf. also Art. 4quater Paris Convention. But see 15 (3) Indian patent law; "If it appears to the Controller that any invention...might be used in any manner contrary to law, he may refuse the application, unless the specification is amended by the insertion of such disclaimer in respect of that use of the invention, or such other-reference to the illegality thereof, as the Controller thinks fit."

77) 3 (b) Indian patent law; 32 (ii) Japanese patent law.

78) For details see 1. out an. a., loc. Cit. (supra note 59), at p. 237 with further references.

79) Cf. Moufang, loc. cit (supra note 59), at p. 245 et seq.

80) During a certain period, the Japanese Patent Office interpreted the exclusionary provision to preclude any inventions producing or utilizing recombinant DMA in higher animals. Cf. Bent et al., loc. cit. (supra note 23), at p. 504; but cf. now Whaite/Joneses, Biotechno1ogica1 Patents in Europe -The Directive,11 EIPR 145 (1989). Cf. also Brody, An Evaluation of the Ethical Arguments Commonly Raised Against the Patenting of T r a n s g e n i c Animals, in; Animal Patents; The Legal, Economic and Social Issues (ec. Lesser), London 1989 (forthcoming),

81) For the legal situation in the United States, cf. the decision of the PTO In re Allen, 2 USPQ 2d 1425 (1987) = GRUR Int. 1988, 601; Quigg, 69 JPOS 328 (1987); on 13 April 1988, Harvard University was granted a patent covering (but not limited to) a new breed of genetically altered mice. Cf. also Clark, Animal Invention Protection, 16 AIPLA Q.J. 442 et seq. (1988/89); Raines, 4 Issues in Science and Technology 64 et seq. (1988/89); Raines. 4 Issues in Science and Technology 64 et seq. (1988); for Japan cf. Whaite/Joneses, loc. cit. (supra note 80).

82) The WIPO Doc. WO/INF/29, p. 96, lists 45 countries in which this exception exists,

83) Art. 53 (b) EPC.

84) 2 No. 3 Austrian Patent Law.

85) Art. 13 (2) Italian Patent Law.

86) Art. 112 (3) (ii) UIIF'O model law.

87) Mention should further be made of Rule 39.1 of the PCT which provides that an International Searching Authority (ISA) is not required to search any international application to the extent it is directed to plant and animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products thereof. Since the PCT itself does not contain any definition of patentable subject matter, this is, however, not a prohibition against filing an international application directed to such subject matter, but only means that no international search need be carried out. Cf. Bent et al., loc. cit. (supra note 23), at p. 426.

88) Cf. Ramachandran , Biotechnology and Patent Protection, Lecture Held at h) IP 0 Worldwide Forum on the Impact of Emerging Technologies on the Law of Intellectual Property, Geneva, September 14 to 16, 1988, Doc,, No. 22 add., at p. 14 et seq.; Swaminathan, loc. cit. (supra note 43), at p. 62.

89) Cf. also Art. 3(I) (1) of the proposed EC directive.

90) Cf. Press release No. 10/1989 of the EPO; Dick son, Europe Says No to Animal Patents, 245 Science 25 (1989). The application was the same on which the first animal patent was granted in the United States; cf. supra, note 81,

91) :Lubrizol decision, cf. infra, marg. no. 46.

92) C f. Bent et al., loc. cit. (supra note 23), at p. 150, 156;curry, The Patentability of Genetically Engineered Plants a, n d Animals in the US and Europe, London 1987, p. 31. The definitions contained in Art.5,,6, and 19 of the proposed EC directive open the door even more in this direction:

Art. 5: "Microbiological processes shall be considered patentabl subject matter. For purposes of this Directive, this term shall be taken to mean and to include a process (or processes) carried out wit It the use of or performed upon or resulting in a micro-organism."

Art. 6: "A process consisting of a succession of steps shall be regarded a microbiological process, if the essence of the invention is incorporated in one or more microbiological steps of tne process.

Art.19:; "For the purposes of this Directive:

(a) the word 'microorganism', where used, shall be interpreted in its broadest sense as includign all microbiological entities capable of replication, e. as comprising, interalia , bacteria, fungi, viruses, micoplasmae, rickettsiae, algae., protozoa, and cells;..

93) Cf. for details Moufang, loc. cit. (supra note 59), at p. 200.

94) Cf. infra, IV

95) This corresponds to the "prohiblition of double protection" prescribed by Art. 2(1) UPOV, cf. infra, marg. no. 73.

96) The WIPO Doc. WO/INF/29, p. 96, lists 44 countries in which this exception exists.

97) 2 No. 3 Austrian Patent Law.

98) Art. 53 (b) EPC.

99) Art. 112 ,(3) (ii) U)IPO model law. In this respect, great attention' should be paid to the critical

remarks made by Murray Haddrick, Deputy Commissioner of the Australian Patent Office, during a speech in 1989 (Reflections on Some of the Issues Bearing on Intellectual Property Protection for Plants from a Patents Perspective); "It is true that under WIFPO influence and as part of the accepted wisdom developing countries have so far excluded patents for plant varieties. But ... this has not led to acceptance of the UPOV system by them. It has simply excluded the incentive of patent protection in what is potentially one of their best fields of economic activity."

100) Cf. for details, e.g.,Marchetti/Ubertazzi, (supra note 50), 150, 407.

101) Cf. Ramachandran, loc. cit. (supra note 88), at p. 14 et seg.; Swaminathan, loc. cit. (supra note 88), at p. 62.

102) Cf. Bent et al.., (supra note 23) at p. 504 et seq.; 15 Patents and Licensing No.4, f1985, p. 3; GRUR Int. 1986, 143. For more details c f. also Monya The Legal Protection of Achievements in Biotechnology, Speech Held on 23 November 1984.

103) Cf. In re Hibbert, 227 USPQ 443 (POBAI 1985).

104) Cf. supra. III.B.3.a).

105) T 49/83, OJ EPO 1984, 112 = 17 IIC 123 (1986); cf. also Teschemacher, 19 IIC 18, at 32 (1988).

106) T 320/87, Technical Board of Appeal of 10 November 1988 (not yet published).

107) Cf. WIPO Doc. BioT/CE/IV/2, p. 26; the WIPO-Doc. WO/INF/29 , at p. 89, only lists 9 countries which explicitly exclude microorganisms from patentability.

108) Cf. Teschemacher, The Practice of the European Patent Office Regarding the Grant of Patents for Biotechnoloqical Inventions, 19 IIC 18 et seq., at p. 22 (1988).

109) Cf. 03 EPO 1982, 19.

110) Cf. Ammendola, La brevettabilita nella Convenzione di Monaco, Milano 1981, p. 494 et seq.; Marchetti/Ubertazzi, loc. cit. (supra note 50), at p. 151; with some hesitations also Sena, loc. cit. (supra note 50), at p. 165.

111) Öpat Bl. 1985, 100 = GRUR Int. 1985, 682. Cf. also Marterer. loc. cit. (supra note 35), at p. 667.

112) Cf. Gräser, loc. cit. (supra note 38), at p. 16

113) Cf., e.g., Art. 112 (3)(ii) WIPO model law.

114) Diamond v. Chakrabarty, 206 USPQ 193 = GRUR Int. 1980, 627

115) For further details cf. Hayashi, A Japanese Perspective on Patenting Microorganisms; Prospects and Considerations, 7 APLA Q.J. 306 et seq. (1979); Yamasaki, Genetic Engineering and Japanese Patent Law; Mo Official Rules Apply - Yet Patents and Licensing, June 1987, p. 13 et seq.

116) C f. Swaminathan, loc. cit. (supra note 43), at p. 62; cf. also Narayanan loc. cit. (supra note 43), at p. 26 et seq., p . 32; Ramachandran, f loc. cit. (supra note 8B), at p. 14 et seq.

117) Reference is made to WIPO doc. WO/INF/29, p. 97, which, in this respect, lists 42 countries.

118) 2 No.3 Austrian Patent Law.

119) Cf. Art. 13 (2) Italian Patent Law (excluding essentially bio logical processes for the production of animal varieties) and Art. 1 (7) D. P. R. of 12 August 1975 (excluding essentially biological processes for the production of plant varieties); cf. also Uberttazzi/Vohland, loc. cit. (supra note 44), at p. 444.

120) Cf., e.g. Bent et al. loc. cit. (supra note 23), at p. 160 et seq.5 Moufang, loc. cit. (supra note 59), at p. 193 et seq. ; Straus, loc. cit. (supra note 59), at p. 67 et. seq.

121) Cf., e.g., Straus, loc. cit. (supra note 59), at p. 79 et seq.; Teschemacher, Patentable Subject Matter Under the European Patent Convention (EPC) in the Field of Biotechnology, in; Symposium on the Protection of Biotechnological Inventions,, Geneva; WIPO Publication 1987, p. 87-102, at p. 95. See also Art. 7 of the proposed EC Directive.

122) Cf. supra, marg. no. 44.

123) Cf. 5(a) Indian Patent Law. The WIPO Doc. WO/INF/29, p. 96. lists 49 countries in which this exclusion prevails.

124) Art.16 7 EPC admits for a certain transitory period (10 years from the entry into force of the Convention, plus - under certain circum stances - additional 5 years) reservations of any Contracting State to provide that European patents, insofar as they confer protection on pharmaceutical products, be ineffective or revocable in accordance with the provisions applicable to national patents.

125) However, under former Austrian patent law, pharmaceutical products could not be protected. When ratifying the EPC, Austria entered a reservation under Art. 167 (2) (a) EPC. By the Amending Law of 1984, Austria abolished the exclusionary provision in its national law, but stipulated that this legislative change would enter into force only on the day following the expiry of the validity of the reservation under Art. 167 EPC. In 1987 pharmaceutical products became patentable in Austria. Cf. Leberal/Marterer, loc. cit. (supra note 41), at p.12 7 et seq.; Gräser, loc. cit. (supra note 38), at p. 16 et seq.

126) For a long period, Italian patent law had, however, excluded pharmaceutical products and processes. But the statutory provision was held unconstitutional in 1978 by a famous decision of the Constitutional Court. For details cf. Ubertazzi/Vohland loc. cit. (supra note 44), at p. 445 (1980).

127) Reference is made to WIPO Doc. WO/INF/ 29, p. 29, which, in this respect, lists 44 countries.

128) Art. 112 (3) (iv) WIPO Model Law.

129) Art. 12 (4) Italian Patent Law.

130) 2 No. 2 Austrian Patent Law.

131) Cf. Beier/Straus, loc.cit. (supra note 68), at p. 455

132) Cf. WIPO Doc. WO/INF/29, p. 96

133) Cf. also Commercial Biotechnology - An International Analysis, Washington 1984, p. 402.

134) Cf. for details Narayanan, loc. cit. (supra note 43), at p. 27 et seq.

135) Cf. Art. 3 (h), 5(a) and (b) Indian Patents Act. Protection is, however, available in India for the methods or processes of manufacture of food products and chemical products.

136) Cf. Art. 54 EPC, 3 Austrian Patent Law; Art. 14 Italian Patent Law; 13 Indian Patent Law; 29 (1) Japanese Patent Law; 35 United States Codes 102.; Art. 114 WIPO model law.

137) Cf. WIPO Doc. BioT/CE/IV/2, p. 21; Straus, loc. cit. (supra note 59), at p. 80 et seq. Cf. also supra, marg. no. 34.

138) 30 Japanese Patent Law.

139) 35 United States Codes 102 (b).

140) Cf. Art. 56 EPC, 1(1) Austrian Patent Law; Art. 16 Italian Patent Law.

141) 25(1) (e) Indian Patent Law.

142) 29 (2) Japanese Patent Law.

143) Art. 115 WIPO model law.

144) 35 United States Codes 103.

145) OJ EPO 1989, 275 - "Polypeptide expression/GENENTECH I"

146) 231 USPG 81 (1986), cert. denied, 480 U.S. 947 (1987).

147) 7 USPQ2d 1673 (1988).

148) C f . also Murashige, Section 102/103 Issues in Biotechnology Patent Prosection 16 AIPLA Q. J. 294 et seq. (1988/89).

149) Cf. Murashige, loc. cit. (supra note 148), at p. 295 et seq. The circumstances of this case clearly underline the already mentioned dangers which result from scientific publications for subsequent patent applications.

150) Cf. Bent et al., loc. cit. (supra note 23), at p. 185 et seq.; Moufang, loc.cit (supra note 59), at p. 278 et seq.; Murashige, loc. cit. (supra note 148), at p. 294 et seq.; Rauh/Jaenichen, Novelty and Inventive Step in Inventions Having Proteins or DNA Sequences as their Subject Hatter, 70 JPOS 313 et seq. (1988).

151) This holds true, e.g., for the EPC, the patent systems of Austria, Italy, Japan, and the MIPO model law.

152) Cf. 2(1)(j); 64 (l)(g) Indian Patent taw.

153) 35 United States Codes 101.

154) Art. 57 EPC.

155) Since this concept has been quite unequivocally clarified in Austrian case law, no explicit definition was felt to be needed when Austria brought its -national patent law in line with the EPC, cf. Leberl/Materer, loc.cit. (supra note 41) at p. 127.

156) Art. 17 Italian Patent Law.

157) Art. 116 WIPO model law.

158) Cf. Straus, loc. Cit. (supra note 59), at p.83.

159) Cf. Narayanan, loc. Cit. (supra note 43), at p. 428 et seq.

160) Cf. Straus, loc. Cit. (supra note 59), at p. 83 et. seq.

161) Cf. WIPO Doc. BioT/CE/II/2, p. 4B.

162) Brenner v. Manson, 148 USPQ 689 (1966).

163) Cf. Beier/Crespi/Straus , loc.cit, (supra note 3), at p. 14 et seq.

164) C f. Art. 83 EPC: "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." Similar provisions can be, found in 87a (1) Austrian Patent Law, Art. 28 (2) Italian Patent Law, 10(4) Indian Patent Law, 36(3) Japanese Patent Law, 35 United States Codes 112(1) 'and Art. 123 (3) WIPO model law.

165) Cf. Rule 28 and 28a EPC..

166) Cf. 87a (2) Austrian Patent Law.

167) Cf.Art.5 Regulations on Patents.

168) In India, there is no explicit provision in the Patents Act or in the Rules framed thereunder. But, as it has been pointed out by a commentator, the Indian Patent Office accepts the reference made by applicants to the deposit of microorganisms. Cf. Ramachandran, loc. Cit. (supra note 88), at p.14 et seq.

169) Cf., e.g., Bent et al., loc.cit. (supra note 23), at p. 505.

170) Cf., e. g., In re Argoudelis, 168.USPQ 99 (CCPA 1970).; Feldman v. Aunstrup, 186 USPQ 108 (CCPA 1975); In re Lundak, 227 USPQ 90 (CAFC 1985).

171) C-f. supra, II.C.3.

172) For more details cf. Straus/Moufang. loc.cit. (supra note 32).

173) The EPO Examination Guidelines, Chapter IV, 3,5., include, e.g., plasmids under the t e r m "microorganism". Also plant or animal cells and h y b r i d o m a s are frequently treated in the same way as microorganisms.

174) Cf. also WIPO Doc. BioT/CE/IV/2, p. 39 et seq.

175) Cf. WIPO Doc. BioT/CE/IV/2, p. 37 et seq.

176) Cf. Notice ;of the President of the EPO, OJ EPO 1982, 19.

177) Cf. Rule 28 (1) EPC, 87a (2) No.1 Austrian Patent Law; Art. 5bis (1) Italian Patent Regulations.

178) In re Lundalk, 227 USPQ 90 (1985).

179) Cf. Rule 28 (3) and (4) EPC

180) Cf. 81a Austrian Patent Law.

181) Cf. Marterer, loc.cit. (supra note 35), at p. 667

182) Art. 5bis, cl. 3, Italian Patent Regulations.

183) Cf. In re Argoudelis, 168 USPQ 99 (CCPA 1970).

184) Cf. Art. 135 (2) WIPO model law.

185) Cf. 22 Austrian Patent Law; Art. 1 and 2 Italian Patent Law; 48 Indian Patent Law; 68 Japanese Patent Law; 35 United States Codes 154, 271. Cf. also Art. 29 CPC. Since a European patent granted under the EPC has to be considered as a collection of national patents, the EPC contains only some rudimentary rules as to the effects of the rights conferred. Art. 64(2) EPC provides, however, for the extension of process patents to products directly obtained from the process.

186) Ct. Fuller, loc. cit. (supra note 58), at p. 533.

187) Cf. 48 (2) (b) ; but see Narayanan, loc. cit. (supra note 43), at p. 483s "where the patent is not for the article manufactured, but for the monde by which the article described is brought into existence the sale by the defendants of articles manufactured by the' plaintiff's process is an infringement whether made within the jurisdiction or elsewhere. "

188) For details cf. Beier/Straus, loc. Cit . (supra note 68), at p.456; Moufang, loc. Cit . (supra note 59), at p. 380 et seq.

189) For details cf. Beier/Straus, loc. cit. (supra note 68), at p. 456; Straus, the Principle of "Dependence" under Patents and Plant Breeders' Rights, Ind. Prop. 1987, 433 et seq ., at p.439;

Moufang, loc. cit. (supra note 59), at p. 380 et seq.

190) Cf. Art. 12 of the proposed EC directive.

191) Cf. also the detailed provision contained in Art. 136 (2) WIPO model law. Art. 32 CPC equally recognizes the exhaustion doctrine.

192) For details cf. Moufang, loc. cit. (supra note 59), at p. 384 et seq.; cf. also Art. 11 of the proposed EC directive.

193) Art. 1(3) (a) Italian Patent Law.

194) 47 (3) Indian Patent Law.

195) 69 (1) Japanese Patent Law.

196) Cf. 35 United States Codes 271 (e)(l). This provision which is the legislative answer to the CAFC decision Roche v. Bolar {221 USPQ 927 (1984)} constitutes, however, only a very specific exemption relating to research on new drugs. I the United States, the experimental non-infringement doctrine therefore remains to be essentially based on case law.

197) Art. 136 (1) WIPO model law,

198) A detailed analysis of the complex problems arising in this respect has been completed by Chrocziel, Die Benutzung patentierter Erfindungen zu Versuchs- und Forschungszwecken, Cologne/ etc. 1986. Cf. also Israelsen, Making, Using and Selling without Infringing; An Examination of 35 U.S.C. Section 271 (e) and the Experimental Use Exception to Patent Infringement, 16 AIPLA Q.J. 457 et seq. (1988/1989).

199) For further details Sena, loc.cit. (supra note 50), at p. 383. p. 383.

200) For Further details cf. Narayanan, loc. Cit. (supran note 43), at p. 247 and 483.

201) As of January 1, 1990, UPOV had the following member countries; Austria, Belgium, Denmark, France, Federal Republic of Germany, Hungary, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Poland, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States of America; cf. Ind. Prop. 1989, 18; in addition, Australia has acceded to the UPOV convention in 19B9, cf. Ind.Prop.l989, 87.

202) E.g., in the Democratic Republic of Germany.

203) There are, however, attempts to introduce such legislation in Austria in the near future, cf. Bent et a1., loc. Cit (supra note 23), at p. 477, referring to P1ant Variety Protection (UPOV Newsletter) No.43, at p, 21.

204) Cf. for details Mangini, the Protection of Plant Varieties in Italy and the UPOV convention, Patent World, November 1987, p. 25 et seq; Piccini Tosato, La recente legge sulla protezione della novita vegetali, Riv. Dir. Civ. 1977 II 44 et seq. ; Ronga, La protezione delle nuove varietà vegetali, Giurisprudenza Agraria Italiana 1976, 447 e t seq.

205) Cf. Art. 1(3) Italian decree

206) Cf. Art. 4(3) (b)(iii) UPOV convention.

207) For Italy', cf. Art. 24 of the Decree No. 974-1975. The taxa currently protected in Italy are listed in Plant Variety Protection Laws and Treaties (ed.; UPOV), Italy, Miscellaneous Information, No.4.

208) Cf. also Art. 4(1) Italian Decree.

209) Judgement of 13 January 1986, cf. Hassan, Ornamental Plant Variety Rights; A Recent Italian

Judgement, 18 11C 219 e t seq. (1987); Mangini, loc. cit.(supra note 204), at p. 27.

210) Cf., e.g., UPOV Doc. IOM/IV/2 of 22nd June 1989.

211) CF. Seidl-Hohenveldern, International Economic Law, Dordrecht / etc. 1989, p. 79. Legal capacity in public international law and principle. Cf. also Kunz–Hallstein, die Beteiligung Internationaler Organisationen am Rechts- und Wirtschaftsverkehr, GRUR Int. 1987, 819 et seq., at p. 820 and 824.

212) For details cf. Kunz–Hallstein, loc. cit. (supra note 211), at p. S19, referring in particular to the World Health Organization (WHO), European Space Agency (ESA), European Organization for Astronomic Research in the Southern Hemisphere (ES0) and Euratom. As regards the should be given to the resolution adopted fifth World Health Assembly on Hay 12, 1982; which reads as follows (cf. Ind.Prop. 1982, 222):

POLICY ON PATENTS
The Thirty-fifth World Health Assembly,
Recognizing the need for affirmative action to make health care resources available to all, and the role of incentives in the development of health technology ihat is not present available;
Convinced that, in contributing to the development of health techro1ogy, WHO would seek to ensure its wide avail -ability to Member States at appropriate cost;
Recognizing that, when desirable, close contacts with respect to policy on patents should be maintained between WHO and other organizations of the United Nations system.,
1. DECIDES that it shall be the policy of WHO to obtain patents, inventors' certificates or interests in patents on patentable health technology developed through projects supported by MHO,, where such rights and interests are necessary to ensure development of the new technology; the Organization shall use its patent rights, and any financial or other benefits associated therewith,, to promote the development, production, and wide availability of health technology in the public interest;!
2. REQUESTS the Director-General to report to the Seventy-first session of the Executive Board, to the Thirty-sixth world Health Assembly, and periodically thereafter, on the progress and the methods of implementation of this policy and on any problems pertaining thereto, as well as on consultations with the international organizations concerned."

213) Cf. Kunz-Hallstein, loc.cit. (supra note 211), at p. 825.

214) Cf. Art. III of the Agreement between the Government of India and UNID0 on Basic Terms and Conditions concerning UNIDO Projects envisaged by the Interim Programme for the ICGEB; Art. III of the Agreement between the Government of Italy and UNIDO on Basic Terms and Conditions concerning UNIDO Projects envisaged by the Interim Programme for the ICGEB. Both provisions refer to the Convention on the Privileges and Immunities of the United Nations or the Convention on the Privileges and Immunities of the Specialized Agencies, as applicable in accordance with Art. 21 of the Constitution of UNIDO.

215) Resolution (69) 29, adopted by the Committee of Ministers of the Council of Europe on September 26, 1969, and Explanatory Report, Council of Europe, in; Privileges and Immunities of International Organizations, Stransbourg 1970. Cited according to Kunz-Hallstein, loc.cit. (supra note 211), at p. 827.

216) Cf. Kunz-Hallstein, loc.cit. (supra note 2115, at p. 826, with further arguments supporting this ;point of view.

217) Kunz-Hallstein, loc.cit. (supra note 211), at p. 827.

218) Ibidem. During the interim period, this obligation of UNIDO follows from Section 31 of the

Convention on the Privileges and Immunities of the Specialized Agencies according to which

> "each specialized agency shall make provision for appropriate modes of settlement of (a) disputes arising out of contracts or other disputes of private character to which the specialized agency is a party."

In the context of infringement issues, it has to be kept in mind that generally the national law of the State applies in which the alleged act of infringement has taken place. As to the activities of ICGEB, an interesting question arises whether the Centre would infringe an Italian patent if the alleged act of infringement takes place in its laboratory in New Delhi.

219) Bodenhausen, loc.cit. (supra no:te 24), at p. 27 et seq.; Kunz-Hallstein, loc.cit. (supra not3 211), at p. 828.

220) Kunz-Hallstein, loc.cit. (supra ;note 211(, at p. 828; Pfanner, Die Lissaboner Konferenz - B. Patente, GRUR Int. 1959,, 60 st sep.' at p. 80.

221) Cf. the references cited by Kunz-Hallstein, loc.cit. (supra note 211) at p. 828 note 81 (Schluter, Jenks, Mann).

222) C f. Kunz-Hallstein, loc.cit. (supra note 211), at p. 830 et seq.; ILO Tribunal Judgment No. 788 - In re Mischung, GRUR Int. 1987, 875.

223) ILO Tribunal Judgment No. 788 - in re Mischung, GRUR Int. 1987, 875.

224) At least, this conforms to the internationally prevailing doctrine in the field of private international law; cf. for details Straus, Die inter national-privatrechtliche Beurteilung von Arbeitnehmererfindungen im europäischen Patentrecht, GRUR Int. 1984, 1 et seq.

225) Cf. ILO Tribunal Judgment No. 788 - In re Mischung;, GRUR Int. 1987, 975. Kunz-Hallstein, loc.cit. (supra note 211), at p. 831, has urged, however, for some caution as to whether the case law of the ILO tribunal should be followed under all circumstances.

226) For details cf. Sena, loc.cit. (supra note 50), at p. 189 et seq.; Ubertazzi, Die Zuordnung von Arbeitnehmererfindungen in italienischen Recht, GRUR Int, 1986,, 365 et seq.; for the legal principles prevailing in India, cf. Narayana, loc.cit. (supra note 43), at 47 et seq.

227) According to Art. 8 (6) ICGEB Statutes, the staff shall be appointed by the Director under regulations approved by the Board. The conditions of service of staff shall conform as far as possible to those of the United Nations common system.

228) 228 For details cf. Kunz-Hallstein, loc.cit. (supra note 211), at p. 31.

229) One of the few international organizations which provide for compensation in favour of staff persons is the European Space Agency. Rule 4.2/7 of its Staff Regulations (cited by Kunz-Hallstein, ibidem) reads as follows:

"(i);Where individual merit is recognized in accordance with Rule 4.2/6(ii), the basic award to be granted per patent shall be:

- 100 AU at the time of deciding to file a first patent application in a country.
- 500 AU at the time of deciding to file a corresponding patent application in at least one other-country, based on a favourable novelty report by the European Patent 0ffice or a national Patent Office.

(ii) Five years at the latest after filing the first patent application, the Patent Group will reexamine the dossier for each patent which has been extended to at least one country, in order to de termine the possible value of the exploitation of the patent on the bases of the following criteria;

- the proceeds of the selling the patent, or royalties received by the Agency for licences,
- an estimate of the savings made in Agency programs due to the patent,
- an estimate of the benefit to the national program of the Member States.

Having regard to the value of the exploitation of the patent and to the financial investments made by the Agency for this exploitation, the Patents Group will determine the amount of an additional award to be paid to the inventor, even after his departure from the Agency, and will make a recommendation to the Director Generals.

Art. 1.4.05 of the Staff Rules of the European Molecular Biology Laboratory (cited by Kunz-Hallstein, ibidem) equally provides for the payment of a compensation "whenever the use of the right results in a considerable financial benefit to the Laboratory".

230) Cf. Art. 9 (4) and (5) ICGEB Statutes.

231) Such limits are of even more importance in the area of copyright where numerous national laws restrict the transfer of certain rights of the author. Cf. Kunz-Ha11stein, loc.cit. (supra note 211), at p. 832 et seq.

232) Cf. e.g., 33 Austrian Patent Law, 68 Indian Patent Law, and Art. 2584 Italian Civil Code.

233) Cf. Background Reading Material on Intellectual Property (ed.; WIPO);, Geneva 1988, p. 267.

234) Cf. Background Reading Material,, loc.cit. (supra note 233), at p. 268.

235) Art. 14 (1) Statutes reads as! follows: "The Centre shall publish all results of its research activities provided such publications does not contravene its general policy regarding rights to intellectual property approved by the Board.

236) Cf. infra, C.

237) It is a well-known phenomenon that very often private corporations are not interested in a non-exclusive license when the necessary investments for developing the product are high and can only be risked if a reasonable financial return is secured by an exclusive legal position- Cf. e.g., Haeussler, Universities, Industry and Intellectual Property Rights, Doc. IAUP/ VIII/, 10 July 1989.

238) Brinton, Biotechnology Licensing: Issues from the University Perspective , 16 AIPLA Q. J. 479 et seq , at p. 484 (1988/89). Another commentator! even pointed out that "in today's environment the best way to kill a potential miracle drug is to publish it in the open literature." Cf. Haeussler, loc.cit. (supra note 237), at p. 8.

239) Cf. for details Brinton, loc. cit. (supra note 238), at p. 488 et set).; Rowland, Legal Implications of Letter Licenses for Biotechnology, 1 High Technology L.J. 99 et seq. (1986).

240) In most patent systems, an application fee has to be paid as well as increasing annual renewal fees for the maintenance of the patent.

241) For details of the activities of multinational corporations in this field, cf. Transnational, Corporations in Biotechnology, (ed.: United Nations Centre on Transnational Corporations), New York 1988.