

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(88) 496 final - SYN 159

Brussels, 17 October 1988

PROPOSAL FOR A COUNCIL DIRECTIVE

ON THE LEGAL PROTECTION

OF BIOTECHNOLOGICAL INVENTIONS

(presented by the Commission)

EXPLANATORY MEMORANDUM

PART ONE: GENERAL

C o n t e n t s

Introduction

Purpose and Scope of the Proposed Directive

Subject Matter of Biotechnology

Main Areas of Inventive Work and Their Economic Importance

Categories of Biotechnological Inventions

The Need for Approximation of Laws

- (i) Existing Legal Framework in the Member States
- (ii) Efforts to Improve Legal Protection for Biotechnological Inventions
- (iii) Protection of Biotechnological Inventions under the European Patent Convention
- (iv) Effects of the European Patent Convention upon the Protection of Biotechnological Inventions under National Patent Laws
- (v) Effects of the Community Patent Draft Convention upon the Protection of Biotechnological Inventions under the European Patent Convention and under National Patent Laws
- (vi) Protection of Biotechnological Inventions by the Courts
- (vii) Necessity for the Community to Act

Relationship between the proposed Directive and the European Patent Convention

Relationship between the Patent Protection under the Proposed Directive and the Protection of Plant Breeders' Rights under the UPOV Convention and National Plant Variety Laws

Legal Basis

Part II: Particular Provisions

Chapter 1: Patentability of Living Matter

Chapter 2: Scope of Protection

Chapter 3: Dependency License for Plant Varieties

Chapter 4: Deposit, Access and Re-deposit

Chapter 5: Reversal of the Burden of Proof

Chapter 6: Definitions and Final Provisions

EXPLANATORY MEMORANDUM

**PART ONE: GENERAL**

INTRODUCTION

1. In a 1983 Communication to the Council entitled "Biotechnology in the Community", the Commission emphasised the increasing importance for medicine, industry and agriculture of applications of modern biotechnology<sup>1</sup>. The Commission noted that European lack of strength in this field results principally from the fragmentation of its efforts in research and from the absence at Community level of a favourable environment for innovation. To remedy the situation, the Commission undertook several initiatives covering the problems posed by the recent evolution of modern biotechnology.

In the field of research, the Commission included biotechnology and the various areas covered by the exploitation and promotion of biological resources among the eight priorities of the Framework Programme for 1987-1991. The present Action Programme "Biotechnology" (BAP: 75M Ecu for the period 1985-1989) includes research activities, training and collective action to promote the creation of new processes for better mastery and exploitation by man of the properties and structures of living matter. BAP, based entirely on European cooperation, controls and directs some 350 research contracts grouped into 90 transnational projects and assures each year, for about 100 young researchers, specialised training indispensable for the development of biotechnology; it also includes numerous scientific projects, notably in the fields of plant molecular genetics, of industrial microbiology and of protein genetics, which contribute significantly to the innovatory potential of agriculture and of Community industry. Several programmes will be initiated shortly to permit an increase in ongoing activities and to extend them to solving Community problems arising at the interface between industry and agriculture. This concerns, on the one hand, the BRIDGE Programme (Biotechnology Research for Innovation, Development and Growth in Europe, with a proposed budget of 100M Ecu covering the period 1990-1994), which is in preparation by the Commission services and which will be taken over in 1990

---

<sup>1</sup>COM(83) 672 final/2 - Annex of October 1983.

with BAP; and, on the other hand, two new programmes, ECLAIR and FLAIR, presented by the Commission to the Council in 1987 and 1988, which are aimed at promoting the development in the Community of agro-industrial and agro-alimentary technologies. ECLAIR (European Collaborative Linkage of Agriculture and Industry through Research) has a proposed budget of 80M Ecu covering the period 1989-1993; FLAIR (Food-Linked Agro-Industrial Research) has a proposed budget for mid-1989 to mid-1993 of 25M Ecu. Commission initiatives in favour of research and development in the field of biotechnology would remain incomplete if they were not accompanied by appropriate industrial property legislation which offers to Community science and industry legal protection indispensable for their inventions. The legal situation in the Community was identified in the 1983 Communication to the Council as suffering from deficiencies and discrepancies in statute law and a general shortage of case law. The problem raised by the absence of a harmonised system of laws was said to be particularly harmful and dangerous to an entity like the European Communities in view of the impact on Community industry and on the functioning of the common market. Specific action at Community level was envisaged on the basis of the major unresolved legal issues presented under biotechnology. It was therefore advocated that the Commission should work out proposals to the Council, inter alia, for a European approach to intellectual property rights in biotechnology.

2. Following a "guidelines discussion" at the Research Council of the European Communities of 28 February 1984 on the Communication from the Commission and as to suggested Community action, the Council concluded that it was advisable to take measures as proposed by the Commission to improve the regulatory environment, including the system of intellectual property rights, with a view to facilitating the production, marketing and use of biotechnological products in the Community.<sup>2</sup>

3. Subsequently, in its White Paper on "Completing the Internal Market" approved by the Community Heads of State and Government at the European Council meeting in Milan on 28/29 June 1985, the Commission announced its intention to propose measures concerning patent protection of biotechnological inventions.<sup>3</sup>

-----  
<sup>2</sup>SI(84) 144, Annex IV.

<sup>3</sup>COM(85)310 of 14 June 1985, p.37.

4. The Single European Act, adopted by the Conference of the Representatives of the Governments of the Member States on 28 February 1986 in The Hague, established a new Article 8A of the EEC Treaty providing for the Community "to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992".

5. At the time of signing the text of the Single European Act, the Conference adopted the following declaration on Article 8A:

The Conference wishes by means of the provision in Article 8A to express its firm political will to take before 1 January 1993 the decisions necessary to complete the internal market defined in those provisions, and more particularly the decisions necessary to implement the Commission's programme described in the White Paper on the Internal Market.

6. This proposal is one of the measures aimed at providing industry with the ability to treat the common market as a single environment for their economic activities and to create the conditions necessary for the proper functioning of the common market.

Differences in industrial property laws have a direct and negative impact on Community trade and there is no other field of technology where national patent laws vary on so many points as they do in biotechnology. To create the environment for companies to treat the common market as a single market, it is essential to reduce to a minimum the existing differences in the legal protection of biotechnological inventions and to prevent others from arising.

7. The proposal is necessary to provide authoritative guidance for most of the questions and problems presented in national patent law which arise in connection with biotechnological inventions and which are not directly addressed by such laws. Without such a proposal, the existing lack of uniformity of approach makes it impossible for companies to treat the Community as a single market. Moreover, without approximation of national legislation, the possibility exists for an even greater variation of national approaches in light of the independence of national patent systems and each national judiciary.

Purpose and Scope of the Proposed Directive

8. The main purpose of this proposal for a Directive is to establish harmonised, clear and improved standards for protecting biotechnological inventions in order to foster the overall innovatory potential and competitiveness of Community science and industry in this important field of modern technology. The provisions of the Directive systematically adapt existing patent law principles to the field of biotechnology with the aim of securing the application of patent laws in this important area as effective as possible.

9. By providing improved possibilities to protect biotechnological inventions and greater certainty regarding the scope of protection available, the Directive should allow inventors and investors in the Member States to benefit from patent protection as effective as that in the competitive markets of Japan and the United States of America (USA). This will result in a greater willingness to invest labour and capital in research and development and in exploiting the results thereof in spite of the high risks involved.

10. Establishing a harmonised system of patent law in this area will facilitate the development of Community industry in biotechnology, trade in biotechnological products and the establishment of a common market in this field. Moreover, it will enable Community industry to keep pace with leading nations in biotechnology and to close or narrow existing gaps.

11. The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts. The patent system thus secures costly investment in research and development and industrial exploitation of research results. Simultaneously, the patent system encourages an early and beneficial dissemination of knowledge in the field of activity involved which, without such protection, might be kept secret. The patent system also offers the necessary incentives for exploiting the results of publicly funded research. Such exploitation itself requires costly investment.

12. Biotechnological research and development and industry making use of developments in this field are rapidly evolving and expanding on the international level. Biotechnology is likely to influence and modify the lives of many people through its ultimate impact on human and animal health care, agriculture, the food and chemical industries, energy resources and the environment. It has evolved dramatically through the advance of various genetic engineering techniques in recent years, particularly so in the USA and Japan. It is, therefore, of particular urgency for patent protection to play its important part in these fields in the European Communities.

13. The patent system, when applied to biotechnology, encounters a number of particular problems. A reason for this is that biotechnology, as the name says, is related to living matter, which poses problems in relation to ethics as well as in relation to the traditional patent law concepts of patentable subject matter, discovery, novelty, sufficient written disclosure, industrial applicability and the extent and exhaustion of patent protection.

14. These particular problems have been handled in some respects in a different manner in different Member States and, even where Member States have unilaterally introduced into their laws provisions similar to those of the European Patent Convention, these provisions do not provide for specific rules which relate to and are necessary for resolving the particular problems of biotechnological inventions. In fact, the legal situation suffers from deficiencies as well as discrepancies in statutory law, regulations and their interpretation and a general shortage of case law.

15. The problem is particularly acute in the European Communities, where the existence of a harmonised and adequate body of law, rules and practices is of major importance to the proper functioning of the internal market and the competitive vigour of industry.

#### Subject Matter of Biotechnology

16. Biotechnology is understood to comprise all the techniques that use or cause organic changes in any biological material (such as animal and plant cells or cell lines, enzymes, plasmids and viruses), microorganisms, plants and animals; or that cause changes in inorganic material by biological means.

In its modern appearance, biotechnology includes the techniques of recombinant DNA (deoxyribonucleic acid), gene transfer, embryo manipulation and transfer, plant regeneration, cell culture, monoclonal antibodies, and bioprocess engineering. This understanding of biotechnology covers the areas in which inventive work is most active and promising, and in which the results of that work have particular economic and social importance.

#### Main Areas of Inventive Work and Their Economic Importance

17. Biotechnology is rapidly gaining ground. It is playing an increasingly important role in the future of industry. Inventive work concerns many sectors, such as pharmaceuticals (e.g., the production of human insulin, human hormones, interferons, blood products, vaccines and antibiotics, monoclonal antibodies, genetically engineered heart attack drugs, etc.); specialty chemicals and food additives (e.g., amino acids, enzymes, single cell proteins); commodity chemicals and energy production (e.g., biomass resources); and environmental applications (e.g., pollution control, toxic waste treatment, microbial enhanced oil recovery). Agriculture is another area of biotechnological activities holding the key to innovation crucial for creating new products and for enhancing environmental acceptability in crop production (e.g., improvement of specific plant characteristics, like insect, disease, pesticide, stress or herbicide resistance, use of microorganisms for crop improvements, etc.), and animal agriculture (e.g., diagnosis, prevention and control of animal diseases, animal nutrition and growth promotion, genetic improvement of animal breeds), as well as new bioprocessing opportunities (e.g., alternative fuels, alternative feed and food sources, and other products).

18. Patent documentation gives evidence of an overall increasing patent activity in biotechnology. The most impressive increase took place in the field of "mutation/genetic engineering", i.e., in the core-region of the new biotechnological developments. Genetic engineering is composed of newly emerging methods for inserting, changing or deleting genetic information within a host organism, be it microorganism, plant or animal, to give it new characteristics. The development and use of these new techniques provide the ability to manipulate the genetic character of organisms while overcoming complications and limitations of natural gene exchange. The patent file of

the European Patent Office reveals that, in the field of genetic engineering, the number of patent applications filed rose approximately 600% from 1981 to 1985. About 50% of the applications originated from the USA; Japan contributed more than 20%; some 25% of applications came from the Member States (United Kingdom 12.1; Germany 5.2; France 5.0; the Netherlands 2.3; Denmark 0.5; Belgium 0.2)<sup>4</sup>

19. The modern genetic engineering techniques complement, rather than replace, the methods of traditional biotechnology, which will continue to yield new inventions as well. However, the new techniques do, due to their speed, precision, reliability and scope, offer enormous economic potential. Market forecasts for modern biotechnological products vary considerably. However, in no estimate are these markets valued at less than US \$ 40 billion by the year 2000<sup>5</sup>. It is believed that modern biotechnology has its strongest research base in the USA; and its strongest commercial base in Japan<sup>6</sup>, with Europe remaining below its real potential. Member States, with annual government funding of biotechnology of approximately US \$ 350 million<sup>7</sup> should, therefore, strive such as the Commission has already begun (see paragraph 1 above) to improve future prospects for Community industry, in order to secure an appropriate stake in the world markets for such industry. Patent protection, adapted to the needs of modern biotechnology, is one important measure serving this goal.

#### Categories of Biotechnological Inventions

20. Inventions resulting from modern biotechnological techniques can be grouped according to the usual patent law distinction made between product, process, and use or application inventions.

Inventions relating to products concern living entities of natural or artificial origin, such as plants, animals and microorganisms, biological material, such as plasmids, viruses and replicons, and parts thereof (e.g.,

-----  
<sup>4</sup> Knuth et al., Characterization of Genetic Engineering Inventions in Patent Claims, 1987 World Patent Information 229, at 230.

<sup>5</sup> Hacking, Economic Aspects of Biotechnology, Cambridge etc., 1986, 256, 257.

<sup>6</sup> Hacking, op cit., 254.

<sup>7</sup> Dibner, 232 Science 1367 (1986) at 1369.

organs, tissues, cells and organelles). They may also relate to naturally occurring substances from living entities, biological material and parts thereof. The invention itself may be the plant, animal, microorganism or a specific biological material (e.g., a plasmid) per se or the plant, animal, etc., produced by a particular process.

The second category (process inventions) concerns processes for the creation of plants, animals, microorganisms or any biological material and parts thereof. It includes also such processes as cultivation, isolation, and purification, and also of bioconversion.

The third category of biotechnological inventions (application inventions) comprises specific uses of plants, animals, microorganisms or biological material.

#### The Need for Approximation of Laws

##### (i) Existing Legal Framework in the Member States

21. The existing legal framework for protecting biotechnological innovation in the Member States has been strongly influenced by two international conventions, conceived in the late fifties and early sixties on the basis of the-then state of the art in biological sciences: The "International Convention for the Protection of New Varieties of Plants", established in 1961 in Paris (the UPOV Convention), and the "Convention on the Unification of Certain Points of Substantive Law on Patents for Invention", signed in 1963 (the Strasbourg Convention).

22. The current patent laws of most of the Member States were adopted and introduced in the late seventies and early eighties as a direct result of the more recent 1973 "Convention on the Grant of European Patents" (the European Patent Convention - EPC) and the "Convention for the European Patent for the Common Market" (Community Patent Convention - CPC), signed in Luxembourg in 1975, but not yet in force. With regard to biotechnological innovation, they follow the basic principles of the UPOV and Strasbourg Conventions, which were introduced into the EPC without seriously reconsidering developments which in the meantime had taken place in various areas of biotechnology.

23. The key assumptions of the UPOV and the Strasbourg Conventions, which were taken over into the EPC and the harmonised national patent laws of all the Member states, except Ireland and Portugal<sup>8</sup>, are, firstly, the belief that the traditional concept of "technical invention" renders biological inventions only in rare cases capable of complying with the usual requirements of patentability; and, secondly, that inventions in the field of living matter could be divided into those of microbiology and those of (macro-) biology.

Based on these premises and taking into account certain known needs of traditional plant breeders, the 1961 UPOV Convention established a tailor-made type of protection for new varieties of plants.

Subsequently, the Strasbourg Convention, in view of the long history of patenting microbiological processes and their products in several States party to it, made it mandatory as early as 1963 to protect microbiological processes and their resulting products, but left the signatory States a free hand as regards the protection of new plant or animal varieties and essentially biological processes employed in their production.

The EPC, when adopted in 1973, expressly excluded from patent protection plant and animal varieties and essentially biological processes for the production of plants and animals but allowed patenting of microbiological processes and their products (Article 53b).

24. It should also be mentioned that in 1977, under the auspices of WIPO, the Budapest "Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure" was concluded to which twenty-one States have adhered<sup>9</sup>. The States party to this Treaty, which allow or require the deposit of microorganisms for the purposes of patent procedure, are obliged to recognise, for such purposes, the deposit of a microorganism with any recognised international depository authority.

-----  
<sup>8</sup> These Member States have not yet brought their national patent laws into line with EPC.

<sup>9</sup> As of April 1987. From the Community Member States Greece, Ireland, Luxembourg, and Portugal are not yet party to this Treaty.

Although this Treaty facilitates applications for patent protection of biotechnological inventions abroad, it does not influence the substantive patent law of the "Contracting States". Its influence on patent laws of the Contracting States is limited to purely technical provisions regarding the depositing and redepositing of microorganisms, as demonstrated by Rule 28a EPC, which was inserted into the EPC Regulations as a result of the conclusion of the Budapest Treaty.

25. Achievements in biotechnology reached during the period of time necessary to bring into force this international legal framework at the national level demonstrate that the distinction between micro- and macrobiology, which serves as the dividing line between patentable and non-patentable inventions, is artificial and no longer tenable. Developments originating in microbiology, either as processes or products, are likely to have a direct effect on the macrobiological sector, giving rise similarly to visible changes in the plant or animal world. They should, therefore, enjoy legal treatment according to the same principles as other inventions in microbiology.

26. One major consequence of micro- and biotechnological developments is that "Agriculture has moved from a resource-based to a science-based industry as science and technology have been substituted for land and labor"<sup>10</sup>. A greatly improved understanding and mastery of basic biological mechanisms have given rise to a change in the concept of what may be considered "technical" for purposes of patent law. Beginning in the late sixties, the courts of at least one Member State have held that the general field of biology may be included in the notion of what is "technical".<sup>11</sup> This changed appreciation from that represented by the existing international legal framework, however, has only partially been incorporated into statutory law and into patent practice, at both the national and the international level.

---

<sup>10</sup> Committee on a National Strategy for Biotechnology in Agriculture - Board on Agriculture - National Research Council, Agricultural Biotechnology - Strategies for National Competitiveness, Washington, D.C., 1987, 1, 2. According to the Executive Summary of this report, it is true even for USA that "Yet current political and economic policies governing agriculture neither fully recognize nor take these changes into account".

<sup>11</sup> Decision of March 27 1969, Federal Supreme Court, Federal Republic of Germany, 1 IIC 136 (1970) "Red Dove".

27. Due to its underlying assumptions, outdated by scientific and technological developments, the present legal framework for protecting biotechnological inventions in the Member States is unable to satisfy either the needs of science and industry in this field or the needs of patent granting authorities and courts. Apart from the now rather questionable explicit exclusions from patentability, only in part resulting from the prohibition of double protection established in Art. 2 (1) UPOV Convention, the main and decisive deficiency of the system is to be seen in its almost complete lack of any reliable legislative guidance on such essential questions as:

Patentability of Living Matter, that is, what are the criteria to patent natural material in view of the existing exclusion of discoveries from patent protection and also in view of the novelty requirement; what is to be understood by the terms "microbiological" and "essentially biological process"; can a microorganism per se be regarded as a product of a "microbiological process";

What are the effects of the exclusion from patentability of plant and animal varieties upon the patenting of microorganisms or taxonomic units different from plant or animal varieties or upon the patenting of parts of plant or animal varieties or their uses?;

What is the Scope of Patent Protection for Living Matter, in view of the fact that living matter is self-replicable and, this therefore, causes particular problems in respect of further generations;

Sufficient Disclosure, which in spite of the advances in natural sciences remains a problem of major concern, for example, whether and under what conditions the written description of an invention may be completed by a deposit of a microorganism or other self-replicable matter, and what are the duties of and safeguards for the depositor.

(ii) Efforts to Improve Legal Protection for Biotechnological Inventions

28. OECD. Since the emergence of modern biotechnology, the ability of patent laws to offer effective protection for new biotechnological processes and products has been uncertain. The Organization for Economic Cooperation and

Development (OECD) first initiated an international review on biotechnology and patent protection in 1981. Based on replies to a questionnaire from governments of nineteen members<sup>12</sup> (out of twenty-four), the Final Report<sup>13</sup> detected a great number of deficiencies in patent laws of most of the member countries regarding especially the patentability of microorganisms per se, naturally occurring materials, disclosure, deposit and release conditions and infringement. Moreover, it was observed in this report inter alia:

"In no other field of technology, old or new, do national laws vary on so many points or diverge so widely as they do in biotechnology. The answers to the OECD Questionnaire have brought a wide spectrum of varying legal opinions and practices to light which concern almost every important aspect of patent protection in biotechnology."

The replies from the Member States of the Community reflected no less a divergence either in respect of varying legal opinions and practices or as to existing deficiencies of national laws. It was felt that only US and Japanese laws were on the whole adaptive and flexible in respect of new developments in biotechnology. To improve the present legal situation in the OECD countries, the report submitted a number of recommendations.

29. WIPO. At its fourteenth series of meetings (of September/October 1983), the Assembly of the International (Paris) Union for the Protection of Industrial Property instructed the International Bureau of the World Intellectual Property Organization (WIPO) to

"study the existing situation concerning the protection, by patents or by other means, of inventions in the field of biotechnology (including 'genetic engineering') and possible means of providing for industrial property protection for such inventions, both at the national and international level"<sup>14</sup>.

-----  
<sup>12</sup> Among those countries which answered the Questionnaire were the following Member States: Belgium, Denmark, Germany, France, Ireland, Italy, the Netherlands, Portugal and the United Kingdom.

<sup>13</sup> Biotechnology and Patent Protection - an International Review, OECD, Paris 1985.

<sup>14</sup> WIPO Doc. BIOT/CE/I/2.

A Committee of Experts on Biotechnological Inventions and Industrial Property was established and first convened in 1984. Subsequently the International Bureau of WIPO prepared an Analysis of Certain Basic Issues in Industrial Property Protection of Biotechnological Inventions<sup>15</sup> and then, based on replies to two Questionnaires<sup>16</sup>, submitted nineteen suggestions for solutions concerning industrial property protection of biotechnological inventions<sup>17</sup>. These solutions seem to complete and supplement the recommendations of the OECD Report.

In three meetings, the Committee of Experts discussed the work done by the International Bureau and its consultants, particularly the "Suggested Solutions"<sup>18</sup>. It might initially have been envisaged that the ongoing work of WIPO could have produced the necessary level of harmonisation for the European context. This will unlikely be the case in anything but the very long term in light of the general observation of the Director General of WIPO in the third session of the Committee of Experts, according to which

"At present, WIPO did not intend to provoke changes in national legislations; it only wanted to make governments more aware of what was happening in this field in the various countries and of what were the problems that the legislator might have to solve, so that the patent system could be fully responsive to the need for protection in this exceedingly important technological field."

Moreover, from the remarks made by a number of delegations, especially, but not exclusively from the developing countries, it may be concluded that an agreement on this topic at the universal level either in the form of a special convention or within the current work of the International Bureau of WIPO on the Draft Treaty on the Harmonisation of certain provisions in laws for the protection of inventions<sup>19</sup> cannot be expected for at least several more years.

---

<sup>15</sup> WIPO Doc. BIG 281 and WIPO Doc. BIOT/CE/II/2.

<sup>16</sup> WIPO Doc. BIOT/Q/1, 2.

<sup>17</sup> WIPO Doc. BIOT/CE/III/2.

<sup>18</sup> The work of the Committee is reported in WIPO Docs. BIOT/CE/I/3; BIOT/CE/II/3; BIOT/CE/III/3.

<sup>19</sup> WIPO Doc. HL/CE/III/2.

30. Thus, the efforts of WIPO in this area will most likely end in no more than a recommendation addressed to the Member States of WIPO by its Director General. In view of the complexity of the issues and the interests involved, it is only realistic to note that such a recommendation could result in changes in national legislation, at best, in several years. Notwithstanding well founded and balanced Suggested Solutions, the WIPO initiative is unlikely to bring about a prompt, positive and harmonised response at the world or even the European level. Experience with the revision work on the Paris "Convention for the Protection of Industrial Property" confirms this appreciation.

(iii) Protection of Biotechnological Inventions under the European Patent Convention

31. The legal basis for granting European patents for biotechnological inventions is the previously mentioned Article 53 (b) EPC, which has served as a model for national patent law provisions of nine Member States of the Community. As noted earlier, this article expressly excludes from patent protection plant and animal varieties and essentially biological processes for producing plants and animals but allows patenting of microbiological processes and the products thereof. Article 53 (b), however, is not the only provision of the EPC explicitly dealing with biotechnological inventions. Because inventions concerning microbiological processes and their products incur particular difficulties with regard to the usual requirement of sufficient disclosure, the EPC from the outset introduced special provisions for compliance with this patent law requirement.

In Rule 28 of the Regulations, if an invention concerns a microbiological process or the product thereof and involves the use of a microorganism which is not available to the public and which cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, the disclosure requirement may be satisfied by a deposit of a culture of the microorganism in a culture collection not later than the European patent application date, including with the application identifying details of the deposit. The deposited microorganism must be made available from the culture collection to any person from the date of first publication of the application. Moreover, this provision lays down detailed rules as to the release conditions of the deposited material. Rule 28 was subsequently amended

to introduce the so-called "expert solution" which allows the applicant the possibility to limit the availability of the deposited material to an independent expert until the grant of the European patent.

32. To cope with problems emerging from patent applications in the field of modern biotechnology, additional guiding measures proved necessary under Article 53 (b) EPC. The European Patent Office (EPO) in its "Guidelines for Examination" therefore addressed a number of particular problems, such as, the patentability of naturally occurring substances, the demarcation between "essentially biological" and "essentially non-biological" processes and the interpretation of the terms "microbiological process", "microorganism", and "product of a microbiological process".

As to other questions, such as the effects of the exclusion from patentability of plant and animal varieties upon the patenting of taxonomic units different from plant or animal varieties or upon the patenting of parts of plant or animal varieties or their uses, the guidelines are silent.

33. Although the solutions provided for in the Examination Guidelines of the EPO offer valuable guidance for the examining organs of the EPO, and seem to meet many of the needs of applicants in an appropriate manner, they are handicapped by the fact that they are neither binding on the Board of Appeals of the EPO, deciding in final instance on patentability, nor on national courts competent in nullity procedures regarding European patents. There is no mechanism in the EPC, such as by Examination Guidelines, to provide for mandatory guidance on the questions arising in respect of patenting biotechnological inventions. The Boards of Appeals of the EPO and the national courts enjoy complete discretion whether to follow the practice of the EPO when interpreting the EPC. As regards the scope of protection of biotechnological inventions and the interrelation between the effects of patents and plant breeders' rights, the EPC does not regulate these issues and thus no competence of the European Patent Office exists.

34. Difficult to predict are future developments as regards the EPC. For the time being the EPO is solving problems related to the application of Article 53 (b) EPC on a case-by-case basis in addition to periodic amendment of the Guidelines for Examination. The practical effects of these Guidelines should not be underestimated. In view of their limited legal effects, however, the

EPO Guidelines cannot be viewed as a suitable means to cure the deficiencies caused by the lack of legislative guidance with regard to the most essential problems of patenting biotechnological inventions under Article 53 (b) EPC.

While in theory it may be possible to introduce rules related to the interpretation of substantive patent law provisions of the EPC into the "Implementing Regulations to the Convention" (the amendment of which falls within the competence of the Administrative Council of the European Patent Organization), these Regulations so far have no binding effect on the views to be taken by the courts of the Contracting States when interpreting the EPC. The same is true even for the Boards of Appeals of the EPO: under Article 164 (2) EPC, the Implementing Regulations may be deemed to be in conflict with the wording of the Convention and the Convention may be interpreted in a different way.

Legislative guidance needed under Article 53 (b) EPC could of course be provided by a revision of the EPC. In light of the difficulties presented by the revision mechanism of Article 172 EPC, however, it appears unlikely that the EPC Contracting States would consider any revision at the present time.

(iv) Effects of the European Patent Convention upon the Protection of Biotechnological Inventions under National Patent Laws

35. When considering the possibilities of the EPC to affect the national patent laws of the Community Member States, the special legal concept of the EPC must be taken into account. 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 granted by that State (Articles 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 represent patents with national effects, subject to national laws, although certain minimum standards are prescribed in Articles 64(2) and 67 EPC.

In addition, it results from the design of the EPC that the Contracting States are not obliged automatically to align their national patent laws with the EPC. This has happened in the past but on a purely voluntary, unilateral,

uncoordinated basis. An amendment of the EPC would probably, but not mandatorily, lead to changes in national patent laws of most of the Community Member States. Moreover, in order to secure a harmonised judicial practice on points essential to biotechnological inventions in the Contracting States, such changes of the EPC would require highly specific provisions. An additional difficulty with regard to the EPC results from its membership: whereas four EPC Contracting States are not Community Member States, Denmark, Ireland and Portugal are not yet Contracting Parties to the EPC.

(v) Effects of the Community Patent Draft Convention upon the Protection of Biotechnological Inventions under the European Patent Convention and under National Patent Laws

The "Convention for the European Patent for the Common Market" of 1975 ("CPC") and the 1985 Agreement relating to Community Patents<sup>20</sup> do not themselves address questions as to patentability, but leave these issues to the EPC. The CPC will not, therefore, improve the ability to protect biotechnological inventions. It is only to the extent that the EPC provides for patent protection that the CPC will provide for instruments necessary to secure that Community patents shall have a unitary character as well as:

"have equal effects throughout the territories to which this Convention applies and may only be granted, transferred, revoked or allowed to lapse in respect of the whole of such territories ..." (Article 2 (2) CPC).

Thus, the CPC will not provide a solution to the basic issue of appropriately protecting biotechnological inventions. Even for the positive effects which the CPC may have on the unitary nature of protection, it is difficult to predict its entry into force. This is unlikely to occur before 1993 and may well come into force for less than all Member States of the Community. The possibility also exists that the CPC will leave open a permanent option between a Community patent and a European Patent. Alongside the EPC/CPC structure, national patent laws will continue to exist. Thus, even the entry

<sup>20</sup>Cf. "Texts established by the Luxembourg Conference on the Community Patent 1985" (Council of the European Communities, Luxembourg 1986).

into force of the CPC would by no means make superfluous amendments of national laws providing for legislative guidance as to the protection of biotechnological inventions under national patent law.

(vi) Protection of Biotechnological Inventions by the Courts

36. From past experience with the judicial practice of the courts of the Member States, it may be observed that courts would prefer, perhaps even need to have, more legislative guidance when dealing with problems of patentability in the field of biotechnology. As an example of the difficulties encountered by the courts in the Member States and of the time needed to find solutions for questions not specifically answered in the law, the case law of the German Federal Supreme Court on the repeatability requirement of biotechnological inventions may be mentioned.

This Court first demonstrated its exceptional understanding of the necessity to interpret in modern patent law the concept of invention according to the latest state of scientific knowledge in 1969 and affirmed that a method for breeding animals is eligible for patent protection, provided the procedure is repeatable, i.e. it can be readily duplicated by a person skilled in the art<sup>21</sup>.

Six years later, when the patentability of a microbiological process and of a microorganism per se i.e., a product claim, was at issue, the German Federal Supreme Court affirmed its position as regards the patentability of living matter in general. It also accepted the deposit of a microorganism strain in a publicly accessible depository as a valid support of the written description as far as the microbiological process was concerned, but not in respect of claims directed to the microorganism per se.

In the latter context it stated as follows:

"It is inconsistent with the Patent Act prerequisite of reproducibility of the invention to refer the expert to a product of the inventor according to the invention in order to reproduce his invention. Protection for a microorganism per se or - what amounts to the same thing - for a process of propagating a microorganism in a conventional

<sup>21</sup>-----  
Decision of March 27, 1969, 1 IIC 136 (1970) - "Red Dove".

manner without a teaching to the expert as to how to produce the microorganism is so alien to conventional patent law that it could not be obtained via a change in the conventional case law but only by a change of the Patent Act."<sup>22</sup>

After the German legislature failed to react for another eleven years, the Federal Supreme Court in 1987, in view of criticism expressed and even more so because of a different view taken on the specific issue by the European Patent Office, reversed its former case law. Since 1987, under the German Patent Act, protection for a new microorganism per se is obtainable, if the possibility of reproducing the new breed can be substituted by the deposit and release of a reproducible sample of the microorganism<sup>23</sup>.

The German case law thus suggests that advances in protecting biotechnological inventions by decisions of national courts of the Member States can only be expected after long delays. Legal uncertainties and deficiencies of protection could, as a rule, be remedied only after years, perhaps even decades. Under the present patent law regime in the Community, national judicial decisions, even those of the Supreme Courts, produce legal effects only in the territory of that particular state so that favourable adaptation in one Member State results in divergent adaptation in the Community as a whole. Although case law in one Member State may eventually lead to changes in legislation or have harmonising effects on the case law of other Member States, no certainty can be offered with such an approach and much time would be lost.

(vii) Necessity for the Community to Act

37. It results from this analysis of the existing legal framework at national and international level (see (i) to (vi)) that the law for protecting biotechnological inventions is unsatisfactory and in urgent need of improvements. As a result of the work performed by OECD and WIPO, the main deficiencies have been detected and recommendations for how to improve the situation have been put forward. Particularly the "Suggested Solutions" elaborated by WIPO accord with most of the needs of inventors in modern biotechnology.

<sup>22</sup>-----  
<sup>22</sup>Decision of March 11, 1975, 6 IIC 208 (1975) - "Baker's Yeast".

<sup>23</sup>Decision of February 12, 1987, 18 IIC 396 (1987) - "Rabies Virus".

38. Having regard to the great importance of biotechnology for the future of the Community, the negative effects of the divergent adaptation resulting from the situation described above are unacceptable for the Community. Whereas the two leading nations in biotechnology, the United States of America and Japan, have been able continuously to adapt their patent protection according to the latest needs of industry, science and consumers, the Member States, representing comparable potential of intellectual manpower and capital, are immobilized by a not yet completed and, in respect of biotechnology, in part outdated legal framework. In order to preclude any further negative effects for Community science, industry and consumers arising from the present situation, it is incumbent upon the Commission to propose the necessary remedial measures.

39. The Directive is also a prerequisite to eliminating barriers to the exchange of knowledge and technology transfer between Member States and to trade in the Community. By providing the same clear and improved standards of patenting in the national patent laws of Member States, the readiness to communicate technical knowledge, which in the past has suffered considerable setbacks, will grow. In parallel, harmonised protection of biotechnological inventions will not only give incentives necessary for investments in biotechnology throughout the Community but will also contribute to trade between Member States which under present conditions is hampered by the fact that export of self-reproducible biotechnological products into areas with uncertain, weak or even non-existent protection is less than attractive for obvious reasons. Also as a result of the Directive, the Community will offer investors equal possibilities for protection so that they may treat the Community as a single market with the possibility of securing reasonable returns on their investments. Community based industries will be attracted to repatriate their funds invested overseas in recent years in research and development in biotechnology. Investors from third countries will be more inclined to invest in the Member States.

#### Relationship between the Proposed Directive and the European Patent Convention

40. The proposed directive is intended to coexist, and not to interfere with, the existing international legal network in which the EPC, the UPOV Convention and the Budapest Treaty are the cornerstones. It is therefore indispensable that any proposal must be compatible with the provisions of those conventions.

Therefore, the legislative guidance offered by the Directive to the Member States having in their national patent laws provisions identical or similar to that of Article 53 (b) EPC, necessarily takes the form of provisions of a more detailed nature. This represents the only realistic approach to providing solutions which meet the needs of modern biotechnology and which establish legal certainty throughout the Member States.

41. The proposed Directive does not seek to establish a Community industrial property right for biotechnological inventions. The proposed Directive has, however, methodically made use of existing legal principles in patent laws and Conventions as well as solutions developed in other fora in order to secure an application of national patent laws for biotechnological inventions which is both necessary and appropriate for the Community as a whole. By harmonising national patent law standards for the patenting of biotechnological inventions and the scope of their protection, it will enable science and industry to acquire in the Member States one or more national patents tailored to their needs and the needs of the consumer. Since the EPC and the CPC do not offer the necessary legislative protection, and due to their coexistence with the national patent laws, the Directive will fulfil its tasks even after the CPC has entered into force in all Member States.

42. The proposed Directive respects the limitations existing under the pertinent provisions of the EPC and the national patent laws of the Member States. It is therefore primarily based on the following assumptions:

- discoveries as such are not regarded as patentable inventions;
- plant and animal varieties as such or essentially biological processes for the production of plants or animals are excluded from patent protection;
- microbiological processes or the products thereof are eligible for patent protection; and
- methods for treatment of the animal body by surgery or therapy and diagnostic methods practised on animal body are not regarded as inventions which are susceptible of industrial application if practised for a therapeutic purpose.

43. It is clear that the framework of the current rules on the patenting of living matter now reflects incorrect assumptions. In view of the social and economic importance which biotechnological inventions have for the Community's future, the Directive provides for principles which will ensure that such rules remain strictly limited to their original aims.

44. For this purpose the proposed solutions systematically take advantage of work performed by international organisations such as WIPO, the European Patent Organisation and OECD. Particularly the approach found in the Examination Guidelines of the EPO<sup>24</sup> and the "Suggested Solutions" of the International Bureau of WIPO<sup>25</sup> form the basis of or are even in part incorporated in the solutions of the proposed Directive.

Since the EPO patent grant practice and the Examination Guidelines are developing on a case-by-case basis, reflecting the immediate needs of the Examining Division, they do not address all problems in this area or do not so in an exhaustive manner. The provisions of the proposed Directive necessarily go further, though generally in the same direction as that originated in the EPO Examination Guidelines.

Only in some instances, for example in respect of the availability of deposited matter after the application has been refused or withdrawn or is deemed to be withdrawn, the provisions of the Directive differ slightly from those under Rule 28 of the EPC Implementing Regulations. Moreover, the Directive specifically addresses problems in respect of issues arising under national patent law only, such as the scope of protection, rights conferred, infringement related questions and the like.

45. Thus, on the whole the proposed Directive corresponds to the EPC and to the patent grant practices of the EPO. Although it will not directly or legally affect either the EPC or the practice under the EPC, the indirect effects of the proposed Directive should be substantial.

-----  
<sup>24</sup> Guidelines for Examination in the European Patent Office, published by the European Patent Office, Munich 1983, as last amended in July 1987.

<sup>25</sup> Contained in WIPO Doc. BIOT/CE/III/2 of April 8, 1987.

Firstly, as far as the Directive correlates with the existing patent granting practice based on the EPO Examination Guidelines, it will in fact lead to a harmonised interpretation of European and national patents.

Secondly, where provisions of the Directive clarify questions not yet answered in the Examination Guidelines of the EPO, they do so with the necessary legislative authority and closely following the solutions suggested by the International Bureau of WIPO. This will facilitate the task of the EPO in its constant efforts to improve on firm grounds its Examination Guidelines. For it is virtually excluded that national administrative or judicial authorities of the Member States, competent for example in revocation procedures, will take an approach for European patents different from that for national patents, although they would have been issued on the basis of different but analogous provisions.

As regards the differences in respect of the availability of the deposited biological materials, the proposed Directive does not interfere with the EPC. It only provides for harmonised solutions in national patent laws of the Member States, which under the present regime differ among themselves as well as with regard to EPC Rule 28.

A possible effect of the proposed provisions of the Directive which differ from EPC Rule 28 could result in an adaptation of that Rule to the Directive. Such an amendment could be provided for by agreement between the Administrative Council of the European Patent Organisation, without revising the EPC.

46. From the foregoing it is clear that the proposed Directive will not interfere with the EPC, nor will it establish any interdependence in a legal sense between the two bodies of law. The practical interaction of the two systems is nonetheless likely to be productive. On the one hand, only the Directive is in a position to secure a harmonised practice under the EPC as far as the national phase of that practice in the Member States is concerned. On the other hand, the Directive will offer the EPO firm grounds on which to develop further its patent granting practice according to the latest needs of industry and science in biotechnology.

Relationship between the Patent protection under the Proposed Directive and the Protection of Plant Breeders' Rights under the UPOV Convention and National Plant Varieties Laws

47. The proposed Directive will not fetter the principles or the working of either the plant breeders' system or the UPOV Convention. The principle of the prohibition of double protection, i.e. protection by plant breeders' rights and patents for the same botanical genus or species, as established under Article 2 (1) UPOV Convention, is no longer uniformly applied in the Convention itself<sup>26</sup> and is also very much in dispute.<sup>27</sup> Nonetheless, the Directive leaves that principle untouched.

Notwithstanding extensive criticism of certain UPOV principles by major users of plant variety protection based on the UPOV system, an approach directing the Member States to revise the obligations into which they entered under international conventions outside of the Community legal framework appears inappropriate for the moment. Moreover, certain positive effects, in part experienced with plant breeders' rights in the Community Member States which are also members of the UPOV<sup>28</sup>, in those areas of plant agriculture in which such rights are effectively available<sup>29</sup>, leads to the conclusion that a restrictively applied exclusion of patentability of plant varieties as such will not harm developments in modern plant biotechnology and could be tolerated.

-----  
<sup>26</sup> Exceptional Rules for protection under Two Forms, Introduced into the UPOV Convention by the 1978 Revision (Article 37 (1) allow, under certain conditions, Member States or adhering States to grant plant breeders' rights as well as patents for the same botanical genus or species. So far the United States of America has taken advantage of this possibility. The US Patent and Trade Mark Office (PTO) thus grants patents for plant varieties regardless of whether they are eligible for special plant variety protection established along the lines of the UPOV-Convention (Decision of the PTO Board of Appeals and Interferences of September 24, 1985, 227 USPQ 443 - ex parte "Hibberd").

<sup>27</sup> Proposals of International Non-governmental Organisations for Revision of the Convention, Document UPOV/IOM/III/3.

<sup>28</sup> Greece, Luxembourg and Portugal are not members of the UPOV.

<sup>29</sup> The UPOV Convention allows its contracting States 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 (Article 4 (3)(b)(iii)). As a result of this principle, even in the Community Member States belonging to the UPOV, extensive areas of plant agriculture are not covered by UPOV-type plant breeders' rights.

For it is the modern plant biotechnology which offers the prospects to eventually overcome problems with which Community agriculture is faced and which therefore merits the best possible incentives. Farmers throughout the Community are in great need of new products, commercially desirable as well as environmentally acceptable, which traditional plant breeding techniques are not able to produce. Modern plant biotechnological processes, for example for transferring foreign genes into plant cells or for regenerating transformed cells into whole plants etc., as well as products thereof, such as genetically modified plant cells, plant cell lines, plant tissue culture and transgenic plants, must be offered the best possible protection in order to provide the incentives necessary to mobilize intellectual manpower and to induce capital investment to the extent necessary to maximize the innovatory potential in the Community's agricultural sphere.

48. The UPOV-type protection which is at present available does not offer appropriate incentives. For example, it does not cover process innovation. In addition, the scope of protection provided for products encompasses only the production and commercialization of the reproductive or propagative material, as such, of the protected variety, but not whole plants or parts of plants, such as cut flowers, as end products. Lastly, and far more importantly, plant

breeders' rights are governed by the principle of independence: no authorization is required from and no licence fees are paid to the original breeder for the use of his protected variety as a starting base for breeding and commercialising new varieties. Although this rule was designed to facilitate improvement of plant genetic diversity, it was and remains, in its broad form, an insufficient incentive to lead to investments in truly new developments.

Distinctness, a criterion for protection of new varieties, as applied under the UPOV scheme does not focus on characteristics essential for the working (functioning) of a plant variety. The rule of independence seems to have resulted in investments to achieve minimal variations of existing varieties, rather than in research and development of genuine improvements in genetic diversity. Traditional breeding methods, supported by plant breeders' rights, were not able to prevent the present situation in Community agriculture in which the EEC is unable either to consume or to sell all that it produces.

Biotechnological methods for developing new plant products offer genuine promise for producing commercially desirable and therefore saleable agricultural materials.

In this connection a recently established "Committee on a National Strategy for Biotechnology in Agriculture" of the US National Research Council - a body of the National Academy of Sciences since 1916 - recommends in its 1987 report on "Agricultural Biotechnology" inter alia:

"Patenting and licensing play necessary roles in advancing technology transfer and assuring the commercialisation of research results, especially in capital intensive fields such as biotechnology. Patenting and licensing by universities and government agencies should be encouraged as key instruments used to transfer technology. Universities and government agencies should provide incentives to their scientists to encourage patenting. Public policy should encourage state land-grant universities to confer exclusive licences on patents to private companies with the resources, marketing, and product interests required to translate these discoveries into commercial products."<sup>30</sup>

The Committee in effect is recommending no less than a complete departure from a policy followed for decades in US agricultural economics which generally opposed exclusive rights in the field of publicly funded agricultural research.

49. The principles of the UPOV Convention as applied in the national laws of the Member States will be unaltered by the proposed Directive. Nonetheless it is indispensable to secure the undisturbed functioning of the patent system in areas clearly allocated for patent protection, that principles necessary to clarify the interrelation of the effects of patents and plant breeder' rights be adopted. The pertinent provisions of the Directive safeguard the necessary contents of patent rights, taking account of all the relevant interests involved, including science, industry, breeders, growers, farmers, taxpayers and consumers.

---

<sup>30</sup> Agricultural Biotechnology - Strategies for National Competitiveness, Washington, D.C., 1987, 14.

## Legal Basis

50. In the White Paper on completing the Internal Market under "Creation of Suitable Conditions for Industrial Cooperation" the Commission gave clear notice of its intention to propose to the Council specific measures to improve patent protection of biotechnological inventions in light of the negative impact which differences in national laws have on intra-Community trade and on the ability of industry to treat the common market as a single environment. The present proposal therefore forms part of the Commission's programme for the completion of the internal market before 31 December 1992.

For the achievement of the internal market before 31 December 1992, Article 100A paragraph 1, sentence 2 provides by way of derogation from Article 100:

The Council shall, acting by a qualified majority on a proposal from the Commission in cooperation with the European Parliament and the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

Article 8A paragraph 2 defines the internal market as comprising "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty." Differences in industrial property laws, such as exist in national patent laws in Member States as regards biotechnological inventions, hamper the proper functioning of the internal market. The present proposal will establish equal possibilities for protection of the results of biotechnological research and will thereby create a legal framework facilitating cooperation between enterprises. In addition, the Directive will produce suitable conditions for the exploitation of the results of such research and will encourage industrial development and greater intra-Community trade.

Industry in those countries with clear and established practices of patentability and patent procedure is in a more favourable position than that in countries where practices have yet to be established and where insufficient

experience has resulted in an uncertain situation for the protection of biotechnological inventions. Such differences distort the conditions of establishment and of competition in Member States for firms which engage in activities concerned with biotechnology. The development of a Community biotechnology industry as a whole is hindered. In consequence, the common market fails to develop as it should for its proper functioning.

By providing the conditions for the results of research to be legally protected on a uniform basis in the Member States, innovation and technical progress on an EEC scale will be encouraged.

The Directive will also foster a greater movement of biotechnological goods between Member States because the reluctance to engage in inter-State trade which results from a lack of protection in one or more Member States will be eliminated or will not arise if legal protection is clearly available on an equivalent level in all Member States. Without the improvement in protection and legal certainty anticipated by the Directive, offers for sale of many future biotechnological products would not be made in some Member States and the enforcement of national patent rights in a Member State where protection existed against imports from a Member State where no protection was available could prevent the creation of the conditions necessary for the proper functioning of the common market. The free movement of goods could be adversely affected due to a variable system of national protection in the Member States.

Notwithstanding the benefits to the internal market which would result from the entry into force of the CPC, unlikely in any event before 1993, this Convention will be limited to patents granted under the European Patent Convention only. In consequence, the national systems of patent law would be unaffected by the entry into force of the CPC. Thus, there remains a need for an instrument directed to the national patent systems which encourages biotechnological research in Europe with a reasonable expectation, if desired, of protecting such work via the national patent systems. This in turn will ensure that both a Community biotechnological industry and Community trade in biotechnological products develop as necessary for the proper functioning of the common market.

In the preparation of this proposal the Commission has taken into account the requirements of Article 8c of the Treaty and has concluded that no special provisions or derogations seem warranted or justified at this stage.

Likewise the Commission has studied the question of the high level of health/safety/environmental and consumer protection required by the terms of Article 100A(3) of the Treaty. In the preparation of this proposal, full account was taken of these considerations which are directly dealt with in other Community instruments.

PART TWO: PARTICULAR PROVISIONS

CHAPTER 1

Patentability of Living Matter

Article 1

This Article defines the aim of the Directive: to ensure that national patent laws are in compliance and accord with the terms of the directive. The Directive will have no legal effects vis-à-vis the European Patent Convention (EPC) or any provisions thereof.

Article 2

The aim of Article 2 is to establish legislatively that the condition of being alive or of being living matter would be legally insufficient to render such material unpatentable. This principle must be explicitly recognised for biotechnological inventions. The normal criteria for patentability provide no guidance on how to determine the patentability of living matter. This article is therefore necessary even though the principle to be established is already widely recognised. Where the principle is not completely accepted, under Article 2, the argument can no longer be raised that all living matter must be excluded from patent protection on the ground that the mere fact of being alive disqualifies such inventions from being regarded as patentable, e.g., on the basis that they are natural products.

The history of industrial property protection demonstrates that inventions in newly developing technologies have always encountered difficulties in securing legal protection. Such an explicit legislative provision as is laid down in Article 2 is necessary to remedy certain difficulties and to prevent others from arising when general provisions of patent law are applied to inventions

involving technology that makes use of living entities such as animals, plants and micro-organisms. As all inventive activity involves intervention by man into the processes or products of nature, there is no reason to exclude from protection inventive activity relating to living matter, other than the area of humankind (but this type of provision is already commonplace in patent law on public policy grounds as is found in Article 52(4) EPC).

Only a very few national courts of the Member States, after decades of uncertainty, have managed to develop a coherent doctrine under patent law to protect living matter. Article 2 will establish a minimum level of legal certainty without the delay caused by awaiting judicial resolutions which may not arise. Such certainty is required to foster economic and technical progress. This can only be achieved within an acceptable period of delay by requiring legislative adoption of the rule to recognise the general rule that living matter as such is no less patentable than non-living matter if the required extent of novelty, inventive activity and industrial applicability is present for patent law purposes.

### Article 3

Although biotechnology is an old science involving the use of and deliberate selection by man of organisms which improve agriculture, animal husbandry and baking and brewing activities, research in the new areas of biotechnology is producing an even greater ability on the part of man to intervene in natural biological processes. When attempt is made to determine the extent of patent protection which might be available to inventions in the field of living matter, there is the additional complication of a special system which was devised for the protection of plant varieties. The existence of this special system has generated uncertainty as to the extent to which plant matter as such can be patented.

Biological classification begins with the kingdom descending from the phylum through the genera and species. All members of genera and species possess at least some common characteristics but also usually possess other characteristics which distinguish some members from others. A variety, however, for purposes of variety protection, is defined as a group whose members possess no distinguishing characteristics one from another.

Exceptions to patentability for the categories of inventions relating to plant and animal varieties and essentially biological processes for producing plants and animals were created under certain conventions on the basis that these inventions lacked industrial applicability. It was considered preferable to provide special protection for plant varieties some of which were already patented and patentable in various countries. For animal varieties, the need for protection was less evident and therefore patent protection was not seriously considered.

It is clear today that the new biotechnological techniques, which were unknown to the authors of the relevant exclusions, have come to occupy the territory of both fields. This is demonstrated by the numerous developments which have arisen in microbiology which now lead to the development of new plant and animal characteristics. No justification appears to exist at present to continue to treat the results of different forms of research differently as to the protection which may be obtained. Thus, were patent and plant variety protection systems being formulated on the basis of current scientific developments and technology, different provisions for these systems might be adopted from those chosen thirty years ago. Nonetheless, until the international legal framework can be adapted to the new technologies, these exclusions will remain and must be addressed if greater legal clarity and certainty are to be achieved.

The exclusion of plant and animal varieties prohibits only the patenting of animals, plants and plant propagating material in the genetically fixed form of a plant or animal variety. There is no justification where an invention concerning plant or animal matter, such as plant or animal cells, cell lines, tissue cultures and larger parts, is not covered by the language of the exclusion to either withhold protection from such an invention or to give the exclusion a wider interpretation than is justified by the purpose for which it was developed. It is perfectly acceptable and appropriate for the exclusion to be limited, in conformity with its wording, to those cases in which plants are characterised precisely by their individual phenotype. Article 3 first sentence therefore provides that it is not plants and animals in general which are excluded from patentability but only plant and animal varieties as such,

i.e. in the genetically fixed and stable form of a variety. Thus, Article 3 first sentence will establish the principle that patent protection is available for plant and animal material which is not a variety.

The second sentence of Article 3 is necessary as regards plants in light of the uncertainty created by Article 2(1) of the UPOV Convention which obliges contracting States to provide only one form of legal protection for the same genus or species. The principle is clear that if plant variety protection is available for a variety, patent protection would not. But if patent protection is available for plant material which is not a variety, as is required in the first sentence of this Article, the rule must be legislatively clarified as to how far the patent rights extend. Thus, this sentence acknowledges the principle that protected plant varieties must co-exist alongside patents on plants but requires the further principle to be introduced that the patent rights pertaining to such patent claims must be enforceable even in respect of finished varieties incorporating such patented inventions.

Without Article 3, the patenting of new plant characteristics, such as insect, disease and herbicide resistance, might not be given the proper legal effects which encourage economic progress via the patent system. Article 3 in no way interferes with the role or the legal effects of the system of breeders' rights. However, problems of interaction between exclusive rights granted under the patent and plant breeders' systems may arise where the patentability of plants, parts of plants such as genetic sequences and classifications other than varieties is recognised. The legal uncertainty which is thereby created relating to the extent of the rights which may be enforced between the two systems must be resolved. Article 3 is therefore necessary to ensure that the patent system is allowed to produce its proper effects without hindrance from or to the plant breeders' system. Article 3 is also necessary to respond to the need to determine the effect of patent rights in any invention relating to plants which is subsequently incorporated into a variety and which variety is subsequently protected by a plant breeders' right. Article 3 establishes the principle that in such a case the patent rights would remain effective as to the patented invention.

Article 2(1) of the UPOV Convention directs the contracting States that they may accord only one form of protection to any protected genera or species. This means that both variety protection and patent protection (double protection) cannot be granted to the same plant genera or species. Article 3 ensures that a clear borderline is drawn between protectable subject matter in each system. One may take as an example a genetic sequence inserted into the genetic material of a plant which renders the plant resistant to insects. The genetic sequence is patented and is subsequently incorporated into an existing variety. The new variety now possesses the new characteristic and is eligible for variety protection. There is no reason for such a new variety to be free from the effects of the patent. This would effectively deny the inventor of the legitimate scope of the right to his invention.

Such an approach neither jeopardises nor runs contrary to the principle of Article 2(1) UPOV. It is not the genetic sequence which is protected by the plant breeders' right nor is the variety protected by the patent. There is no requirement in either patent law or in plant variety law that the patent rights associated with a patented invention are extinguished simply because a variety right is also associated with the final product. Nor do any compelling policy reasons exist for such an interpretation. Quite the contrary. Future developments in biotechnology are likely to provide a valuable range of new and enhanced agricultural products incapable of being produced under traditional breeding techniques which will have a ready market demand. It is also foreseeable that new agriculture products will be developed that have new industrial applications, for example, as petrochemical substitutes and in the field of polymer chemistry.

Notwithstanding the historical context and logical inconsistency of present plant variety and patent laws, the Commission considers that it would be harmful neither to the interests of European industry engaged in biotechnological research nor to the purposes for which the directive is designed to allow a certain number of cases, likely to have applications as plant varieties, which would otherwise have been patentable, to be excluded from patentable subject matter under national patent laws when such plants have been produced by a known biotechnological process. The principle of Article 3(2) is necessary to ensure this result.

#### Article 4

Patent law traditionally recognises three types of protectable inventions: process inventions, product inventions and application inventions (also called "uses"). The corresponding categories of patentable biotechnological inventions would be identified as:

- 1) inventions relating to a process for the creation of a living organism or the production of other biological material;
- 2) inventions relating to an organism or material as such; and
- 3) inventions relating to the use of an organism or other biological material.

As most Member States have explicitly excluded from patent protection plant and animal varieties as such, the result is that plant and animal varieties as products are not eligible for patent protection. This does not, however, have the effect of excluding the other two types of inventions from protection if and as these relate to plant varieties, that is, microbiological processes and processes which are not "essentially biological" for the production of plant varieties and specific uses of plant varieties. Article 4 is needed so that these two types of inventions are expressly included in protectable subject matter under the patent laws of the Member States.

Article 4 will thus establish the principle in national patent laws that the traditional categories of patentable inventions relating to processes and uses are not affected by the exclusion of plant and animal varieties from patent protection. In light of the exclusionary provisions of many patent laws along with the principle of the prohibition of double protection in Article 2(1) of the UPOV Convention, Article 4 is necessary to establish clearly that the traditional categories of patentable inventions as these relate to biotechnological inventions constitute patentable subject matter.

#### Article 5

Most Member States' national patent laws mirror the language of Article 53(b) of the European Patent Convention which states that patents shall not be granted in respect of

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

Thus, when the exclusions for plant and animal varieties and essentially biological processes were drafted, the field of microbiology, which did not involve traditional breeding processes, was singled out as being appropriate for patent protection. Microbiological processes and products of such processes were specifically recognised as eligible for patent protection. The underlying motivation for this language was to carve out of patent law protection the results of traditional breeding processes using plants and animals. The results of such breeding processes would enjoy their own protection in the form of plant or animal variety rights.

Because inventions relating to living matter specifically resulting from microbiology are patentable in those Member States with such provisions, it is therefore of considerable importance for the application of patent law to establish what is included in the term "microbiological process". Where the determination of the patentability of a biotechnological invention rests on the criterion of whether a process is microbiological, it is vital to a proper application of patent law that this term be correctly defined. Article 5 of the Directive addresses this problem and establishes a minimum principle in this respect.

No attempt was made to specify the borderline between those areas capable of patent protection - microbiological processes and products - and those areas excluded from protection - plant and animal varieties and essentially biological processes - it being assumed that the results of traditional breeding and microbiological processes would be readily distinguishable. Had science and biotechnology not made the advances they have in the past thirty years, these distinctions would continue to be valid and the two types of protection would have wholly separate fields of application.

As many inventions in the field of biotechnology concern microorganisms, the principle of patent law in Article 5 in respect of microbiological processes corresponds best to the original intentions of the drafters of the exclusions, accords with the exclusions which have been adopted and offers an adequate incentive to potential innovators to pursue high risk and costly research.

Without this Article, it would be possible for widely varying definitions to be adopted throughout the Community of what is considered microbiological and, consequently, for very different decisions to be taken regarding the same factual patent application. Article 5 is therefore necessary to establish a minimum uniform principle of patent law and at the same time avoid an inappropriately narrow principle from being adopted in connection with the patent law concept of "a microbiological process". Thus, the rule must be established that inventions relating to processes which either use or directly operate upon or result in a microorganism should be considered microbiological and thus eligible for patent protection. Article 5 prescribes this rule. In this connection, Article 5 must be read in conjunction with Article 19 of what should be understood by the term "microorganism". Thus the principle of Article 5 would not be limited only to microorganisms as such but would apply to other microscopic animate matter as well.

#### Article 6

Likewise greater certainty and uniformity must be engendered into the application of the criterion in national patent laws of the patent law concept of a "microbiological process". To give optimum effect to developments in biotechnology, it must be legislatively established that neither the entire process nor every step in the process need be of a microbiological nature in order for the process as a whole to be deemed microbiological. If a necessary and important part of a complex process is microbiological, while other steps of the process are merely biological, rejections of patentability on the basis that the process is essentially biological should be prevented. Article 6 is necessary to produce this result.

The Article will make it necessary for the principle to be adopted that a multi-step process in which the essence of the invention is incorporated into a microbiological step is not deprived of its microbiological character simply because the process contains other, non-microbiological, steps. To take an example, the genetic manipulation of a plant cell may be performed which is a microbiological process. Thereafter, the entire plant may be regenerated from the single cell (a process called differentiation). This latter process may be said to be essentially biological, but the entire process should be accorded the character of microbiological because the essence of the process and the invention is a microbiological step. The process should therefore be considered patentable despite the presence of an essentially biological step in the overall inventive process. Without Article 6, the exclusion from patentability of essentially biological processes for the production of plants could result in erroneous rejections to patentability and unsystematic adaptation of national patent law principles when applied in the same factual contexts.

#### Article 7

Because some national patent laws exclude essentially biological processes from patentability, it is necessary to lay down a principle of patent laws which establishes the extent to which human intervention is required in order to ensure that an invention will be considered patentable subject matter. In this connection, it is important to distinguish between traditional breeding activities and other forms of human intervention in biological matter. As essentially biological processes are generally agreed to refer to traditional breeding processes, it is important that the principle laid down differentiate between the use of biological material which falls into the category of essentially biological and that use which may properly be regarded as patentable subject matter.

The EPO Examination Guidelines stipulate in this regard that human intervention must play a "significant part" in determining or controlling the result it is desired to achieve and notes that the question is one of degree depending on the extent to which there is technical intervention by man in the

process (C-IV, 3.4). Article 7 of the Directive, by contrast, is intended to exclude only traditional biological breeding activities based upon selection and as such may be regarded as slightly more liberal than the Guidelines.

Article 7 will ensure that both an appropriate and a consistent rule is adopted for national patent systems in situations where it needs to be determined if sufficient technical human intervention has occurred to render an invention patentable. Such a rule should reflect a liberal approach in view of the now artificial nature of the distinction between "essentially biological" and "not essentially biological" processes. Biotechnological techniques have effectively rendered this difference of little practical value. Thus, for purposes of national patent laws, human intervention of a technical nature into the natural processes of biology need not be at the same time of a drastic nature in order for a process to fall outside the scope of being "essentially biological". Any human intervention aside from selection, such as influencing the crossing procedure or the replication process, would remove the process from the field of "essentially biological" processes. The invention would, of course, thereafter fall to be considered under the criteria for patenting.

#### Article 8

In certain circumstances, patent law recognises the patentability of products or substances which are of natural origin. Usually this occurs in situations where a product exists in a naturally occurring mixture of substances without it having been identified in the mixture. The invention typically consists of identification of the substance and isolation for useful purposes in a usable or pure form in which it did not exist in nature.

With the new biotechnological techniques, many substances are now capable of being selected and adapted for industrial, commercial and medical uses. The possibility of legally protecting such developments in the field of biotechnology is important to ensure that the necessary investment and research are undertaken.

Not all national patent systems have recognised the patentability of naturally occurring matter which fulfils the criteria for patentability, such as that in a mixture (either natural or modified) notwithstanding the fact that the substance existed in an unidentified form prior to the recognition of its existence and utility and prior to adapting the matter for use in an industrial application. Article 8 will establish that, as long as a claimed product has not been sufficiently disclosed, it should not be considered unpatentable simply because it was part of a pre-existing natural material.

Although an invention may involve a naturally occurring substance, such as an alkaloid isolated from a plant root, or a biological factor isolated from an animal organ, there will be a considerable difference between the product as it existed in nature and the product in a useful form. As such it is different from the product as it existed in nature. The so-called natural material has been changed by human intervention and the form in which it is claimed for patent purposes is not the same as that in which it exists in nature. Such products must in any event comply with all the criteria of patentability (novelty, inventive step and industrial applicability).

The EPO Examination Guidelines also recognise this rule. There, it is said that if a substance found in nature must first be isolated from its surroundings and a process for obtaining it is developed, such process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by any other parameters, and it is "new" in the sense of having no previously recognised existence, then the substance per se may be patentable (C-IV, 2.3) unless it is specifically excluded, such as plant or animal varieties.

This Article is different from Article 2 which addresses the question of the patentability of living matter as such, whether microorganisms, plants or animals. Here, the products are likely to be other than living organisms themselves, for example, plasmids, DNA (deoxyribonucleic acid) segments, proteins, peptides, enzymes and the like.

Article 9

A basic principle of patent law is that a mere discovery is unpatentable. A discovery is defined in the Geneva "Treaty on the International Recognition of Scientific Discoveries" of 1978 as the recognition of phenomena, properties or laws of the material universe. Objections to patentability of natural substances - living or non - may be raised on the basis that such products are discoveries and therefore that they are not "new". Such objections are usually raised in the biotechnological context, as noted above, for the sole reason that the products were present in a pre-existing material which itself may or may not be part of the prior art for patent law purposes. Article 9 deals with the two related issues of discovery and lack of novelty.

According to the EPO Examination Guidelines, if a new property of a known material or article is discerned, it would constitute a discovery and would be unpatentable. If, however, the new property is put to practical use, the result may be a patentable invention. If a natural substance is sought to be patented, the Guidelines note that the line of demarcation between the mere discovery of a natural substance and its patentability will depend on the degree of human technical intervention necessary to obtain it (C-IV, 2.3).

Where a substance is claimed in a form which results from human intervention in the material world, it is more than mere discovery, irrespective of whether the intervention is simple or complex. Article 9 is necessary to ensure that this distinction is correctly applied in patent law. As to the argument that such products are not "new", a product is considered "new" under the patent laws of most Member States if it does not form part of the "state of the art". The state of the art is deemed to be everything which has been made available to the public by means of a written or oral disclosure, by use or in any other way before the patent application was filed (for example, Article 54 EPC). The fact that a product may have existed in a mixture before its identification, isolation, purification and usefulness have been established does not render it part of the state of the art for purposes of patent law because it was effectively "not available" to the public by any means.

The principle required by Article 9 does not prejudge the issue of the novelty of the product. If information was available as to the existence of the particular mixture in question, and if the information available could have made the particular product foreseeable as a separate entity and would have enabled the person skilled in the art to render it into useful form, such product may be considered not to be new. In the absence of specific information, and if a product isolated from a mixture or synthesised is physically different from the mixture which was available to the public prior to the invention, novelty should be admitted as a matter of principle. Article 9 will ensure that an invention is not erroneously considered unpatentable as a discovery simply because it was once part of a pre-existing mixture.

## CHAPTER 2

### Scope of Protection

#### Article 10

Article 10 is addressed to the issue of experimental use of a patented invention involving living or self-replicable matter. The issue of experimental use in patent law is not dealt with in the EPC. Article 31(b) of the "Convention on the European Patent for the Common Market" (CPC) states only that the rights conferred by a Community patent shall not extend to:

acts done for experimental purposes relating to the subject-matter of the invention.

Under national patent laws as well, experimental use of a patented invention does not constitute patent infringement but interpretations vary of what acts constitute experimental use.

If a patented biotechnological product is employed to produce an improvement over the previous product, such use may legitimately be regarded as experimental use. If the improved product is a biotechnological product which is self-replicating, the patented starting material need only be prepared once in small quantities. To obtain commercial amounts it would not be necessary to reuse the product enjoying patent protection or to find a new way of production, avoiding the direct use of the patented product, as would be the case, for example, with a patented chemical product unable to reproduce itself. Replication of the small amount obtained in the first "experiment" with self reproducing material would suffice.

In order to safeguard the patent rights granted for the first invention and thereby place the inventor in such a case on an equal footing with inventors in other fields, Article 10 is necessary to qualify the first use of the patented product to obtain even a small amount of a new or improved product as

experimental use so long as the improved product is multiplied for other experimental purposes. If multiplication were for commercial purposes, then such use of the new product would not be covered by the patent law doctrine of experimental use.

It would be irrelevant whether an improved product is obtained from a product enjoying patent protection in one or several process steps. What is essential is whether any new product obtained by using a patented product is manufactured by multiplication of the material obtained from the patented product. Article 10 establishes the minimum necessary point beyond which the use of patented self-reproducing products will not be considered experimental, that is, at commercialisation.

Article 10 is needed in part because of the variety of interpretations of what acts constitute experimental use. More importantly, it establishes a rule for patented living matter consistent with patent law doctrine applicable in other fields of patentable subject matter.

#### Article 11

Under traditional patent law doctrine, the purchaser of a patented product may use such product in any manner he deems fit. A purchaser may put the product to such use as is consistent with its purchase, for example, a patented machine may become part of a factory production process; a patented chemical may be used to treat plants or kill insects, etc.

It is a well-established patent law principle that a purchaser of a patented product is not allowed, unless it has been specifically agreed, to manufacture the patented product itself. The jurisprudence of the Court of Justice has recognised the patentee's right "to use the invention with a view to manufacturing industrial products and putting them into circulation for the first time" (Centrafarm B.V. et al. v. Sterling Drug Inc. 1974 ECR 1147 at 1162).

The Treaty's articles on the free movement of goods should not be confused with the patentee's exclusive rights to produce patented products. The principle in the Treaty of Rome in respect of the free movement of goods

(Articles 30 to 36) has also resulted in the development of an exhaustion principle as applied to trade between Member States including goods covered by industrial property. Once a patented product has been placed on the market by a patentee or with his consent, no control over the further use of the product in intra-Community trade may be exerted by the patentee or a licensee.

The exhaustion of rights which applies under the Court's interpretation of these articles relates to three activities: the use, offer for sale and sale of a product covered by industrial property rights. Use in such a case relates to use of the product in commerce in intra-Community trade. It does not include the manufacture of products covered by industrial property rights. Patent rights would not be exhausted for the production of the patented product until the patent term itself expired.

The purpose of Article 11 is to establish this rule for patented living or self-replicable matter. Thus, the purchaser of, for example, patented barley may use his barley to make whisky without infringing the patent; the purchaser of patented malt or yeast, for example, may use these products to make beer without infringing the patent. Both uses involve a certain amount of multiplication (such as germination) of the product sold but such uses are clearly intended by the sale.

Where patented self-replicating material is sold for purposes of propagation, for example, seeds, the purchaser usually a farmer will have the right without patent infringement to use the products for the purpose for which he purchased such seeds, i.e. to grow a crop for harvesting even though such use unavoidably involves multiplication of his seeds. The patent rights would not be exhausted in respect of the use of the crop grown from the patented seeds as a source for the sale of new propagating material (seeds) as this would involve production for the purposes of selling the patented product itself. (Any variety rights inherent in seeds protected by plant breeders' rights would similarly be unexhausted in respect of the use of the crop grown from the seeds as a source for the sale of new propagating material).

Article 11 will ensure that the use which is intended in a sale of patented self-reproducing material is not confused with a use which involves patent infringement. The provisions of Article 11 are needed because the issue of

the extent of patent rights in respect of patented living or self-replicating material has not been dealt with in any national patent system and the provisions of the EPC do not address this question, save that the rights conferred by a European patent are said to be the same as would be conferred by a national patent (Article 64(1) EPC). Infringement of European patents is considered under national law principles taking account of EPC requirements regarding claim interpretation. The issue which is addressed in Article 11 therefore is not regulated by any specific provision of the EPC.

The CPC, of which seven out of the nine original signatories have adopted laws ratifying this Convention, at Article 32, provides that the rights conferred by a Community patent shall not extend to acts concerning a patented product within the territories of the contracting States after the product has been put on the market in any State by or with the consent of the proprietor of the patent unless there are grounds under Community law which would justify the extension of the patent rights to such acts. Article 81 of the CPC provides the same principle in respect of national patents.

The intention of the drafters of these provisions was to incorporate into the provisions of the CPC the prior and future jurisprudence of the Court of Justice dealing with the interpretation of Articles 30 and 36 of the Treaty of Rome. These provisions, as has been demonstrated above, relate to different principles of Community law than those dealt with in Article 11 of the Directive.

Article 11 is necessary therefore to distinguish between the meaning of "use" for different purposes of national patent law, the EPC and the CPC. For national patent laws, it needs to be legislatively established that use which involves propagation solely for the purpose of obtaining additional propagative or self-replicating material does not come within the scope of intended use which would be exhausted upon the sale of a patented product. The patent rights inherent in the use of material such as seeds are not exhausted for a use which consists of multiplying such material solely to obtain more thereof. Without Article 11, the relationship of the exhaustion principle under Articles 30 to 36 of the Treaty of Rome and exhaustion of patent rights for self-replicating material under national patent laws might have remained unclear.

Article 12

In traditional patent law doctrine, the protection conferred by a patented process extends to the product produced by the protected process. This principle exists in the laws of most Member States and is also found in the EPC (Article 64(2)).

Where a patented invention is a process which makes use of living or self-replicable matter, the scope of the patent rights conferred must be ascertainable. Putting things differently, both a patentee and third parties must be apprised of the point at which patents rights in such material are exhausted. Article 12 addresses this issue.

The product obtained from the patented process may be either living matter or other matter which is capable of self-replication, for example, a microorganism which can be cloned or a plant cell which can be differentiated to yield the plant itself. It will readily be recognised that matter which is capable of reproducing itself may be purchased in small quantities and subsequently made to reproduce under appropriate conditions. The effect of the patent rights conferred by the process would be completely nullified if further generations of the microorganism or differentiated plants would no longer benefit from the patent protection accorded to the process.

Two specific situations in which a need for the principle of Article 12 may be envisaged are:

- (1) where a patented process is carried out in a country where no patent protection exists and either the first generation of said product but, more usually, a second - usually multiplied - generation is imported into a country where patent protection has been accorded; and
- (2) where the direct product of the process is, for example, a seed or a cell which can be regenerated to a plant, the seed or the cell is produced in a country where no patent protection exists and the plant or plant material produced therefrom is imported into a country where patent protection does exist.

Article 12(1) will therefore establish that patent protection will extend not only to those products initially obtained from the process but also to further generations of microorganisms and to plants grown from cell tissue. Such further generations of microorganisms or regenerated plants are products whose properties which were initially obtained by the process are still present and are determinative of their value. Such products should properly be regarded as "direct" products of patented processes. Thus plants would benefit from the protection of the direct product of a process for the production of a plant cell or parts of plants when regenerated from such cells or parts.

There may also be cases where the product of a protected process takes the form of a variety. Article 12(2) is necessary to ensure that protection is nonetheless accorded, even where the patented process produces plant varieties. Although varieties are excluded in most national patent laws as such from patent protection, they are not excluded from protection as products of patented processes.

This view is found in the Report on the 1975 Luxembourg Conference on the Community Patent Convention (CPC), 1981,<sup>31</sup>. During the discussion of Article 29(c) CPC, it was questioned whether it would be possible to protect a plant variety or animal variety by means of the principle in Article 29, that is, as a "direct product" of the patented process. It was agreed by the Conference to revise Article 29(c) following the interventions of two Member States to the effect that protection of plant and animal varieties as direct products of patented processes was not excluded even though varieties were excluded per se in the EPC (Article 53(b) EPC). This was felt to result from the patent law principle that the protection conferred by a patented process extends to the products directly obtained by such process (Article 64(2) EPC).

The European Patent Office (EPO) has not yet adopted a definitive position on this issue. The Commission agrees with the views of the governmental Conference and has therefore proposed the same rule in Article 12(2) in respect of national patent laws. Article 12(2) will therefore legislatively

<sup>31</sup>-----  
Minutes of the Conference published in Records of the Luxembourg Conference on the Community Patent, 1975, Luxembourg 1981, footnote 75, p.234.

establish the principle for national patent laws that the protection of a patented process will extend to the products of such processes, even where these include plant and animal varieties.

Since national patent laws contain the same wording as the CPC in this regard, it is envisaged that adoption of this principle for national patent systems will result in a greater degree of harmonisation between the EPC and the CPC on the one hand and the national patent systems on the other.

### Article 13

As a result of the Directive greater possibilities will exist for patenting products consisting of or containing genetic information, such as a particular DNA segment. Where such biological products are incorporated into a more complex product, such as where the DNA is incorporated into a host microorganism which may be multiplied, the patent protection enjoyed by such products should extend to all products in which the particular genetic information which was essential for the invention remains of essential importance for the products concerned.

Where the patented material is incorporated into a plant or animal variety, such variety may legitimately be subject to the rights granted in the patent. Article 13 will establish this principle for national patent rights. Two arguments have been advanced to suggest that this result would be inappropriate: first, because manufacturing steps were required to obtain the variety from the patented product; and secondly, because plant varieties are excluded from patentability.

As to the first argument, if the particular industrial applicability or usefulness of a variety directly results from an invention which has been patented, then such a variety owes its unique characteristics to the effects of the invention and should therefore come within the scope of protection accorded by the patent. Where an invention is of no commercial importance for the variety, then a different issue would be raised. This situation is not addressed in the Directive because Article 13 specifically stipulates that the patented invention must be of essential importance for the utility or industrial applicability of the final product.

As to the second argument, an exclusion of varieties from patentability is not synonymous with being free from the scope of a relevant patent. In future there are likely to be inventions capable of application in many different plant varieties. For example, resistance to disease or herbicide tolerance may be genetically incorporated into a broad range of plants covering many different varieties. Thus, to be excluded from patentability does not mean that a variety should be free from the effects of a patent granted in a case where an invention in the field of plants concerns a generic concept which is characterised by new generic information and which can be realised in a multitude of different varieties.

Article 13 is necessary so that this important principle of patent law is explicitly recognised for inventions which do not permit their direct exploitation but which must become part of another entity in order to be used effectively. It would be an insufficient incentive for ensuring that necessary research is undertaken to accord patent protection only to material which on its own has no commercial value. Patent rights must be legislatively prescribed for any final product whose utility, commercial value or industrial applicability depends on a patented invention. The rule must be legislatively mandated in light of the variety of views on this issue for which existing patent laws provide no solution. Without Article 13, it might be considered that the patent protection of a biological product would be lost if such product becomes part of a more complex final product even though such biological product is of essential importance for commercialising the final product.

### CHAPTER 3

#### Dependency License for Plant and Animal Varieties

##### Article 14

It is foreseeable that if patents are granted to genetic material, to products containing such material and to biological classifications of plants or animals different from varieties, the situation will arise that new varieties

will be bred incorporating such material which will fall under the scope of one or more patents. Commercialisation of such new varieties without authorisation by the patentee could constitute patent infringement.

The implications for granting such patents require that a balancing of interests be made as regards the value for society of promoting new technologies and as regards the public interest in maintaining a reasonable limitation on exclusive rights in sensitive areas. This is particularly true in the agricultural sector where the interests of breeders, growers, farmers, science-based industry, the environment, tax payers and the consumer must be taken into account.

Article 14 is necessary to provide for the possibility commercially to exploit new varieties which represent significant technical progress under a non-exclusive license as of right, provided the patentee enjoys the right to receive fair remuneration for the exploitation of his invention. Provision must also be made for the patentee to be granted a non-exclusive royalty-paying license from the variety rightholder because in some cases the inventor himself may not be able to exploit his invention in a commercially usable form unless he can commercialise the results obtained by his licensee.

The basic principle provided for in this article is needed in order to give effect to the public interest in promoting further developments of agricultural inventions through breeding activities and to recognise the interests of the patentee to enjoy his exclusive rights which rights provide the incentive for engaging in innovatory activities.

The patent laws of some Member States already provide for a dependency or compulsory license in the event that a subsequent patentable invention cannot be worked without infringement of an earlier patent. This article is similar in that a variety could not be commercially exploited without a license granted by the patentee if such variety came within the scope of relevant patent rights. The provisions of Article 14 differ from existing national patent law provisions in according a license of right, not to a subsequent patentee, but to a subsequent rightholder of a variety developed using the patented invention.

There is no principle of compulsory licensing between patent and plant variety rights which exists in any patent or plant variety law. Article 14 is crucial therefore to an effective exploitation of patented biotechnological inventions in the plant field. Without Article 14, a plant variety rightholder would have to rely on the willingness of the patentee to enter into voluntary bilateral agreements for the use of the patented invention, which agreements the patentee otherwise may or may not be willing to enter into, on terms the breeder may or may not be willing to agree.

To benefit from the provisions of Article 14(1), a variety must represent significant technical progress compared with the teaching of the patent. The significance of the technical progress required for this purpose is a different notion from that of distinctness as currently used in plant variety protection law. This provision ensures that licenses of right would only be available where the new variety represents a genuine agricultural achievement in the first instance, for example, in successfully introducing a genetic sequence into an existing variety. This requirement would preclude licenses from being issued for only minor improvements to varieties which had been initially bred by incorporating patented inventions.

Article 14(2) provides that an application for compulsory licenses may only be made after the expiration of a certain period of time. This period is a reasonable measure to ensure that a patent applicant will have a limited opportunity to make exclusive use of or even to develop for commercial marketing his invention prior to encountering competitors and competition in the market place. In normal circumstances, competitors would be required to await the expiration of the full patent itself i.e., twenty years from the date of filing of the patent application, before being able to use the invention as of right (albeit without the payment of royalties).

Article 14(3) anticipates the situation where the original patentee would like to exploit his invention in the form of a plant variety into which it has been developed by a breeder. This provision of the Article would accord the patentee the right to obtain a non-exclusive license from the breeder to exploit on a commercial basis any variety into which his invention may have been incorporated, upon payment of reasonable royalties. This provision is

necessary, for example, to give an inventor who is not a breeder the possibility of commercially exploiting his invention in cases where such exploitation may only be possible in the form of a variety.

Article 14(4) allocates to a national tribunal the task of resolving disputes between patentees and holders of breeders' rights as to the significance of the technical progress or whether the royalties are reasonable. This is both a reasonable safeguard and a necessary measure as it may be expected that disagreements could arise over these issues in the same manner as they may arise over whether a plant variety development falls within the claims of a patent, especially in the context of exploiting new and commercially superior products in the plant field. A neutral adjudicating body having the power to enforce its judgements will be necessary for the effective implementation of the principles in Article 14. Paragraph 4 of Article 14 is therefore necessary to direct that the resolution of disputes concerning the application of the principles prescribed in this article should be determined by a court of competent jurisdiction. This would normally be a court seised of a patent infringement case.

#### CHAPTER 4

#### Deposit, Access and Re-deposit

#### Article 15

##### Deposit

It is a fundamental requirement of all patent laws that an enabling disclosure must be made with an application for a patent. All Member States have enacted a similar standard in this regard. An enabling disclosure is one which enables a person skilled in the art to carry out the invention. This principle also appears in the EPC (Article 83). It is a requirement whose purpose is justified by the grant of exclusive rights to an inventor in exchange for disclosure the invention. This in turn contributes to technical progress for the general public and to an advance in the technical state of the art. Once

the patent has expired the enabling disclosure provides a description of how the invention may be reproduced for those who wish capitalise on the no longer patented invention.

In the case of biotechnological inventions, the complexity of biological material generally makes it impossible either to describe in a written fashion the living material itself or to describe in a written fashion all the steps and parameters involved to reach the result which is sought to be patented. It is therefore impossible in many cases for the inventor to state how a person skilled in the art could successfully repeat his invention.

The unique aspect of inventions dealing with biological matter is that they usually self-reproduce themselves under appropriate conditions. In such a case, reproduction by a person not the inventor of the steps and parameters originally employed to develop the invention ceases to be important because the result desired can be obtained much more simply and reliably by self-replication of the material.

Although the patent laws require an enabling disclosure, there is no legislative requirement that such disclosure be in written form. The fact that product inventions in traditional fields of technology could only be disclosed in the required manner by a complete written description of how to make the product must not have as a logical consequence that, in a new technological field, the legal requirement cannot be satisfied in another manner, namely through a reference to a deposit. It is therefore possible and desirable, in order to secure the patentability of biotechnological inventions which cannot be described in a written form, to require that a system of deposit be established for all national patent systems not unlike that which already exists for the EPC. Many Member States already, as a practical matter, permit but do not require deposit while at least one requires that patent applications for living matter be supplemented by reference to a deposited sample of the animate material.

Several Member States are already parties to the Budapest "Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977". This Treaty establishes accepted procedures for deposits to be made for patent purposes. It regulates the technical and legal

aspects of the depository institution and of the deposit and binds the signatories who require or admit such deposits for patent purposes to accept, for purposes of their national patent procedure, a deposit made in accordance with the Treaty in any depository institution provided by the Treaty. This Treaty does not oblige the signatories to accept a deposit for purposes of national patent law procedures.

Article 15 of the Directive requires the principle to be adopted that the deposit mechanism will be recognised in all national examining offices for patent application purposes both for process and product patents. Such a principle is necessary in light of the differences in national practices and requirements. Without the principle that a deposit may suffice as an enabling disclosure, the patentability of many important inventions, for example, in the field of new hybridoma cells for the production of antibodies, vaccines or other biological factors, or of microorganisms isolated from their environment which may be valuable agents in the fields of ecology or agriculture or as a means of producing antibiotics or biological factors, could be jeopardised or rendered less certain.

The EPC regulations have established rules for deposit of living matter in connection with applications for European patents. The provisions of Article 15 of the Directive correspond to these rules (Rule 28) for depositing living matter in connection with European patent applications with one exception and three differences. EPC Rule 28 applies to inventions whose claims relate to microbiological processes or products thereof. The rule in Article 15 is not limited to inventions involving a microbiological process but could apply to virtually any invention which involved the use of either a microorganism or other self-reproducing material, which might be claimed in any form (i.e. product, process or use claims). In practice, the rule of Article 15(1) should provide a clearer, but not substantively different, rule than that found in Rule 28 EPC.

Unless such a clear statement of the principle of the extent to which a deposit may complete or replace a traditional written description of the invention is adopted legislatively, considerable difficulties would be encountered in patent enforcement procedures in determining the validity of a patent, such as occurred in the German Federal Supreme Court decision in the

"Tollwutvirus" case which endorsed a similar deposit rule for product claims in Germany but which had to overrule longstanding prior jurisprudence to do so.

#### Access/Release

The Budapest Treaty does not regulate the question of the release of samples of deposited material to the public. Issues such as the time at which release is required, to whom and under what conditions such release should take place were left to national and international laws - with the exception of the minimum requirement that, generally, release is only made if the patent application has been published (Rule 11, Regulations of the Budapest Treaty).

Unlike a traditional written description of an invention which always requires a third party seeking to work the invention to invest a perhaps substantial amount of time, effort and expense, access to deposited living matter enables competitors and would-be users of the invention to obtain instantly and without cost the results of the applicant's research. A single sample may, under appropriate conditions, be sufficient to begin commercial activities. In some cases, a microorganism will represent an entire factory. Unless the issues of the time and conditions of release are satisfactorily resolved, inventors will be tempted to refrain from disclosing their inventions to the detriment of the public and of technical progress in this field, and at considerable risk to the inventor whose invention may be re-invented by another or may lose its confidential nature.

For these reasons a standardized deposit systems with sufficient safeguards for the applicant as to the time and conditions of release needs to be established for national patent laws so that equal possibilities will exist for protecting inventions in this field.

The practice of early publication of a patent application in Europe came about as a result of the introduction of deferred examination of such applications because most patent offices had thousands of pending, unexamined, applications on file at any given moment. Publication of the patent application alerted the public of the existence of the claims in pending applications which

otherwise would have remained unknown for several more years. This avoided duplication of research and production in fields covered by others. The adoption of a system of publication and deferred examination was not initially intended to provide industry with a source of valuable technical information on the relevant state of the art. Rather, it was more of a practical necessity. The importance and use of the publication of patent applications as a source of technical, commercial and industrial information for interested circles developed subsequently.

Thus, the purpose for which the publication of patent applications was adopted was to give notice to the interested public of areas likely to be covered by future exclusive rights. There was no intention or desire to create the capability of exploiting the invention for commercial purposes although, even with a written disclosure, such a possibility was not excluded. For this reason, a system of compensation was devised for the use of an invention prior to patent grant following publication.

Since a written disclosure in a patent application is open to the public in Europe at the date of first publication, it has been argued that the same criterion should apply to a deposit and that deposits should likewise be open to the public. This problem does not arise in the USA where no publication of the application is made prior to the grant of a patent. If a patent is not granted, no release is made of deposited material. An applicant could then make use of his invention as a trade secret. In Japan, a distinction is made between the initial publication of the application and third party access to deposited material, so that samples are only made available to the public during the period allocated for the opposition procedure after the second publication indicating the notice of patent grant.

In European countries with an early publication system, a rule imposing public access rights to deposits from the date of first publication could produce considerable disadvantages for the inventor of a biotechnological invention. If release to the public of deposited material is made before patent grant, an inventor whose application is withdrawn or denied would not have the possibility of using his invention as a trade secret. Release of such material to third parties could enable them, in some cases, to begin commercial activities. While the possibility of losing the confidential

nature of an invention exists for all published but subsequently unsuccessful patent applications, the release of material which greatly facilitates the use of an invention distorts the disclosure rule to the unwarranted advantage of a competitor because of the greater immediate value of a sample of the deposited material than that of a written description.

In respect of deposited animate matter, therefore, it is necessary to separate the desired notice function of the early publication from the undesirable effects of providing the capability for the public to employ the invention for other than verification or experimental purposes. Thus, restrictions and conditions on access to and transmission of any samples of matter deposited in connection with patent application procedures must be established.

Patent applicants who have considered making or have made deposits in connection with their applications have expressed dissatisfaction with certain aspects of the EPC deposit rules (Rule 28 EPC) and similar provisions of national patent systems. Under the EPC rules, where a deposit has been made pursuant to a patent application, a party requesting a sample must undertake not to make it available to third parties and to make use of the sample only for experimental purposes. These undertakings expire if the patent application is unsuccessful, is withdrawn or is deemed to be withdrawn, or if the patent has expired in all designated States.

The undertaking to restrict the use of samples of deposited matter to experimental uses prescribed in EPC Rule 28 expires as soon as the application is refused or withdrawn and at the moment a patent is granted. In cases where the patent is granted, the patent rights themselves would prevent other than experimental use of such samples. In the cases where no patent is granted, an applicant not only is obliged to allow samples of his material to be delivered to third parties without any compensation he also loses the confidential nature of his work and the possibility of exploiting the invention as a trade secret.

Rule 28 EPC was amended in 1979 following wide-scale dissatisfaction with this aspect of the release conditions to contain mainly two improvements:

- (1) adoption of the expert solution; and
- (2) an extension of the undertaking required from the requesting party to include cultures derived from the sample.

The expert solution is an option which an applicant may elect which provides for release of a sample up to the moment of patent grant or refusal thereof or of withdrawal of the application if a third party requests a sample of the deposit. Release is made to an independent expert who is himself bound to use the sample only for experimental purposes and not to transmit it to others including the third party. The expert is free, however, to report the results of his experiments and verification of the sample to the third party. The expert solution has been introduced into the national patent practices of Denmark, France and Italy. The Italian practice is a variant of the EPC rule in that the expert solution is not optional and applies for the entire patent term.

The expert solution of EPC Rule 28 does not protect the applicant in a situation where an application is withdrawn, not pursued or refused. In addition, it has been questioned whether the rule is compatible with the requirement that an application must disclose an invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). There have as yet been no judicial decisions on this question and thus on the issue of the sufficiency of the disclosure for purposes of the EPC. Both difficulties need to be addressed in the context of national patent laws.

The obligation for a patent disclosure to enable the public to carry out an invention applies to the public in the jurisdiction of the patent right involved. According to the accepted theory of patent law, whereby the granting authority and the inventor effectively enter into a contract to the effect that the inventor is accorded exclusive rights in exchange for disclosing his invention, there is an absence of the quid pro quo between the patentee and the grantor where disclosure in the form of a sample of self-replicating material is provided to the public of a jurisdiction where no patent has been granted or applied for.

There is no legal requirement in patent law that an applicant must enable the public of other countries to exploit his invention nor is there any interest on the part of a State which has granted exclusive rights in respect of an invention to make samples available to another jurisdiction where no protection exists. Transmission of a sample of the deposit to another jurisdiction where release has been requested, despite the absence of rights associated with a patent application or a patent, serves no genuine purpose of the patent system. Such a possibility should be minimised for inventions in the field of living matter.

It has been suggested that to eliminate the possibility of inappropriate release of samples, the rule would need to be adopted that samples of the deposit may only be delivered to parties residing in a country for which or in which a patent application had been filed or where a patent had been granted. Such an approach is unlikely to meet with much support in light of the well-established principle of open disclosure in all patent laws. A similar result can be achieved, as is done in Article 15(3)(b)(ii), by imposing an undertaking on a requesting party that the sample will be used only for experimental purposes irrespective of the countries to which such samples may ultimately be brought or transmitted. This restriction, along with the undertaking not to transmit a sample to any third parties, will enable an applicant to monitor whether undertakings have been respected as well as to ensure the effectiveness of the undertakings given.

For some inventions, patent applications will concern biotechnological inventions starting from living material which was previously deposited in connection with another patent application by either the same or another person. If such an earlier deposit had legally become available to the public not later than the time of the new patent application, it would belong to the relevant state of the art for all patent law purposes. The patent law concept of the state of the art comprises everything which has been made available in some form to the public prior to the filing of a patent application. The novelty of an invention, as is its inventive step, and its disclosure are judged against the standard of the state of the art of the relevant technical field concerned. If a microorganism had become available to the public and thus formed part of the state of the art at the time of a subsequent application, there would be no need for the applicant to re-deposit this

material or to maintain such earlier deposit. This result follows from the fact that the microorganism forms part of the state of the art and would be the same in any other technical field for purposes of patent application procedures.

Any restriction on the release of samples of a deposit which was made for purposes of patent procedures which prevents the public in the country of the patent right from having access to the deposit after first publication may put into question the loss of novelty normally accompanying the initial publication, that is, it may be queried whether or not such material is deemed to be part of the state of the art. If a microorganism or other deposited animate matter has become part of the state of the art, which occurs in all technical fields upon publication of the patent application, such matter should be regarded as available to the public within the meaning of novelty or disclosure for national patent law purposes. In consequence, samples could cease to be available to the public from the depositary institution without affecting the novelty-destroying or disclosure effect of the published application. In as much as the public was provided with access to the technical details of an invention either directly or through an expert and in view of the fact that such access will be considered to constitute an adequate disclosure of the invention, it follows that a published application becomes part of the prior art independent of the outcome of the application. Article 15(10) establishes this principle.

Such a principle needs to be established particularly for those cases involving living or self-reproducing matter where an application does not result in the grant of a patent and where the application is published so that one or more samples could have been released either to the public or to an expert. The application of such a principle in these cases is analogous to the situation where a product has been exhibited for a time at a public trade fair and has consequently become part of the state of the art for all time and is thus considered as being available to the public. No obligation exists to provide another enabling disclosure to the public.

The system of early publication and deferred examination of patent applications is unlikely to be changed in Europe in the foreseeable future. The requirements for disclosure of inventions are closely similar in all

Member States both for European and national patent applications. In view of the work already done and the consensus already achieved in respect of EPC Rules 28 and 28a, any harmonisation of the provisions of national patent laws regulating the conditions of access, release and re-deposit should parallel those of the EPC taking into account the shortcomings from which the EPC rules are thought to suffer.

Thus, the differences between Article 15 of the Directive and EPC Rule 28 may be summarised as follows:

1. The undertaking required in Article 15 paragraph 3(b)(i) - that a party requesting a sample of deposited material will not make it available to third parties - does not expire while the undertaking in EPC Rule 28 expires if "the application has been refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, before the expiry of the patent in the designated State in which it last expires" (Rule 28(3)(a)).
2. The undertaking required in paragraph 3(b)(ii) - to use the sample for experimental purposes only - will expire only in those countries where a patent right comes into existence. Once a patent right is created, the patent laws themselves would limit a third party to the use of a patented invention for experimental purposes. This rule permits those who have received samples to use the material in other countries for experimental purposes. Under EPC Rule 28, if a patent is refused or an application is withdrawn, this undertaking would expire, enabling third parties to commercialise the deposited material. This is an undesirable consequence resulting from a misconstrued application of the system of early publication wherein physical access to deposited material is equated with the notice function of the publication.
3. The sample would no longer be available to the public or to an expert if the application fails or otherwise does not lead to the grant of a patent where the application had been published and the deposit was available either to the public or to an expert.

Article 16

Re-Deposit

It may happen that a depository institution will no longer be able to provide a sample of a valid deposit to a requesting party entitled to it for reasons other than those regulated under the Budapest Treaty, for example, because of the dangerous character of the material or the end of the contractual period of maintenance. It would be unjust to refuse an application or to declare invalid a patent right on the basis of such incapacity of the depository institution, unless the applicant/patentee or owner of the right could not provide the requesting party with a sample of the material, certifying its identity with the originally deposited material (similar to the provisions of Article 4(1)(h)(ii) of the Budapest Treaty).

Article 16 is needed to ensure that an applicant or patentee in all national patent systems will be allowed to re-deposit a microorganism or other animate matter for patent law purposes if his original deposit ceases to be available from the institution with which it was deposited, as is provided in EPC Rule 28a and in similar provisions of some Member States' laws. The provisions of Article 16(1) - (5) are virtually identical to those of EPC Rule 28a except that the Directive explicitly mentions other self-replicable matter in addition to microorganisms.

Situations may arise where a re-deposit cannot be effected by the original depositor/patentee even where the original deposit has given rise to the grant of a patent. In such a case, the validity of the patent may be questioned as an enabling disclosure no longer exists relative to the patent. Article 16(7) is necessary, therefore, to establish the principle that any ruling declaring the invalidity of a patent on the basis of the patentee's inability to re-deposit a sample of the original material will not retroactively invalidate the patent. This rule is needed because the original grant of the patent was based on a deposit which initially complied with all the procedural requirements for patent grant but which deposit only subsequently became unavailable to the public.

EPC Rule 28a does not address the question of validity and nullity. It is all the more important, therefore, to establish this rule for national patent laws as it will affect the validity of European patents in that questions of validity not regulated by provisions of the EPC are subject to national patent law principles concerning validity.

## CHAPTER 5

### Reversal of the Burden of Proof

#### Article 17

After a patent has been granted, uncertainty as to whether the patent is being worked on an unauthorised basis by one or more third parties may arise. If a patentee decides to initiate litigation in the belief that his patent claims are being infringed, he must, in certain situations, bear the burden of establishing by a preponderance of the evidence that infringement has likely taken place.

For patents involving new products, produced by new processes, the burden of proof that the patent has not been infringed in the event of dispute usually rests with the alleged infringer. This is based on the premise that no method other than that revealed in the patent application is known to produce the product in question, it being non-existent theretofore. This principle has been codified into many patent laws of the Member States and is also found in the CPC (Article 75).

In the situation where a patentee of a process patent suspects patent infringement is taking place, it is often difficult to establish whether a particular product, which is identical to another product itself obtainable by a patented process, has in fact been manufactured or produced using the patented process. This is particularly the case with biotechnological inventions where microorganisms may be used in patented processes and where neither such use nor the nature of the process can easily be detected in the final product.

In cases where the product is previously known so that a process different from the one protected in the process patent must have been available, no legal provisions on the burden of proof in patent disputes exist in the laws of the Member States or in the EPC or the CPC. The normal rules of evidence would apply to the effect that the patentee of a process for producing a known product would bear the burden of establishing a prima facie case by a preponderance of the evidence that infringement of his process has probably occurred.

If a sample of deposited self-reproducing material has been released, it will be difficult, if not impossible, for a patentee to prove that an alleged infringer has used the patented process to manufacture the known product, as it may always be claimed - without need of proof - that the known unpatented process was used. If the burden of proof remains with the patentee, he is unlikely to be able effectively to defend his patent. If the alleged infringer is not using the patented process, it is far easier for him to prove his non-infringement by, for example, demonstrating how he produced the products, than it is for the patentee to prove the infringement.

Thus, in connection with the use of the deposit mechanism to complete an enabling disclosure, where necessary for patent application purposes, Article 17 is necessary to provide that the burden of proof would be reversed if release of a sample of deposited material has been made which represents a sufficient mechanism for working the invention. The rule of Article 17 is limited to the narrow situation where two conditions are satisfied: a sufficient means of carrying out the patented invention must have been deposited in a culture collection and a sample of such deposit must have been released.

If the rule were limited to only those persons who have physically received a sample from a depository institution, it would be easy to circumvent the reversal in the burden of proof by use of an intermediary who requests the sample and thereafter transmits it to the interested party. Thus the rule must be established, and Article 17(1) is necessary in order to establish, that the reversal of the burden of proof is applicable without restriction if the conditions have been fulfilled. Nonetheless, sufficient safeguards must be provided so that alleged infringers are not subjected to abusive use of

this provision by patentees wishing to learn of their competitors' manufacturing methods. Such a principle of the reversal of the burden of proof therefore must and does include a provision excluding the need for an alleged infringer to disclose his confidential business secrets in adducing his proof even if the burden of proving non-infringement does lie with him.

## CHAPTER 6

### Definitions and Final Provisions

#### Article 18

New production methods in animal biotechnology may require steps which might be qualified as "surgical methods". These include processes for breeding cattle, for example, by estrous synchronisation, super-ovulation, artificial insemination and embryo recovery and transfer (a procedure wherein embryos are removed, frozen and reimplanted in surrogate mothers elsewhere) and processes for improving the food conversion ratio in animals, for example, by surgical implantation of growth stimulating or regulating substances.

Most patent laws and the EPC (Article 52(4)) exclude the patenting of surgical methods for treating human and animal bodies on the basis that such methods are not industrially applicable. For those methods of treatment which were developed for or are applied to treating and preventing diseases or physical impairments in humans and animals, it is usually the case that such methods do not have an industrial character, but possess rather a medical or a therapeutic character. Developments in biotechnology have resulted in logical inconsistencies not foreseen in the principle as originally drafted. A method of adding a chemical substance to animal food to improve food conversion is considered patentable because it is not surgical but an equivalent surgical procedure to implant slow-release hormones to improve food conversion is not patentable because it is surgical in nature.

It was not the intention to exclude from patent protection developments which fulfil the criteria of patentability if they have an industrial character. It was simply unforeseen that surgical techniques would be developed which would also be industrially applicable.

For biotechnological techniques for animal production which are of an industrial or commercial nature and which are not therapeutic, such as those mentioned above, the rule should be amended so that such methods may be patentable if practiced for reasons which are other than therapeutic and if practiced on an animal body. Thus the rule in this regard should be changed to the extent necessary to encourage research in this field without undoing the original intention of the drafters of the exclusion. Without Article 18, an important set of biotechnological inventions would not be eligible for patent protection.

#### Article 19

The term "microorganism" is used in two different ways in the Directive. First, in Articles 3 and 5, this term relates to substantive criteria for patentability and establishes rules regarding living matter and certain patent law exclusions from patentability. Secondly, in Articles 15 and 16, this term is used in relation to procedural requirements regarding disclosure for purposes of patent applications. The Directive must avoid limiting the application of patent law, both substantively and procedurally, to only those inventions which concern living matter literally coming within the biological classification of microorganisms.

When the Budapest Treaty on microorganism deposit was instituted in 1977, the problems of accepting deposits of living matter were only partially appreciated. In light of subsequent developments, this Treaty has quite sensibly been interpreted to apply to other forms of living matter in addition to microorganisms. The problems which led to the Budapest Treaty will continue to be of importance where matter is sought to be patented which contains genetic information to replicate or to direct its replication. All such material should in principle be admitted to the deposit system for purposes of patent procedure. Thus, any usage of the term microorganism for

patent law purposes must not be limited and should be understood to include any living matter which can be deposited in a culture collection of the type acknowledged by the Budapest Treaty and its implementing regulations.

The substantive requirements of patent law should be construed in such a manner that living matter may always benefit from patent protection. The notions of the term "invention" should always be sufficiently broad to include all new developments in biotechnology.

Thus Article 19 is needed to establish the rule that the term microorganism should not be too narrowly construed and that future developments in biotechnology in respect of animate matter which is capable of being deposited in a culture collection such as fungi, viruses, mycoplasmae, rickettsiae, algae, protozoa and cells can benefit from the principles of the Directive and fulfil both the substantive and procedural requirements of patentability. This approach corresponds to the definition of "living material" which was suggested for use with the kinds of material that should be accepted for deposit under the Budapest Treaty (BioT/CE/II/INF/4).

**Council Directive**  
**of .....**  
**on the legal protection of biotechnological inventions**  
**(.../.../EEC)**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

In co-operation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the Member States and such differences could create barriers to trade and to the creation and proper functioning of the internal market;

Whereas such differences in legal protection could well become greater as Member States adopt new and different legislation and administrative practices or as national jurisprudence interpreting such legislation and practices develops differently.

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

Whereas the patent system must adapt to new technological developments which may involve living matter but which also fulfil the requirements for patentability;

Whereas no prohibition or exclusion exists in national or international patent laws which precludes the patentability of living matter as such;

Whereas national patent systems have in the past successfully adapted to technical developments and scientific breakthroughs in according patent protection to such developments where appropriate;

Whereas the investments required in Research and Development particularly for genetic engineering are especially high and especially risky and the possibility for recouping that investment can only effectively be guaranteed through adequate legal protection;

Whereas without effective and approximated protection throughout the Member States of the Community, such investments might well never be made;

Whereas some inventions developed through biotechnology and genetic engineering are at present not clearly protected in all Member States by existing legislation, administrative practice, and court jurisprudence; and such protection, where it exists, is not the same or has different attributes;

Whereas the uncoordinated development in the Community of the legal protection for biotechnological inventions in the Member States could result in the creation of new disincentives to trade to the detriment of further industrial development in such inventions and of the completion of the internal market;

Whereas existing differences having such effects need to be removed and new ones having a negative impact on the functioning of the common market and the development of trade in biotechnological goods and services prevented from arising;

Whereas international developments in the field of legal protection of the results of biotechnology and genetic engineering demonstrate the advantages to be gained from approximation of national legislation;

Whereas scientific and technological developments are often a result of international collaboration on research and, in consequence, need exists to ensure that biotechnological inventions may benefit from comparable protection on an international level;

Whereas international instruments exist or are under consideration to harmonise various aspects of the legal protection of biotechnological inventions, they are not sufficient for Community purposes which must take account of the needs of Community science and industry and a Community market;

Whereas the patent laws applicable at present in the Member States contain disparities which hinder the development of trade in biotechnological goods and services, distort competition within the common market and therefore directly affect the establishment and functioning of that market; whereas it is particularly important to remove these disparities because at the stage reached at present in establishing the common market, there would appear to be an urgent need to ensure that undertakings will be offered the possibility of obtaining effective and equivalent legal protection in all Member States for the results of their research activities in any part of the Community;

Whereas an approximation of the legislation of the Member States is also necessitated by existing language in national laws originating in certain international patent and plant variety conventions which have given rise to considerable uncertainty as to the possibility of protecting biotechnological inventions concerning plant matter and microbiological inventions, language such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals;

Whereas it is necessary to encourage potential innovation in the full range of human endeavors by recognising that human intervention which consists of more than the selection of biological material and allowing such material to perform inherently biological functions under natural conditions should be considered patentable subject matter and should not be regarded essentially biological;

Whereas it is seemly that the legislation of the Member States should be harmonised in such a way so as not to conflict with the existing international conventions on which many Member States' patent and plant variety laws are based;

Whereas the Community's legal framework on the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of living matter as such; to the ability to use a deposit mechanism in lieu of written descriptions to satisfy the enabling disclosure requirements for patent application procedures; to a reversal of the burden of proof where release of self-replicable matter has occurred and to the right to a non-exclusive dependency license for plant and animal varieties;

Whereas, in view of the fact that the function of a patent is to reward the inventor with an exclusive but time bound right for his creative efforts and thereby encourage inventive activities, the rightholder should be entitled to prohibit the use of patented self-replicable material in situations analogous to those where it would be permitted to prohibit such use of patented, non-self-replicable products, i.e. in respect of the production of the patented product itself;

Whereas, in the area of agricultural exploitation of new plant characteristics resulting from genetic engineering, guaranteed remunerated access in the form of licenses of right must be provided for as an exception to the general principles of patent law,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER 1

### Patentability of Living Matter

#### Article 1

Member States shall ensure that their national patent laws comply with the provisions of this Directive.

#### Article 2

A subject matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter.

#### Article 3

1. Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material thereof of the kind protectable under plant variety protection law shall be considered patentable subject matter. Claims for classifications higher than varieties shall not be affected by any rights granted in respect of plant and animal varieties.
2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process.

#### Article 4

Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter.

#### Article 5

Microbiological processes shall be considered patentable subject matter. For purposes of this directive, this term shall be taken to mean and to include a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism.

#### Article 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 the process.

Article 7

A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter.

Article 8

A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered unpatentable for the reason only that it formed part of said natural material.

Article 9

A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered as an unpatentable discovery or as lacking novelty for the reason only that it formed part of said natural material.

CHAPTER 2

Scope of Protection

Article 10

The use of a product protected by a patent comprising or consisting of genetic information to develop another such product or the use of a patented process to obtain such a product shall not be regarded experimental for purposes of establishing patent infringement, if the developed product obtained from the experiments or its progeny in identical or differentiated form, is used for other than private or experimental purposes.

#### Article 11

If a product enjoying patent protection and put on the market by the patentee or with his consent is self-replicable, the rights conferred by the national patent shall not extend to acts of multiplication and propagation only where such acts are unavoidable for commercial uses other than multiplication and propagation.

#### Article 12

1. If the subject matter of a patent is a process for the production of living matter or other matter containing genetic information permitting its multiplication in identical or differentiated form, the rights conferred by the patent shall not only extend to the product initially obtained by the patented process but also to the identical or differentiated products of the first or subsequent generations obtained therefrom, said products being deemed also directly obtained by the patented process.
2. Any extension of the protection conferred by the patent to a process as indicated under paragraph 1 to a product obtained thereby shall not be affected by any exclusion of plant or animal varieties from patentability.

#### Article 13

The protection for a product consisting of or containing particular genetic information as an essential characteristic of the invention shall extend to any products in which said genetic information has been incorporated and is of essential importance for its industrial applicability or utility.

## CHAPTER 3

### Dependency License for Plant Varieties

#### Article 14

1. If the holder of a plant breeders' right or a variety certificate can exploit or exercise his exclusive rights only by infringement of the rights attached to a prior national patent, a non-exclusive license of right shall be accorded to the breeders' right holder to the extent necessary for the exploitation of such breeders' right where the variety protected represents a significant technical progress, upon payment of reasonable royalties having regard to the nature of the patented invention and consistent with giving the proprietor of such patent due reward for the investment leading to and developing the invention.
2. A license under paragraph 1 shall not be available prior to the expiration of three years from the date of the grant of the patent or four years from the date on which the application for a patent was filed, whichever period last expires.
3. If a license according to paragraph 1 has been granted, and if a variety protected by a plant breeders' right or variety certificate can be exploited by the patentee only by infringement of the rights attached to such variety, a non-exclusive license shall be accorded to the original patentee to the extent necessary for the exploitation of the breeders' right or variety certificate, upon payment of reasonable royalties having regard to the nature of the improvement and consistent with giving the proprietor of the breeders' right due reward for the investment leading to and developing the new variety.
4. Where disagreements arise with regard to the significance of the technical progress and as to the level of royalties, Member States shall provide for a court of competent jurisdiction to resolve the dispute.

CHAPTER 4

Deposit, Access and Re-Deposit

Article 15

1. If an invention involves the use of a micro-organism or other self-replicable matter which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, or if it concerns such matter per se, the invention shall only be regarded as being disclosed for purposes of national patent law if:

- (a) the micro-organism or other self-replicable matter has been deposited with a recognised depositary institution not later than the date of filing of the application;
- (b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism or other self-replicable matter;
- (c) the depositary institution and the file number of the deposit are stated in the application.

2. The information referred to in paragraph 1(c) may be submitted:

- (a) within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date;
- (b) up to the date of submission of a request for early publication of the application;

- (c) within one month after the national patent office has communicated to the applicant that a right to inspection of the files exists pursuant to paragraph 3(a)(ii) below.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited matter being made available to the public in accordance with this Article.

3.a) Unless the application has been refused or withdrawn or is deemed to be withdrawn, the deposited matter shall be available upon request:

- (i) to any person from the date of publication of the patent application, and

- (ii) to any person having a right to inspect the files under the provisions of national patent law relating to applications under which rights are invoked against such a party, prior to the date of publication;

b) Subject to the provisions of paragraph 4, such availability shall be effected by the issue of a sample of the deposited matter to the person making the request (hereinafter referred to as the "requester"). Said issue shall be made only if the requester has undertaken vis-à-vis the applicant for or proprietor of the patent:

- (i) not to make the deposited matter or any matter derived therefrom available to any third party;

- (ii) to use the deposited matter or any matter derived therefrom in any country only for experimental purposes concerning the invention, with the proviso that this restriction will cease, in the country of the patent right on the basis of which the sample of the deposited matter was obtained, with the grant of a patent or other enforceable right in the invention involved. This provision shall not apply in the country of the patent right on the basis of which the sample of the deposited matter was obtained insofar as the requester is using the

matter under a compulsory license. The term "compulsory license" shall be construed as including ex officio licenses and the right to use patented inventions in the public interest.

4. Until the date on which the technical preparations for publication of the application are deemed to have been completed, the applicant may inform the national patent office that, until the publication of the mention of the grant of the patent, the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.

5. The following may be nominated as an expert:

(a) any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

(b) any natural person recognised as an expert by the national patent office. The nomination shall be accompanied by an undertaking from the expert vis-à-vis the applicant; paragraphs 3(b)(i) and (ii) shall apply, the requester being regarded as a third party.

6. For the purposes of paragraph 3(b), any matter derived from the deposited matter shall be deemed to be any matter derived therefrom by culturing or in any other way of replication which matter still exhibits those characteristics of the deposited matter which are essential to or for carrying out the invention. The undertaking referred to in paragraph 3(b) shall not impede a deposit of derived matter, necessary for the purposes of patent procedure.

7. The request provided for in paragraph 3 shall be submitted to the national patent office on a form recognised by that office. The national patent office shall certify on the form that a national patent application referring to the deposit of the micro-organism or other self-replicable matter has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of the micro-organism or other self-replicable matter.

8. The national patent office shall transmit a copy of the request, with the certification provided for in paragraph 7 to the depositary institution as well as to the applicant for, or the proprietor of, the patent.

9. Member States shall designate recognised depositary institutions for purposes of this Article.

10. If a micro-organism or other self-replicable material has been deposited in accordance with paragraphs 1 and 2 and has become available to any person or an expert in accordance with paragraph 3 or 4, it shall henceforth be regarded available to the public in accordance with paragraph 1.

#### Article 16

1. If a micro-organism or other self-replicable matter deposited in accordance with Article 15 ceases to be available from the institution with which it was deposited because:

- (a) the micro-organism or other self-replicable matter is no longer viable, or
- (b) for any other reason the depositary institution is unable to supply samples,

and if the micro-organism or other self-replicable matter has not been transferred to another depositary institution recognised for the purposes of Article 15, from which it continues to be available, an interruption in availability shall be deemed not to have occurred if a new deposit of the micro-organism or other self-replicable matter originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the national patent office within four months from the date of the new deposit stating the number of the application or of the national patent.

2. In the case provided for in paragraph 1(a), the new deposit shall be made with the depository institution with which the original deposit was made; in the cases provided for in paragraph 1(b), it may be made with another depository institution recognised for the purposes of Article 15(9).

3. Where the institution with which the original deposit was made ceases to be recognised for the purposes of the application of Article 15, whether entirely or for the kind of micro-organism or other self-replicable matter to which the deposited micro-organism or other self-replicable matter belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited micro-organisms or other self-replicable matter, and the notification referred to in paragraph 1 from the depository institution is not received within six months from the date of such event, the three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the official publication of the national patent office.

4. Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited micro-organism or other self-replicable matter is the same as that originally deposited.

5. If the new deposit provided for in the present Article has been made under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail in case of conflict.

6. If a deposit is not accepted or if the deposited material is no longer available from the depository institution and a re-deposit according to paragraphs (1) through (5) does not or could not remedy the unavailability, such unavailability shall not affect the patentability of the invention if the applicant/patentee provides the requesting party entitled to receive a sample with such sample certifying its identity with the material used in the invention or obtained as the invention or with the originally deposited material, as the case may be.

7. If a patent is deemed invalid because the patentee can no longer provide for a sample of the deposited material in accordance with this article, such invalidity shall in no case have retroactive effects.

## CHAPTER 5

### Reversal of the Burden of Proof

#### Article 17

1. If the subject matter of a patent is a process for obtaining a new or known product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process, if a necessary means to carry out the process had been deposited in accordance with Article 14 and had been released to a third party.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

## CHAPTER 6

### Miscellaneous

#### Article 18

Any exclusion from patentability or from the field of industrial applicability of surgical or diagnostic methods practised on an animal body shall apply to such methods only if practised for a therapeutic purpose.

Article 19

For the purposes of this Directive:

- (a) the word "micro-organism", where used, shall be interpreted in its broadest sense as including all microbiological entities capable of replication, e.g. as comprising, inter alia, bacteria, fungi, viruses, mycoplasmae, rickettsiae, algae, protozoa, and cells; and
- (b) the words "self-replicable matter", where used, shall be interpreted to comprise also matter possessing the genetic material necessary to direct its own replication via a host organism or in any other indirect way, e.g. as comprising, inter alia, seeds, plasmids, DNA sequences, protoplasts, replicons and tissue cultures.

Article 20

1. Member States shall bring into force the laws necessary to comply with this Directive not later than 31 December 1990.
2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, ... .. 198 ..

For the Council

The President