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NTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Thirteenth Session
Geneva, April 4 and 5, 1984

BIOTECHNOLOGY AND PLANT VARIETY PROTECTION

Document prepared by the Office of the Union

INTRODUCTION

1. Recapitulation of decisions. - At its seventeenth ordinary session, the Council decided that the Union was to study "the possible impact on plant variety protection of new developments in the fields of biochemistry and genetic engineering--and of the wish of inventors in these fields to obtain patent protection for their inventions" (paragraph 120 of document C/XVII/15 in conjunction with heading UV.05 in chapter II of document C/XVII/4). It further decided that the symposium to be held within the framework of its eighteenth ordinary session, on October 17, 1984, would have as its subject "industrial patents and plant breeders' rights--their proper fields and possibilities for their demarcation" (see paragraph 106(i) of document C/XVII/15). At its twelfth session, the Administrative and Legal Committee decided to enter on the agenda for its current session (thirteenth) the matter of biotechnology and plant variety protection (see paragraph 40 of document CAJ/XII/8 Prov.).

2. What is biotechnology? - The term biotechnology has been recently coined. As with all new coinages designating a relatively novel concept, it would be foolhardy to propose a definition since such a definition is likely to change as its subject matter changes. Stated simply, biotechnology refers to the methods that consist in using microorganisms and the cells of higher organisms as industrial tools. This attempt at a definition shows that the field concerned is far from being a new one. 8000 years ago already the Sumerians and the Babylonians knew how to use yeast for making beer. However, this new term can be justified by the enormous scientific advance that has been made. Whereas, until recently, man did no more than to use the microorganisms as they existed in nature, or slightly modified, he is now capable of transforming them--optimists would even claim, at will--using "genetic engineering" techniques (another new term that would seem to have been accepted in place of "genetic manipulation"), whereby these techniques are themselves based on that of "recombinant DNA". This advance foretells an industrial revolution whose impact may be illustrated by the fact that it has become possible to extract by microbiological means metals such as copper at a cost in energy that is ridiculously low compared with that of conventional metallurgical technology.

3. In the field of concern of us, that of plant breeding, the terms "biotechnology" and "genetic engineering" are wrongly applied by some people to techniques in which no use is made of genetics, particularly vegetative multiplication in vitro. Such people are in too much of a hurry to lump together

biotechnology and *in vitro* techniques, thereby forgetting the venerable age of the earliest work done on tissue culture and protoplasts which was carried out at the beginning of our century. Nevertheless, three factors should lead us to deal with biotechnology in its broadest meaning in the course of the discussion: the fact that the techniques are utilized in one place (the laboratory) and the equipment used is the same (test tubes or Petri dishes); the links of dependency (a genetic manipulation *in vitro* has of necessity to be followed by regeneration of whole plants, that is to say the essential element of *in vitro* propagation); the similarity of the questions raised by these techniques from the industrial property point of view.

4. Biotechnology and industrial property. - The matter is not in itself a new one; a well-known example is that of Pasteur who took out a patent in 1873 for a beer yeast. It nevertheless raises new and difficult problems for the industrial property world--both administrators and users of the patent system--as a result of recent achievements and, even more so, of future prospects for industrial microbiology (or bioindustry). It may be noted that the World Intellectual Property Organization (WIPO) has also scheduled a meeting of a Committee of Experts on Biotechnological Inventions, to take place in Geneva from November 5 to 9, 1984, during the same week as the Technical Committee and the Administrative and Legal Committee of UPOV will meet.

5. UPOV has already approached these matters. It has organized a symposium on the topic of "genetic engineering and plant breeding" within the framework of the sixteenth ordinary session of its Council, on October 13, 1982 (the records are contained in UPOV publication No. 340 (E)). The symposium dealt both with technical aspects (covered by Dr. LAWRENCE and Mr. RIVES) and intellectual property aspects (covered by Dr. WILLIAMS from the point of view of American law and by Dr. KREYE from the point of view of European law based on the European Patent Convention). From the legal point of view, the papers and subsequent discussions showed that the current new techniques--and even more so those it is hoped to develop in the near future--raised a problem of protection for inventions in the field of plant biology (not in itself new) and a problem of coexistence between patent law and plant breeders' rights.

6. The true potential of biotechnology in the field of plant breeding. - The scientific and technical background should incite us to prudence as regards the potential of the new genetic techniques in the field of plant breeding. This was clearly shown in the papers given at the 1982 UPOV Symposium on the technical aspects of genetic engineering: the contributions by Dr. PADWA and Dr. LAWRENCE--who are deeply committed to advanced genetic engineering--set out the future prospects and the limitations of new techniques, whereas Mr. RIVES above all emphasized the potential of conventional plant breeding and great interest of advanced techniques for the latter. SNEEP (1984) provides useful additional information in this matter.

7. Both the general press and the popular scientific press have shown a lack of prudence in extrapolating recent achievements in applied microbiology and imagining the creation in the near future of miracle plants, of which the most realistic is, for example, a "pomato" (a hybrid of potato and tomato) bearing both potatoes and tomatoes. For the time being, the pomato is a laboratory plant which produces neither the one nor the other. In any case, from the agronomic and economic point of view, such a plant is of no interest whatsoever: to harvest the tubers it would be necessary to pull up the plant, thus limiting the growing period available for producing tomatoes. Another dream is that of cereals that would fix the atmospheric nitrogen either by themselves or by means of a symbiotic microorganism. This dream systematically avoids two questions: firstly, would the wheat that was produced, for example, still be suitable for making bread or for use in the meal industry? What would be the metabolic cost of fixing nitrogen, that is to say the relationship between the savings made on production factors (reduction in the cost of "fertilizers" in particular) and the unavoidable loss of yield? There again, the value of the plant concerned is far from being certain.

8. The preceding considerations should not however be taken to mean that the technologies involved have no future, quite the contrary. Progress will be made, but it will probably not be as spectacular, even in the medium term, as some imagine at present. Indeed, it is likely to be altogether comparable with that already achieved, and yet to be achieved, by conventional plant breeding. Even when reduced to more realistic proportions, the hopes placed

in genetic engineering fully justify the considerable means invested by certain business circles and certain scientific circles in applied research, and even in basic research, in the hope, of course, of profitability. The concern for profitability of investments logically poses the problem of legal protection for inventions and other achievements of inventive genius. However, examination of that problem will only give a useful result if it is also based on realistic notions of biotechnology.

9. The tenor of this document. - The purpose of this document is not to give definitive replies to the questions raised by the protection of inventions in the field of plant biology and by the coexistence of patent law and plant variety protection; indeed such is not possible. Those replies are largely to be given by national statute law and case law. This document will therefore do no more than to give indications of a legal, technical and practical nature to permit an objective analysis of the situation and the formulation of recommendations. To assist the understanding of the various current problems, it will first set out the principle characteristics of patent law and of plant variety protection, together with the historic events that caused the latter to be instituted.

OUTLINE OF PATENT LAW

10. The legal basis for the protection of inventions is constituted by patent law. This mainly bases on the following social and economic considerations, to which varying degrees of importance are attached:

(i) a patent acknowledges the right of the inventor in the fruits of his intellectual activities in the industrial field;

(ii) a patent is an instrument for promoting and disseminating technical progress and for stimulating inventive activity;

(iii) a patent is an instrument for the transfer of technology.

11. The national patent laws are based on the same fundamental principles, particularly since the concept of protection of industrial property became accepted in its modern shape in the course of the last century and at the beginning of the present one; some of the principles have been incorporated in the Convention for the Protection of Industrial Property, signed in Paris on March 20, 1883, and since revised on six occasions. In addition, they have been subject to a great deal of harmonization from the fifties onwards and have been capped by international and supranational arrangements. The start was given for this trend principally by the work on European patent law, which led to the European Patent Convention. Two complementary treaties were drawn up in parallel, the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention and the, worldwide, Patent Cooperation Treaty (PCT). In addition, the World Intellectual Property Organization (WIPO) drew up a "Model Law for Developing Countries on Inventions"; that Model Law had been prepared by experts acting in a personal capacity and was given the approval of the WIPO Coordination Committee and the Executive Committee of the International Union for the Protection of Industrial Property (Paris Union). It therefore constitutes the outcome of an international consensus and a model for up-to-date legislation on patents and, consequently, a valid basis for this study. Extracts from the WIPO Model Law and from the European Patent Convention are given in Annexes I and II, respectively, to this document.

12. The basic principles of patent law may be stated as follows:

(i) A patent is granted for an invention which, for the purposes of this document, may be, principally:

(a) a product (a substance) as such, independently of the process used to obtain it;

(b) a process for manufacturing a product (in this respect, it may be noted that numerous patent laws automatically extend the protection afforded by a process patent to the product that results directly from use of the process).

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(ii) The invention must be new, must involve an inventive step (not be obvious) and be capable of industrial application (be useful).

(iii) A patent is granted for a limited period.

(iv) A patent affords to the patentee the right to prevent other persons from working the invention (manufacture, offering for sale, selling and other forms of use).

(v) A patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out, in accordance with the description, by an average person skilled in the art concerned; this requires that the invention be "reproducible."

13. Patents may be dependent on each other. Thus, where a patent has been granted for a product and a patent for a new process for manufacturing that product, the holder of the process patent cannot manufacture and market the product without the authorization of the holder of the product patent who, in turn, cannot use the patented manufacturing process without the authorization of the holder of the process patent.

14. Certain fields are considered, by their very nature, to be excluded from patent protection. This is the case, in particular, of discoveries and scientific and mathematical theories, treatments of the human and animal body by surgery or therapy and diagnostic methods and methods for performing mental acts. As far as legal doctrine is concerned, the reasons for exclusion are varied. Other fields are excluded for other reasons, for example inventions whose publication or implementation would be contrary to public policy or to morality. Finally, some categories of invention cannot be given a patent, or certain types of patent, for reasons that are mostly of an economic nature. The recent trend is, however, to abolish that exclusion, that was frequent in earlier times, particularly as regards foodstuffs and product patents for pharmaceutical and chemical substances, and to open up the possibility of a patent for all categories of invention. Article 167(2) and (3) of the European Patent Convention illustrates this trend (see Annex II).

15. However, this opening up does not go without problems. Thus, the patentability of computer programs is not universally admitted. Another field in which legal writers have disagreed and case law has fluctuated for a number of decades is that of plant and animal varieties and processes for breeding plants and animals. The main objections to patentability for plant varieties are summarized below.

PATENTABILITY OF PLANT VARIETIES PRIOR TO THE INTRODUCTION OF THE UPOV CONVENTION

16. An objection that is repeatedly raised to the patentability of the result of plant breeding work is the fact that the creation of a new variety results from joint action by man and by nature. Can one therefore speak of "inventing," "that is to say (to use the definition given by Littré 'creating a new object by the sole force of the mind'?" (LE GRAND, 1961). This question, put some months before the signing of the UPOV Convention, echoed a remark made half a century earlier that "a new variety ... [is] the fruit of the forces of nature brought into play by a given process" (La Propriété industrielle,* 1911).

17. However, the main obstacle was seen in the fact that a new variety was created by means of a non-reproducible process which did not enable a man skilled in the art "to carry out the invention without having himself to act as an inventor or to possess particular gifts" (FREY-GODET, 1923). In that objection, the fact that man has at his disposal a whole range of methods of reproduction or vegetative propagation starting from the original plant was completely ignored. And where that obvious fact was admitted, it was often in order to deny patentability on the grounds that the methods were not faithful or again to restrict it to vegetatively propagated varieties, as was done by the Congress of the United States of America in 1930 when it adopted what has since been known under the name of the "Plant Patent Law." Credit must nevertheless be given to Congress for having innovated.

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* Periodical, formerly published by BIRPI, now by WIPO also in English ("Industrial Property").

18. Finally, it was objected that the breeder of a variety was faced with the impossibility of providing a complete description that was valid for every plant. "A level is always a level; a rotating shaft is always a rotating shaft and even a complex chemical compound always maintains the same molecular structure. On the other hand, as conditions change, plants also change... The result is that a verbal description, or even well prepared color plates, are not sufficient when it is necessary to define a new plant variety with the required accuracy" (unsigned article published in 1933 in La Propriété industrielle following the adoption of the Plant Patent Law of the United States of America). That objection had also been waived by the Congress of the United States of America.

19. However, the above-mentioned note concluded in the following terms: "The Courts will have to attenuate yet further the rigidity of the principle that the inventor, in exchange for the rights afforded to him, must reveal his invention to society in such a way that any person 'skilled in the art' may carry it out; apply in a broad sense the theory which considers the products of nature as excluded from patentability... In fact, it would seem that even if the law represents good seed, case law will have to prove that it is not unfertile ground!" In actual fact, the innovation adopted by the Congress of the United States of America was only rarely to be copied by lawmakers and the judiciary was to prove incapable, in the majority of countries, of finding a satisfactory solution to the problem of protecting the breeder's work within the framework of patent law.

PLANT VARIETY PROTECTION LAW - ITS INTRODUCTION AND ITS GENERAL PRINCIPLES

20. The uncertainty of protecting plant varieties by means of patents led a number of States, as of the 1920s, to give breeders a different form of protection. This was based, to begin with, on the exclusive use of a denomination of a category of seed or seedlings (e.g., elite seeds) or of a denomination trademark--thereby doing violence to trademark law--or both (Czechoslovakia in 1921, France in 1922), and subsequently on a limited form of exclusive commercial exploitation of the variety (Netherlands in 1942, Federal Republic of Germany in 1953). In some States, the special arrangements assumed a place in the legal order side by side with the patent law. Such is the case, in particular, in the Federal Republic of Germany where the patent system finally opened up to plant varieties. However, already then, the legislator took care to clearly demarcate the respective fields of the two systems and to avoid double protection: the special arrangements being applicable to certain agricultural and vegetable species and the patent system, de facto, to the other plants since Article 68 of the 1953 Seed Law stipulated that where a variety was protected under both systems, the rights deriving from a patent could not be relied on except where they were not in contradiction with the provisions of that Law. In Italy, patents have become the sole form of protection for new plant varieties after case law had removed all objections that had been raised in opposition. Finally, no form of protection was available to breeders or could be obtained by them in countries such as Denmark, Switzerland or the United Kingdom.

21. The summary of the situation made in the preceding paragraph suffices to show that it was unsatisfactory, both for the breeders and for the industrial property specialists. In view of that state of affairs, the industrial property circles expressed an opinion at the AIPPI Congress in Vienna in 1952 that it was necessary to protect new varieties by means of patents or by any other means. As for the breeders, grouped together within ASSINSEL, they expressed an urgent wish at their 1956 Congress, held in Semmering in Austria, that an international conference be held to study the matter at an official level and if possible to lay down in a convention the principles governing such protection. It may be noted in passing that these initiatives also followed on work undertaken from 1946 onwards within FAO but which had failed for reasons expressed as follows by the latter's Technical Activities Committee: "It is the duty of governments to make discoveries in the field of agriculture available in all countries; too many obstacles would prevent the building-up of reserves; the research institutes are governmental and the true nature of reproduction is opposed to a patent" (MATTHEY, 1954).

22. As the final stage in the historic process described above, the UPOV Convention basically does no more than to adopt solutions that already existed, either in theory or in practice, and to assemble them into a coherent legal system adapted to the aims pursued. The provisions of the Convention of concern within the framework of this study are the following:

(i) The purpose of the Convention is the granting of a title of protection for a variety. It is similar in that respect to the product patent, as opposed to the process patent.

(ii) The substantive conditions for obtaining protection are adapted to the subject matter to be protected, that is to say a variety. These conditions are distinctness from any other existing variety that is a matter of common knowledge, homogeneity and stability, commercial novelty and the denomination. The Convention therefore does not contain the notion of inventive step (any variety is protectable whatever the means by which it has been bred) nor the concept of industrial applicability (every variety is presumed to be usable in agriculture). It contains a modified concept of novelty formed by the combination of distinctness and commercial novelty; this latter refers to the availablility of the variety to the public and not to the disclosure of its description (based on publication, in particular) since a published description would not generally enable the variety to be recreated or reproduced.

(iii) The effects of protection are limited: firstly, in a simplified way, the exclusive right of exploitation is limited to production for the purposes of commercial marketing, offering for sale or marketing of seed and planting material of the variety. This gives a farmer the legal possibility--supposing that he has the technical capability--of producing his own seed without having to apply for a license and to pay royalties. Secondly, the right that is afforded comprises no rights in any further variety that is created (but not produced by repeated use) from the protected variety. Three further differing features are involved as compared with patents: the scope of protection is restricted and does not generally extend to the products of the variety; there is no system of dependency (except in the special case of varieties requiring repeated use of another variety for their commercial production); there are no claims that may define the scope of protection.

(iv) Article 2(1) of the Convention lays down that the rights afforded to the breeder may take the form of a special title of protection--thus following the views of the great majority of States that signed the Convention--or of a patent--following the views of Italy. It further stipulates that where both forms of protection coexist in a State, they may not be available simultaneously for the same botanical genus or species. The possibility of double protection is therefore excluded. In the 1978 Act of the Convention, a derogation was added to the provision, contained in Article 37 of the Act, with the main purpose of enabling the United States of America to become a member of UPOV. In that country, the allocation of the respective fields of application of the Plant Patent Law and the Plant Variety Protection Act is, for historical reasons, a function of the mode of propagation of the variety to be protected, meaning that double protection can only be the exception.

THE PATENTABILITY OF PLANT VARIETIES UNDER PRESENT LAW

I. Exclusion of Plant Varieties from Patentability

23. International instruments. - In particular in view of the fact that it was drawn up at about the same time as the UPOV Convention and that to some extent the same experts were involved, the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention reads as follows in Article 2:

> "The Contracting States shall not be required to grant patents for:
>
> ...
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

24. Similar provisions are contained in other international instruments, in particular:

(i) in Article 53(b) of the European Patent Convention, in the form of a strict exclusion from patentability (see Annex II hereto);

In fact, applicants for patents will be faced in those countries with the same objections that were put forward in the 1920s to their predecessors. That may indeed be the reason for which the patent approach would seem to remain theoretical in those countries.

30. Above all, however, exclusion from patentability may derive from application at national level of the provision in the second sentence of Article 2(1) of the UPOV Convention prohibiting the coexistence of a special title of protection and of a patent for varieties of the same botanical genus or species. Such application may result from:

(i) a constitutional principle that international law applies directly at national level;

(ii) failing that, a principle under which the interpretation of national law endeavors to conform with international law;

(iii) the rule under which priority should be given in resolving a conflict of laws to the specialized legislation (it being understood that, generally, the plant variety protection law is to be considered a specialized law in comparison with the patent law) or to the most recent law.

II. Patentability of Plant Varieties where there is no Exclusion from Patentability

A. Product patents

31. The legal point of view. - In those countries in which there is no plant variety protection legislation, case law determines whether patent law is applicable to plant varieties. Experience has shown, however, that case law remains (still) incapable of adapting the patent system to plant varieties. It is highly probable that the major obstacle will remain the non-reproducibility of the breeding method, thus not permitting an average person skilled in the art to "carry out the invention." A further obstacle could perhaps be the requirements of inventive step (in some laws, non-obviousness). Thus, in its decision in the Abitibi (1982) case, concerning a mixture of fungi, the Canadian Patent Office held, incidentally, as regards the patentability of higher organisms, as follows in respect of reproducibility: "If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature) and can recreate it uniformly and at will, and if it is useful, for example, to destroy the spruce budworm, then it is every bit as much a tool of man as a microorganism. With still higher life forms, it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But, if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently." These considerations, which hardly differ from the objections raised half a century ago already, thus close the door on patents for varieties produced by conventional plant breeding programs, of which the greater part are non-reproducible, and on varieties produced by advanced genetic engineering processes such as protoplast fusion, which are not always reproducible.

32. This objection is also put forward at present in countries such as the Federal Republic of Germany, where there is a long tradition of variety protection by means of patents and where the principle of patentability of certain plant varieties is acknowledged (see paragraph 26 above). HESSE (1969), the author of a detailed study (for his conclusions, see Annex III), and KREYE (1983), for example, are in favor of the requirement that the breeding method of the variety should be reproducible, thereby adopting the same approach as the Federal Supreme Court of the Federal Republic of Germany in its 1969 decision in the Red Dove case and the Patent Court in its 1973 decision in the Saintpaulia case, respectively. The old controversy is therefore not yet finished and it would even seem that a new battlefield has presented itself in the form of microorganisms and cell elements.

33. Doubts had also been cast in relatively old writings (particularly HESSE (1969)) as regards the effectiveness of protection afforded by a product patent. The latter affords the patentee an exclusive right in the manufacture of

(ii) in Article 112(3)(ii) of the WIPO Model Law for Developing Countries on Inventions, also in the form of a strict exclusion from patentability (see Annex I hereto);

(iii) in Rule 67(1)(ii) of the Regulations under the Patent Cooperation Treaty (PCT), in the form of the faculty given to International Preliminary Examining Authorities not to carry out such examination in the case of applications whose subject matter is an invention in this field.

25. National laws. - Exclusion from patentability of plant varieties, animal varieties and essentially biological processes for the production of plants and animals is to found in the national laws of most of the UPOV member States. From the historical point of view, that exclusion was incorporated in the patent laws for the purpose either of applying Article 2(1) of the UPOV Convention or for harmonizing national law with the patent conventions concluded at European level. This is shown clearly by the changes in the statutory arrangements: in the first case, it appeared in the plant variety protection law, in an article of the final provisions amending the patent law, and in the other case, in a law amending the patent law that was mainly adopted with a view to aligning national law on European law.

26. In those countries that in the past admitted the principle of patentability of plant varieties, exclusion may be limited to those genera and species that enjoy protection under the special law on the protection of plant varieties, thus obliging patent law to provisionally play a stop-gap role (although this is very theoretical) pending extension of the plant variety protection law to the whole of the plant kingdom. Such is the case in France, the Federal Republic of Germany and in Spain (but not in South Africa). In the Federal Republic of Germany, exclusion from patentability of essentially biological processes for the production of plants is also limited to those concerning genera and species covered by the Plant Variety Protection Law. The explanation is that the lawmaker was unable to see his way to an overall solution (despite the controversies on the patentability of varieties and of related processes) and, consequently, he went no further than partial exclusion to avoid duplication of protection by means of a process patent covering the variety as the product of the process (Official Memorandum to the Plant Variety Protection Act of May 20, 1968, and RITGEN (1968)).

27. In some States, the patent law remains silent as regards the fate to be reserved to them. In Europe, such is the case of Belgium and of Ireland, pending adaptation of the legislation to European law. Elsewhere in the world, such is also the case, for UPOV member States, in Japan and New Zealand (but the law of this latter country, that is relatively old, excludes foodstuffs from patentability).

28. In order to make a complete survey, mention should also be made of a number of States that have adopted the system of patents for protecting plant varieties (and also animal varieties in some cases) on the basis of the UPOV Convention, such as Hungary or Italy, or by setting up special provisions, such as the United States of America (for vegetatively propagated varieties), Bulgaria, Romania and the Soviet Union.

29. In those member States of UPOV (which therefore have a special law or special provisions under the patent law for the protection of new plant varieties) whose patent legislation does not exclude plant varieties from patentability as industrial inventions, it can be accepted that, theoretically, a variety could be protected at the same time by an industrial patent and by a special title. This has been suggested by WILLIAMS (1983) in respect of the United States of America, based on the Supreme Court decision in the Chakrabarty case (which concerned a man-made microorganism). However, the authorities of that country have expressed a more guarded point of view (document C/XVII/6, page 48):

> "The extent to which plant varieties are eligible for protection under the General Patent Law has not yet been judicially determined. The Patent and Trademark Office has, therefore, adopted a case-by-case procedure for determining eligibility. In general, asexually reproduced varieties not patentable under the Plant Patent Law and sexually reproduced varieties not protectable under the Plant Variety Protection Act may, upon satisfaction of the statutory criteria, be patented under the General Patent Law."

the product by whatever process. It has been held that the reproduction or propagation of a variety, that is to say the multiplication of seed or planting material does not constitute "manufacture" within the meaning of the patent law since it requires the prior existence of the product that is to be manufactured, so that the only activity covered by the patent would be production of the variety in accordance with a method of variety creation, whether stated in the patent document or not. Moreover, if this point of view was not accepted, the patentee would be confronted with the principle of exhaustion of rights afforded by the patent which applies as soon as the product has been lawfully put on the market. In fact, the patentee could no longer exercise control over the use made of the product and the purchasor could exploit at will the properties of the product, particularly, in the case of a plant variety, its faculty to reproduce itself or to propagate. It is not certain that these objections are still valid at the present time in view of the progress made by bioindustry, which is using microorganisms that themselves have the faculty of self-propagation.

34. The social and economic point of view. - The patentability of plant varieties is not only confronted with obstacles of a legal nature. Both the patent law and the plant variety protection law seek to establish a balance between the objectives they have adopted, that is to say to reward the inventor or breeder and to promote economic development, thus requiring that the public interest should also be taken into due account. This is shown clearly in the preamble to the WIPO Model Law, which sets out the following two recitals:

> "(a) that the protection of inventions and the remuneration of innovations involve both private and public interests;
>
> "(b) that the grant of rights with respect to the protection of inventions or the remuneration of innovations is to be balanced by the imposition of obligations."

In the UPOV Convention, this necessary balance is described as follows in the preamble:

> [The Contracting States,] "Conscious of the special problems arising from the recognition and protection of the right of the creator in this field and particularly of the limitations that the requirements of the public interest may impose on the free exercise of such a right."

35. Compared with patent law, the balance achieved by the system of plant variety protection gives more advantage to the public interest, as appears clearly from the limitation of the effects of protection (see paragraph 22(iii) above). Such modification was necessary to make the plant variety protection system acceptable both to the public and to the governments. Sight should not be lost of the fact that a large number of patent laws previously contained provisions that excluded foodstuffs from patentability and the people who demanded protection of new plant varieties by means of patents generally limited their claims to an exclusive right in the reproduction or propagation of the variety to take into account not only the difficulty of ensuring respect for a patent with more far-reaching scope by all farmers but also the general reticence in respect of monopolies in a field as vital as that of foodstuffs.

36. This differing balance is still as necessary today as is shown by the hostile attitude of some circles to the protection of new plant varieties. This explains why opening up the patent approach to plant varieties would have serious implications for the patent system, particularly where the lawmaker has pronounced positively in favor of this differing balance by establishing suitable specialized legislation. Indeed, this legislation can but make such an act altogether inappropriate since the need has not made itself felt. It would be a disservice to the public, mainly by reason of the greater scope of a patent, in two ways. By carefully drafting the claims, it is possible to extend the exclusive right of industrial exploitation to the final product of the variety, for example, the preserved green peas, thus annihilating Article 5(1) of the UPOV Convention. Further, a patent could cover a range of varieties that had been created or even that were yet to be created, defined by a limited number of characteristics that had been given pride of place in the claims, for example blue roses or thornless roses, which in this case would annihilate Article 5(3) of the Convention and also the principle that specific protection is afforded only to a variety that truly exists.

37. It would also be a disservice to the public for a special title of protection and patent to exist simultaneously in the same hands or, even worse, in different hands: the coexistence of two titles of protection having the same subject matter but differing in the effects and the conditions of their granting could but impair the clarity of the legal and economic situation, mainly to the detriment of users.

38. Finally, one cannot remain silent on the profound injustice that such a situation would bring with it. It is clear that if the current criteria of patentability and the interpretation given to them are maintained as they stand, a part only of the plant varieties could become the subject matter of a patent, mainly those created by means of a reproducible process. This would favor the breeder of a new variety who had used a variety creation process meeting the criteria--entirely ill-adapted--of the patent law to the detriment of a breeder using processes that did not satisfy them. It is not inconceivable that two breeders could obtain the same variety, for example a variety has been made resistant to a pathogen by the insertion of exogenous DNA by means of a vector or by the conventional technique of back-crossing. A further injustice would also reside in the fact that the breeder of the initial variety, that was not resistant, would have carried out a far greater amount of variety creation work but would have to be content with a special title of protection.

39. Conclusion. - The product patent as a form of protection is poorly adapted to plant varieties, as is the whole patent system. Only a small number of varieties could profit from that type of protection, not because only those few varieties "merit" protection, but for reasons that are in no way related to the importance of the breeding work or to the value that its result, the plant variety, renders to society. There would be a lack of equality before the law for plant breeders--not only for breeders using conventional methods, but also for those using genetic engineering. This disparity of treatment, not being compatible with the notion of justice, has, on the contrary, been eliminated by the special system for the protection of plant varieties.

B. Process patents

40. As biotechnology develops, there will be an increasing number of patent applications for process inventions with the aim of creating plants with new properties, particularly in relation to recombinant DNA, or which represent steps taken towards that aim. The patent offices will have to decide in such cases whether the inventions meet the normal requirements of patentability, that is to say, basically, whether the inventions are reproducible, new, involve inventive step and are industrially applicable. Those patent offices whose legislation contains an exclusion as described above in paragraphs 25 to 28 will further have to decide whether they are not in fact "essentially biological processes for the production of plants" that cannot be deemed microbiological processes. It is not to be excluded, at least in the future, that the requirements of patentability may be met by certain of these process inventions and the question therefore arises whether the granting of process patents of this type will lead to overlapping with plant variety protection.

41. Where protection of the process itself is concerned, there can be no overlapping since plant variety protection does not protect processes. On the other hand, breeders will of course be affected by patent protection for such processes. Positively, due to the fact that certain of these processes will provide additional and attractive means for their breeding work and also, negatively, in that the use of such processes will require them to obtain the consent of the owner of the patent and to pay royalties to him. It is to be assumed that the advantages will far outweigh the disadvantages and breeding circles have indeed already stated that the breeders will always welcome with gratitude the development of new processes that facilitate their work and increase their success and they agree that the inventors of such processes have a right to fair remuneration.

42. Fears have nevertheless been expressed that the patent law rule--already mentioned above--that applies in numerous countries, to the effect that protection under a process patent also extends to a product directly obtained by the protected process (see paragraph 12(b) above and, as examples, paragraph 135.2(b)(ii) of the WIPO Model Law, of which extracts are given in Annex I hereto, and Article 64(2) of the European Patent Convention, of which

extracts are given in Annex II hereto), could lead to difficulties since its application could mean that protection given by a process patent would extend to a product for which new plant variety protection was available. It is feared that in this way double protection could be obtained for the same product under a patent and under plant breeders' right, based on differing systems of protection having a differing scope and differing effects. Such double protection was held unacceptable by the Contracting States or the national legislators who introduced into the treaty or the law concerned the exclusion provisions referred to in paragraphs 24 to 28 above. They were of the opinion that this danger could be adequately countered by an explicit exclusion of inventions that were "essentially biological processes for the production of plants." However, it is to be feared that future developments may well thwart that aim and that in the other countries that do not have such exclusion provisions the difficulties which such double protection could possibly create would assume even larger dimensions. Those fears may be commented as follows.

43. It should first be made clear that the directly obtained product can never constitute the variety itself. A product can only be understood as a tangible object. In the case of a variety, however, this is an abstract object or, as the experts who drafted the UPOV Convention expressed it, an intangible object (see Records of the Conferences, 1957 to 1961, 1972, page 36). A plant variety comprehends all those plants that show the characteristics of the variety, even those that are produced in ways other than from the patented process, e.g. in nature, with the aid of conventional breeding methods or with the aid of other genetic methods. The product obtained by the patented process can therefore only constitute a given plant stock. On the other hand, this plant stock does not need to meet the requirements that normal usage and plant variety protection law places on a protectable variety. There is no need for such a plant stock to be distinct, or new, or homogenous or reproducible, it can full well be material that already exists in nature or that has already been obtained by means of another process. This latter circumstance is not likely, however, to allay the fears expressed above, but shows, on the contrary, that if patent protection were to be extended to such material it would indeed result in undesirable overlapping which, as a result of just that difference in the protected material, would be very difficult to check legally.

44. A further question arises, however, as to the extent to which the effects of a process patent for plants obtained by biotechnical processes, can become practical. The following comments may be made:

(i) Protection under a process patent is enjoyed only by the product obtained directly by means of the process. As things stand at present, however, a genetic engineering process for the creation of new plants achieves at most the production of a transformed plant cell which furthermore has to be selected from the mass of other cells for which the process has not been successful and from which, in addition, one or more whole plants have to be regenerated. Whether the result of this selection and regeneration may still be claimed as a direct product is doubtful, to say the least. Furthermore, it is necessary for the economic exploitation of this new plant that it be multiplied in sufficient quantity for marketing. If patent laws are strictly interpreted, the result would have to be that the plants finally produced for marketing are no longer directly obtained by the patented process, but result from subsequent--conventional or other--multiplication processes. However, it should be taken into account that in some countries case law has held in respect of patented chemical processes that measures for extracting or cleansing the manufactured product do not impair its direct quality. Following such court decisions, the conclusion could possibly be reached that even where there is subsequent selection and multiplication the direct quality of the product is still to be accepted if the patented process for the production of the plants has played a decisive part. However, it would definitely not be possible to extend protection under a process patent to material that has only made use of the plant stock obtained directly by the process as initial material for subsequent breeding operations. The result of crossing such material with another plant variety would therefore cease to be covered by protection under the process patent.

(ii) A further aspect is also worthy of attention. Protection under a process patent only extends to the product, of course, if it has in fact been obtained by means of the process. Obtaining the same material by means of a

different process would not be covered by the patent. This shows that protection under a process patent would in no way be suitable as a basis for effective protection of varieties.

(iii) Where the product obtained directly by the patented process has to be selected or multiplied for marketing, the question is already raised whether the selected and multiplied material may still be regarded as a direct product. It must also be taken into account, however, that most patent laws contain the principle of exhaustion of rights afforded by the patent. Once the seed or planting material has been lawfully procured through the trade, from the owner of the patent or his licensee for example, the person acquiring it is free to use it in accordance with the principle of exhaustion referred to and, in particular, he is free to multiply the material, whether for his own purposes or for marketing.

(iv) It should be pointed out, however, that when the creation of the new plant coincides with the production of the seed that is suitable for marketing, e.g. in the case of a hybrid variety, the direct quality could exist, meaning that the feared double protection could occur. However, it is doubtful whether any appreciable number of such cases would occur since the processes liable to be involved are generally no longer new.

45. As a result, therefore, it may be concluded that the statutory extension of the process patent to a given stock of seed or planting material obtained directly by a patented process can only affect plant variety protection to a limited extent. Nevertheless, problems are conceivable that make it desirable to take action to ensure that cases of this type cannot occur or can only occur in very small numbers. For that reason, the exclusion of "essentially biological processes for the production of plants" from patent protection, whereby the greater part of such patent conflicts could not arise in the first place, would seem altogether justified and should in any event be maintained in those cases where it is already stipulated. In addition, developments in those countries that do not have exclusion should be followed with particular care.

GENERAL CONCLUSIONS

46. Recent progress in the field of industrial genetic engineering and future prospects in this sector have led to rash hopes being placed in the application of biotechnology to the vegetable kingdom. These hopes have in turn fed an apprehension that the work of the breeders will be inhibited by a series of patents of wide-ranging scope. An objective analysis of the technical and legal facts shows that the advent of biotechnology is far from having eliminated those objections against the patentability of new plant varieties that led to the establishment of a special system. This system thus proves itself as a form of protection for all varieties, whether created in the conventional way or by genetic engineering. Nevertheless, action is necessary since the patent offices will have to decide in the near future on applications in a field with which, for practical reasons, they are not very familiar. Plant breeding and plant variety protection circles should take a number of measures:

(i) They should inform other circles, in particular those of industrial property, of their working methods, their tools and their achievements. The aim is to show that they possess an arsenal of means of great complexity and great efficiency, which have stood the test of time. This arsenal also comprises methods and tools which nowadays are classified as genetic engineering. Further, the limits of genetic engineering should be pointed out, it should be made known that genetic engineering can often achieve but isolated improvements, myths should be destroyed, "hallucinations of maize that whistles and radishes that ride bicycles," (PADWA, 1983) and it should be made clear that conventional plant breeding and genetic engineering are complementary, whereby the latter has need of the former if it is to achieve anything.

(ii) They should remind the other circles that the system of protection is a tool adapted to the activities and needs of those who create new varieties, and that it is also adapted to the interests of society.

(iii) They should establish a system of cooperation with the patent offices in order to enable them to examine patent applications in full knowledge

of the matter, that is to say, based on relevant information on the state of art and on industrial applicability. For this task, the cooperation of researchers should also be obtained?

(iv) They should establish a system of cooperation between all plant breeding circles. Once the limits of the patent system, defined both its own rules and regulations and by the existence of a special system of protection are perceived, there is a danger that part of the new knowledge will be subject to trade secrecy and dissemination will therefore be a slow process, to the detriment of all concerned.

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[Annexes follow]

ANNEX I

EXTRACTS FROM WIPO MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS

Section 112

Inventions

1) For the purposes of this Law, "invention" means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.

2) An invention may be, or may relate to, a product or a process.

3) The following, even if they are inventions within the meaning of subsection 1), shall be excluded from patent protection:

i) discoveries, scientific theories and mathematical methods;

ii) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such processes;

...

Section 113

Patentable Inventions

An invention is patentable if it is new, involves an inventive step and is industrially applicable.

Section 114

Novelty

1) An invention is new if it is not anticipated by prior art.

2)a) Prior art shall consist of everything disclosed to the public, anywhere in the world, by publication in tangible form or, in the country, by oral disclosure, by use or in any way, prior to the filing or, where appropriate, priority date of the patent application claiming the invention.

...

Section 115

Inventive Step

An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the patent application claiming the invention, it would not have been obvious to a person having ordinary skill in the art.

Section 116

Industrial Application

An invention shall be considered industrially applicable if it can be made or used in any kind of industry. "Industry" shall be understood in its broadest sense; it shall cover, in particular, handicraft, agriculture, fishery and services.

Section 123

Application

1)a) The application for a patent ("the application") shall be filed with the Patent Office and shall contain a request, a description, one or more claims, one or more drawings (where required), and an abstract.

b) Where the applicant's ordinary residence or principal place of business is outside the country, he shall be represented by an agent admitted to practice before the Patent Office.

...

3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be evaluated, and to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate the best mode known to the applicant for carrying out the invention.

4)a) The terms of the claim or claims shall determine the scope of the protection. The description and the drawings may be used to interpret the claims.

b) Claims shall be clear and concise. They shall be fully supported by the description.

5) Drawings shall be required when they are necessary for the understanding of the invention.

6) The abstract shall merely serve the purpose of technical information; in particular, it shall not be taken into account for the purpose of interpreting the scope of the protection.

...

Section 125

Unity of Invention

The application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Section 135

Effects if Grant of Patent; Definition of "Exploitation"

1) Once the patent has been granted, the exploitation of the patented invention in the country by persons othen than the owner of the patent shall require the latter's agreement.

2) For the purposes of this Law, "exploitation" of a patented invention means any of the following acts:

a) when the patent has been granted in respect of a product:

i) making, importing, offering for sale, selling and using the product;

ii) stocking such product for the purposes of offering for sale, selling or using;

b) when the patent has been granted in respect of a process:

i) using the process;

ii) doing any of the acts referred to in paragraph (a), in respect of a product obtained directly by means of the process.

[Annex II follows]

ANNEX II

EXTRACTS FROM THE CONVENTION ON THE GRANT OF EUROPEAN PATENTS AND ATTACHED ANNEXES

Section 52

Patentable inventions

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

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

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

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

(d) presentations of information.

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

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

Section 53

Exceptions to patentability

European patents shall not be granted in respect of:

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

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

...

Section 64

Translation of the specification of the European patent

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

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

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

Section 167

Reservations

(1) Each Contracting State may, at the time of signature or when depositing its instrument of ratification or accession, make only the reservations specified in paragraph 2.

(2) Each Contracting State may reserve the right to provide that:

(a) European patents, in so far as they confer protection on chemical, pharmaceutical or food products, as such, shall in accordance with the provisions applicable to national patents, be ineffective or revocable; this reservation shall not affect protection conferred by the patent in so far as it involves a process of manufacture or use of a chemical product or a process of manufacture of a pharmaceutical or food product;

(b) European patents, in so far as they confer protection on agricultural or horticultural processes other than those to which Article 53, subparagraph (b), applies, shall, in accordance with the provisions applicable to national patents, be ineffective or revocable;

...

(3) Any reservation made by a Contracting State shall have effect for a period of not more than ten years from the entry into force of this Convention. However, where a Contracting State has made any of the reservations referred to in paragraph 2(a) and (b), the Administrative Council may, in respect of such State, extend the period by not more than five years for all or part of any reservation made, if that State submits, at the latest one year before the end of the ten-year period, a reasoned request which satisfies the Administrative Council that the State is not in a position to dispense with that reservation by the expiry of the ten-year period.

EXTRACT FROM THE GUIDELINES FOR EXAMINATION
AT THE EUROPEAN PATENT OFFICE,
ISSUED BY THE GENERAL SECRETARIAT
OF THE COUNCIL OF THE EUROPEAN COMMUNITIES IN 1976

Article 53(b)

3.4 Also excluded from patentability are "plant or animal varieties or essentially biological processes for the production of plants or aninals". One reason for this exclusion is that, at least for plant varieties, other means of obtaining legal protection are available in most countries. The question whether a process is "essentially biological" is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded. To take some examples, a method of crossing, interbreeding, or selectively breeding, say, horses, involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a method of treating a plant or animal to improve its properties or yield or to promote or suppress its growth by some mechanical, physical or chemical process--e.g. a method of pruning a tree--would not be essentially biological since, although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.3)."

...

3.5 The exclusion referred to in the preceding paragraph does not apply to microbiological processes or the products thereof. Thus, patents may be obtained not only for processes involving microorganisms, but also for microorganisms themselves (as well as inanimate products) when produced by a microbiological process. In the case of microbiological processes particular regard should be had to the requirement of repeatability, as mentioned in item II, 4.11.

[Annex III follows]

ANNEX III

THE CONCLUSIONS OF H.G. HESSE AS REGARDS THE PATENTABILITY OF ANIMAL AND PLANT VARIETIES

1. Whether or not patents for breeding can be granted has still not been decided by recent legislation (Plant Varieties Protection Law, amendment of Section 1 of the Patent Law), but has intentionally been left in suspense.

2. The decision of the Federal Court dated March 27, 1969--Red Dove--is of significance for patentability not only of animal varieties but also of plant varieties; no distinction can be made between animals and plants under patent law.

3. The patent law equation of planned exploitation of natural biological forces with the concept of technical activities in the traditional meaning proposed by the Federal Court promotes the flexibility and development potential of patent law and is therefore to be welcomed.

4. The planned breeding of plants and animals is in no way a discovery, but belongs in the realm of inventions.

5. The Federal Court is to be commended for having made the patentability of breeding processes dependent in any event on their reproducibility--and not only in theory--and for requiring that a reproducible method of production be stated for a substantive or application patent; the natural multiplication of the product of breeding does not constitute such a method.

6. Breeding processes that are so time consuming, complex and expensive that it becomes pointless to reproduce them once genetically consistent propagating material of the new species is available, are not industrially applicable.

7. Variety protection under a process patent cannot extend via the second sentence of Section 6, second sentence, (now Section 9(3)) of the Patent Law to F_{1+x} generations since these are not directly obtained by the process.

8. Propagation patents for new varieties of plants or animals cannot be granted since natural propagation is not an invention.

9. The natural propagation of a new plant or animal variety cannot belong to the modes of fabrication that are protected on behalf of the owner of a substantive patent in the product breeding.

10. The unavoidable application of the concepts of reproducibility and industrial applicability lead to the conclusion that patent law is not suitable for providing adequate protection to breeding activity. Likewise, other basic concepts of patent law, such as novelty, progress and inventive step, do not correspond to the special features of breeding. Patent law does not contain the concept of loss of genetic consistency that is necessary as grounds of nullity if breeding activities are to be patented. International legal developments would seem to be moving towards the exclusion of breeding activities from patent law. For all these reasons therefore, although not excluded, it is nevertheless inappropriate and contrary to the warranted interests of the breeders to direct them towards patents in their justified quest for industrial property protection. Legislative measures would, on the other hand, seem indicated: removal of the list of species from the Plant Varieties Protection Law and creation of specific protection for animal breeding.

[Annex IV follows]

Patent Protection in the Field of Genetic Engineering

A. HÜNI and V. BUSS*

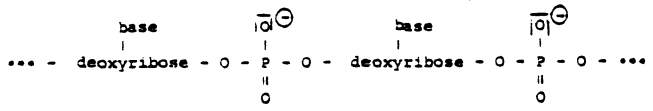
I. Introduction

Starting from the second half of the last century, classical chemistry has influenced technology and our environment to an ever more rapid and ever increasing extent. It would seem that genetic engineering (recombinant DNA technology) is at present on the threshold of a similar development, the extent of which can scarcely be imagined.

Current developments in the field of genetic engineering are focused primarily on the production of microorganisms with artificially modified genes. The microbes engineered to date have principally been bacteria which, on account of their modified genes, are able to produce valuable products (e.g., insulin, interferon, somatostatin, etc.) during their fermentation, or to degrade harmful or otherwise undesirable products (e.g., refuse, oil pollution) by means of their metabolism.

In order that the subject matter under discussion may be understood more fully, a much simplified outline of some basic principles of genetic engineering is first provided.

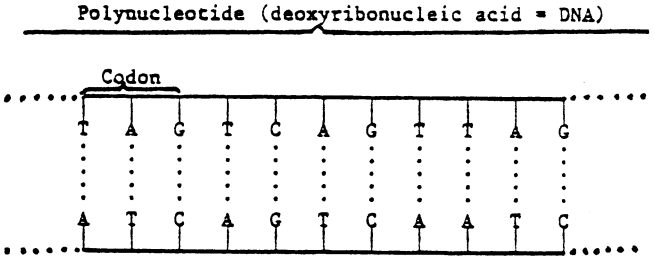
The building blocks of the genotype are called nucleotides. They consist of a base, deoxyribose and phosphoric acid, with the base and the phosphoric acid forming a covalent bond at the deoxyribose. The base is either adenine (A), cytosine (C), guanine (G) or thymine (T), with adenine and thymine, on the one hand, and guanine and cytosine, on the other, being "complementary" to each other, i.e., hydrogen bonds may be formed between adenine and thymine and guanine and cytosine, respectively. Nucleotides can be connected one to the other through ester formation to form strands (chains) of polynucleotides which can be illustrated as follows (fig. 1):



(fig. 1)

Two such polynucleotide strands that are held together via hydrogen bonds between complementary bases and form a double helix constitute the hereditary substance (DNA = desoxyribonucleic acid, a chemical substance). The hereditary substance can be subdivided into the individual genes. A gene can direct the synthesis in the cell of a particular "polyamino acid" (enzyme, peptide, protein, e.g., insulin, etc.) for which it is specific, so that a particular sequence of three nucleotides, called a codon, always directs the incorporation of a particular amino acid into the peptide chain. However, a number of codons can be associated with one specific amino acid (degeneration of the genetic code).

A gene may therefore be illustrated as follows (fig. 2):



(fig. 2)

The production of microorganisms with artificially modified hereditary material and their metabolism products can be subdivided into five process steps:

(A) making available the desired gene;

(B) splicing the gene obtained in (A) into a vector to form a so-called recombinant vector;

(C) introducing the recombinant vector into a host cell;

(D) separating the successfully engineered cells from the unwanted ones;

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

These five steps will now be illustrated in greater detail.

Step (A): Obtaining the Desired Gene

The gene can be obtained by:
(a) chemical synthesis; or
(b) cleavage of naturally occuring DNA.

(a) The synthesis of a gene can be accomplished, for example, by "normal" chemical reactions, at least to some extent using automatic synthesizers. Synthesis requires knowledge of the nucleotide sequence of the gene. This knowledge is obtained either by isolation and sequence analysis of the naturally occurring gene or of its secondary products, e.g., the so-called messenger ribonucleic acid (mRNA); or it can be postulated theoretically as one of the possibilities deduced from the (degenerated) genetic code on the basis of the known amino acid sequence of the polypeptide to be coded.

(b) The DNA to be cleaved can be isolated from a naturally occurring cell by known methods (destruction of the cell wall and separation from other cell compo-

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nents). The obtained DNA is cleaved, for example, by the action of certain specific enzymes, known as restriction endonucleases. Some of these enzymes cut each of the two base-paired DNA strands always at a specific chemical bond of a specific nucleotide sequence, generating "blunt ends" ["flush(ed) ends"] if they cut bonds opposite to each other in the two strands, or generating single strand DNA-protrusions, so-called "sticky ends" ("staggered ends") if they cut bonds which are some nucleotides apart from each other in the two strands. The nucleotides of these sticky ends are, of course, complementary to each other.

A blunt end can be converted into a sticky end, for example, by adding nucleotides to one DNA strand.

Step (B): Splicing the Gene into a (Parental) Vector to Form a Recombinant Vector

A parental vector is a DNA molecule, e.g., a plasmid or a DNA molecule of a virus, into which a gene can be spliced, and which makes possible the replication (identical reproduction) of this gene after transfer of the thus obtained recombinant vector into a host cell (step (C)). A plasmid is a comparatively small circular, double-stranded DNA molecule which is able to replicate in a host cell. Plasmids are present in many bacterial cells in addition to the much bigger chromosome. The simplest form for joining the gene obtained in step (A) to a parental vector consists in generating the same sticky ends at the gene and at the vector (e.g., by preparing the gene from a larger DNA-molecule by cutting with the same restriction endonuclease which is used for cutting the vector), incubating a mixture of the two components under condition favoring hydrogen-bonding between the thus formed single strand protrusions that are complementary to each other, and sealing the nicks within the joined molecule with DNA-ligase (fig. 3).

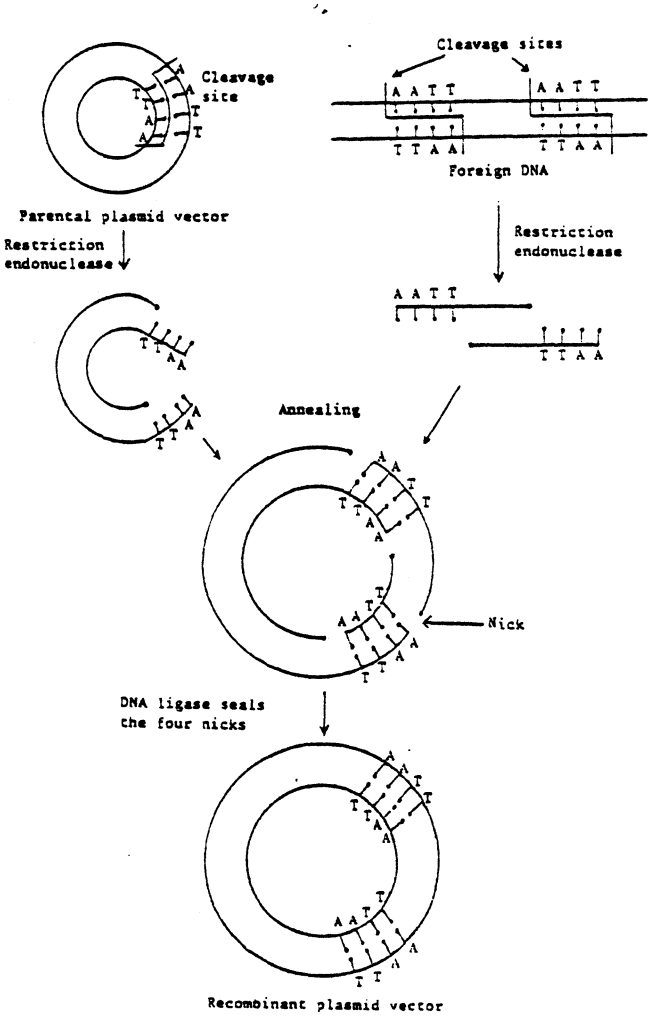
Step (C): Introducing the Recombinant Vector into a Host Cell

Only two of the available methods will be touched on here: transformation and transfection. A recombinant plasmid vector can be introduced into a host cell after the cell wall has been made more permeable by treatment with calcium ions (transformation). Analogously, a recombinant virus vector can be introduced into the host cell (transfection). Transformed and transfected cells differ, *inter alia*, with respect to the replication of the recombinant DNA introduced into the host cell. To date only certain host cells have been used, mainly the bacterium Escherichia coli. Statistically, at most one recombinant DNA molecule per 1,000 host cells is usually introduced during the transformation or transfection of E. coli.

Step (D): Separating the Successfully Engineered cells from the Unwanted Cells

This is a most important step, as the successfully engineered cells and the genetically identical cell populations (clones) obtained by asexual replication from them are always accompanied by a more or less large number—usually a huge surplus—of clones that do *not* produce the desired DNA. The causes are:

(a) the statistically low success rate of the transformation or transfection referred to above and the fact



(fig. 3)

that, in step (C), the following unwanted DNA, for example, has been introduced into the host cell: unmodified plasmid vector (parental plasmids), e.g., those that, although cleaved in step (B) with an endonuclease, were ring-closed without prior insertion of a fragment of foreign DNA or dimerised or the like; or DNA fragments that have been obtained in step (A) by cleaving DNA and which have not been spliced into a vector; and

(b) the fact that, for example, in step (B), i.e., for splicing the desired gene into the vector, DNA mixtures have been used that were enriched with the desired gene

only to a greater or lesser extent, and an undesired piece of DNA has been spliced into the vector, or the desired DNA sequence has not been introduced in the correct orientation.

In the case of (a), the identification and separation of the successfully engineered clones is made possible, for example, by using, in step (B), a parental vector that contains at least two genes W and Z which code for suitable phenotypical traits W and Z of their future host cell, such as the viability in a nutrient medium that contains specific antibiotics W or Z which kill those clones that do not possess these phenotypical traits. If, for example, a foreign gene is spliced into the nucleotide sequence of gene W of the parental vector, the resultant recombinant vector, in contrast to the parental vector, confers on a host cell, which alone is not resistant, resistance only to antibiotic Z but not to antibiotic W. If then the mixture of unwanted and desired clones, on a plate, is exposed first to the action of antibiotic Z and afterwards to that of antibiotic W, it is possible to locate the position of those clones on the plate which are resistant to antibiotic Z but are killed by antibiotic W, i.e., those which contain recombinant vectors. Living clones in the same position as these clones are then obtained from a "replica plate," which has been prepared beforehand as a kind of "copy," and has not been treated with antibiotic W.

The identification and separation in the case of (b) can be accomplished on the basis of a specific activity of the inserted gene or by so-called hybridization methods. For example, the peptide (e.g., insulin) formed in the host cell as a consequence of the inserted gene can sometimes be detected by means of biochemical test methods in positive cell clones, which are then separated from the negative cell clones and further cultured.

Separation by means of hybridization methods consists in treatment with, for example, radioactively labeled probes of DNA that have a nucleotide sequence complementary to the desired DNA and identify and associate with it in the host cell, and which, by means of their radioactivity, indicate in which clones the desired DNA is present.

Step (E): Fermentation of the Successfully Engineered Cells and Isolation of the Fermentation Product

These steps do not differ from the practice long in use when working with strains of microorganisms which have been isolated from nature.

II. General Aspects of Patent Protection in the Field of Genetic Engineering

The rapid development in chemistry has undoubtedly been given added stimulus by the patent laws which, in some countries, existed already at the beginning of this development or were introduced shortly afterwards. It is not surprising that many concepts in patent law, when applied to the field of chemistry, have been given an interpretation appropriate to the circumstances as they were at the time. However, this should not mean that binding precedents have been established regarding the application of these concepts to a new set of circumstances arising out of related, yet independent, sciences such as biochemistry. The application of patent laws to new fields of technology must be, and remain, open to appropriate interpretations, otherwise there is the danger that the patent system will become a straight jacket for these fields and be out of step with the economic realities prevailing in them.

Some aspects of how the patent system applies to the results of research and development in the field of genetic engineering will now be discussed.

The basic question is whether processes using living organisms, or living organisms themselves, can be regarded as falling under the concept of what constitutes a patentable invention. The answer to this question will depend on the respective legal definition of the term "invention" and the interpretation put upon it by patent offices and the courts.

New products and processes of genetic engineering that do not themselves constitute, make use of or modify living organisms are not affected by this basic question. New deoxyribonucleic acids are examples of such products. Such inventions may be classified with ease among the existing categories of invention and are accordingly patentable.

Subject to legal provisions which explicitly exclude living organisms or specific forms of living organisms from the concept of patentable inventions, an assessment of the basic question may start from the following general considerations.

1. Patent Protection for the Industrial Use of Living Organisms

The industrial use of living organisms, such as microorganisms, by man for technological purposes is very ancient. One need only consider the wide range of fermentation processes which were used in the earliest civilizations. Over the last half-century or so, however, the number of such processes and the importance of the products obtained by them has increased at an astonishing rate. One example is the broad field of antibiotics obtained by fermentation and the modification of chemical compounds by means of fermentation methods, such as the structural conversion of steroids. Medicine, in particular, would no longer be conceivable without the results of this development.

There is no reason why these uses and processes should not be patentable. Use is made as a rule of chemical reactions, i.e., of natural forces, and it is immaterial whether these reactions are extracellular, cellular or extracellular under cellular influence.

Such uses and processes, as well as the products obtained by them, have therefore long been patented without reservations in most countries within the scope of the permissible claim categories.

2. Patent Protection for Organisms Per Se

What is the situation as regards living organisms, whether microorganisms in the broad sense, such as bacteria, fungi, yeast, viruses, animal or plant cell lines, protozoa or algae,[1] or plants and animals, as products of a technical process? Do they not come under the customary statutory concept of a product just because they are living or may exist in nature? Do ethical reservations constitute a bar to their patentability? Does their patentability offend against morality?

From the statutory point of view, products may qualify for patent protection if they can be considered as having been made by the work of man in the form in which patent protection is sought for them and if they belong to the technical art in the broadest sense. Living organisms modified by genetic engineering, especially those considered at the present time as belonging to the technical art, e.g., plants and microorganisms, are able to fulfill these conditions.

Where the results of genetic engineering are products which do not occur in nature, the problem of the patentability of natural substances does not arise. But even in those cases where products of genetic engineering are affected by this problem, e.g., new plasmids extracted from existing organisms, it should be possible in accordance with recent opinion[2] to obtain patent protection for these products in their isolated form, as they have not simply been discovered but have been made available to the public as a result of a technical manipulation.

As regards ethical objections, the following considerations should be borne in mind. Product protection comprises the sum of the protection of all uses of the product. If conscientious objections have not been raised against patenting the use of certain living organisms, e.g., microorganisms, then from the ethical point of view there can be no reason why it should not also be possible to obtain product protection for these organisms themselves. Naturally, the proviso must be that all the other conditions necessary for patentability, such as novelty and inventive step, are fulfilled. Economic considerations at the very most, such as considerations regarding the strength of the patent protection to be accorded, may be taken into account. However, no one can doubt that the same considerations which, in many industrially developed countries, have led to product protection for chemical compounds are also applicable to product protection in the field of living organisms. The inventor and research organizations investing in research must be offered in this field the same quality of patent protection as in other fields of technology.[3]

Where genetic engineering—and other fields of technology also—may lead to socially undesirable results in isolated instances, it should be supervised by other means. As circumstances may require, particular inventions of this kind which are contrary to the public interest or morals can be excluded from patent protection under the relevant articles of patent law, but not simply on the ground that these inventions are classified as belonging to the category of genetic engineering.

In accord with these thoughts, the view has become accepted in most highly industrialized countries that living, technically useful organisms obtained by human ingenuity, and especially microorganisms in the broadest sense of the term, may not be excluded from patent protection just because they are living organisms.

As representative of this viewpoint, aside from individual patent laws, there may be cited decisions handed down by the Supreme Courts of the United States of America, Germany (Federal Republic of) and Switzerland, and also decisions of the Australian and Canadian Patent Offices.

For example, the Federal German Supreme Court—after approvingly taking note of the fact that (a) methods of breeding in which growth, properties, yield, etc., especially of plants, are influenced by chemical or physical means, and (b) fermentation processes for the production of foodstuffs and antibiotics, have long been patented—has ruled as follows in connection with a method of breeding leading to a red pigeon[4] (translation):

> "If the methods referred to under (a) and (b) are in principle patentable, then it is only logical that the breeding of animals may not be excluded from patentability solely on the grounds that both the means employed and the result are in the biological field."

The court stated that a claim to the pigeon itself would not have been patentable for other reasons, thus acknowledging its patentability in principle.

This view has been confirmed for microorganisms by the *"Bäckerhefe"* decision[5] of the same Court in connection with the culturing of new species of yeast (translation):

> "If, however, the inventor describes a reproducible method, i.e., one which may be repeated by others with reasonable prospects of success, of how the new microorganism can be produced by an induced mutation or by culturing, then product protection for the new microorganism is allowable."

In a much earlier case, the Swiss Supreme Court ruled on this question in a decision of January 27, 1953,

[1] Cf. with regard to the term "microorganisms" from the patent point of view, Budapest Diplomatic Conference, Draft Treaty, document DMO/DC/3, p. 6, and Guideline Z-100, para. 1.1 of the Swiss Intellectual Property Office.

[2] Cf. *In re Bergy*, 195 UPSQ 344; *Lactobacillus bavaricus, Gewerblicher Rechtsschutz und Urheberrecht (GRUR)*, 1978, p. 586; Hüni, *GRUR*, 1970, p. 9; Utermann, *GRUR*, 1977, p.1.

[3] Teschemacher, *Gewerblicher Rechtsschutz und Urheberrecht, Internationalen Teil (GRUR Int.)*, 1981, p. 357.

[4] *"Rote Taube," GRUR*, 1969, p. 672.

[5] *Blatt für Patent-, Muster- und Zeichenwesen (Bl.f. PMZ)*, 1975, p. 171.

Meilland v. Swiss Intellectual Property Office, [6] in connection with the breeding of roses (translation):

> "Swiss law does not, it is true, exclude the patentability of inventions in the domain of agriculture or horticulture. As the message of the Federal Council to Parliament concerning the revision of the Patent Law states (*Feuille fédérale (FF),* 1950, p. 955), an invention which makes it possible to obtain in this domain a specific result by influencing physiological phenomena, may be considered as a technical invention capable of industrial exploitation and may hence benefit from legal protection."

Finally, the Supreme Court of the United States in its decision in *Diamond v. Chakrabarty* [7] rejected the view that living things may not be comprehended by the statutory concept of "manufacture" or "composition of matter." Accordingly, in the USA living organisms, including plants and animals, may not be excluded from patent protection simply on the grounds that they could not in themselves be patentable products. The Supreme Court ruled in favor of the patentability of novel microorganisms obtained by genetic engineering after it had drawn attention to the non-patentability of natural laws, physical phenomena and abstract ideas:

> "Judged in this light, respondent's microorganism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"

In Australia, the Commissioner of Patents has ruled in the case of *In re Ranks Hovis McDougall Ltd.*,[8] that the objection that a claim for a new microorganism is not directed to a manner of manufacture is too narrow an interpretation of the Statute of Monopolies.

In Canada, the Patent Appeal Board and the Commissioner of Patents considered a cell culture infected with a virus as a patentable product.[9]

One may therefore proceed on the basis that, under the respective patent laws, provided they do not explicitly exclude living organisms from patent protection, and in the absence of a restrictive interpretation of the statutory concept of invention by the courts, technical living organisms constitute in principle patentable subject matter.

Of particular importance with respect to restrictions in the patent laws is the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Convention), which, in Article 2(b), leaves it to the discretion of the Contracting States[10] to exclude from patentability plant varieties and breeds of animals and essentially biological methods of breeding animals and plants. As Teschemacher says,[11] this Convention started from the assumption that a separate system of protection for plant varieties in plant breeding is to be preferred and breeds of animals are not patentable. This exclusion of plant varieties and breeds of animals has to be seen in the light of biology as it then was and will certainly stand in need of revision in view of the latest developments in biology and, in particular, in genetic engineering. However, the Strasbourg Convention makes provision in the second part of Article 2(b) that this exclusion from patentability, if made, may not relate to microbiology in the form of its processes and their products. Whether the unclear formulation of Article 2(b) chosen for this obvious aim was intended to establish the notion that microorganisms are not plants or animals or to nullify the unwanted result of (erroneously) including microorganisms under the term plants or animals[12] remains a matter for speculation. This restrictive optional provision to exclude plant varieties and breeds of animals as well as essentially biological processes for breeding plants and animals was incorporated in the European Patent Convention (EPC) and figures in the same or somewhat modified form in the laws of different States which have been brought into conformity with the EPC.

In view of the generally inexplicit legal situation in other countries and of the few decisions of courts and patent offices, it is difficult to obtain a clear and comprehensive picture of the actual possibilities of obtaining patent protection for living organisms per se. Nonetheless, the results of a WIPO questionnaire (document DMO/II/2) of 1974, and legal or official provisions, do make it possible to provide the following survey of the situation in a number of countries.

Microorganisms should be patentable as products in:

— *Algeria:* Ordinance Relating to Inventor's Certificates and Patents for Inventions, Section 5 (if product of a microbiological process or neither plant variety nor breed of animal);
— *Australia: In re Ranks et al., supra* (indication of a reproducible process is necessary and cannot be replaced by deposit);
— *Bulgaria:* WIPO document DMO/II/2; Law on Inventions and Rationalizations, Section 14 (protection only under inventor's certificate);
— *Canada:* WIPO document DMO/II/2;
— *Czechoslovakia:* WIPO document DMO/II/2; Law on Discoveries, Inventions, Rationalizations and Industrial Designs, Section 28 (protection only under inventor's certificate);
— *Denmark:* Patents Act, Section 1 (if product of a microbiological process or neither plant variety nor breed of animal);
— *European Patent Convention:* Article 53(b); Teschemacher, *supra* (if product of a microbiological process or neither plant variety nor breed of animal);

[6] *Entscheidungen des Schweizerischen Bundesgerichts (BGE).*, 79 I, 77.

[7] 206 USPQ 193.

[8] *International Review of Industrial Property and Copyright Law (IIC)*, vol. 8, p. 453 (1977).

[9] *Re Application No. 086556*, 35 C.P.R. (2d) 56.

[10] At present: France, Germany (Federal Republic of), Ireland, Italy, Liechtenstein, Luxembourg, Sweden, Switzerland, United Kingdom.

[11] *Op. cit.*,

[12] Trüstedt, *GRUR*, 1981, p. 95.

— *Finland:* Patent Law, Section 1 (if product of a microbiological process or neither plant variety nor breed of animal);
— *France:* Patent Law, Section 7 (if product of a microbiological process or neither a plant variety excluded from patent protection nor breed of animal);
— *Germany (Federal Republic of):* Patent Law, Section 2.2; Patent Office Guidelines for Examination 24.6.1981, Chap. V (indication of a reproducible process is necessary and cannot be replaced by deposit; if product of a microbiological process or neither a plant variety excluded from patent protection nor breed of animal);
— *Hungary:* WIPO document DMO/II/2; Law on the Protection of Inventions by Patents, Sections 6(2), 67 to 72;
— *Ireland: Ranks Hovis McDougall Ltd., v. The Controller, FSR,* 1978, p. 588 (if manufactured);
— *Israel:* The Patents Law, Section 7 (with the exception of microorganism existing in nature);
— *Italy:* Law on Patents for Inventions, Section 13 (if product of a microbiological process or plant variety);
— *Japan:* Examination Standard "Applied Microbiol. Industry" (indication of a reproducible process is necessary and cannot be replaced by deposit);
— *Luxembourg:* Patent Law, Section 1(3) (if product of a microbiological process or neither plant variety nor breed of animal);
— *Netherlands:* Patents Act of the Kingdom, Section 3(2) (if product of a microbiological process or neither plant variety nor breed of animal);
— *New Zealand:* WIPO document DMO/II/2;
— *Nigeria:* WIPO document DMO/II/4 (1st supplement to DMO/II/2);
— *Norway:* Patents Act, Section 1 (if product of a microbiological process or neither plant variety nor breed of animal);
— *Romania:* Law on Inventions and Innovation, Section 14 (only State Socialist organizations);
— *South Africa:* WIPO document DMO/II/4; Patents Act, Section 25(3) (if product of a microbiological process or neither plant variety nor breed of animal);
— *Soviet Union:* Statute on Discoveries, Inventions and Rationalization Proposals, Section 21; WIPO document DMO/II/2;
— *Sweden:* Patents Act, Section 1 (if product of a microbiological process or neither plant variety nor breed of animal);
— *Switzerland:* Federal Law on Patents for Inventions, Section 1a; Message of the Federal Council to Parliament (24.3.1976) 5, 68 (indication of a reproducible process is necessary and cannot be replaced by deposit; if product of a microbiological process or neither plant variety nor breed of animal);
— *United Kingdom:* WIPO document DMO/II/2; Patents Act 1977, Section 1(3) (if product of a microbiological process or neither plant variety nor breed of animal);
— *United States of America: Diamond v. Chakrabarty, supra.*
— *Zambia:* WIPO document DMO/II/2.

Microorganisms are not patentable in:
— *German Democratic Republic:* WIPO document DMO/II/2;
— *Philippines: Ibid.;*
— *Poland: Ibid.;*
— *Yugoslavia:* Law on the Protection of Inventions, Technical Improvements and Distinctive Signs, Section 23.

Plant varieties and/or breeds of animals are patentable in:
— *Bulgaria:* Law on Inventions and Rationalizations, Section 14 (protection only under inventor's certificate);
— *Czechoslovakia:* Official Notice 104/1972; Law on Discoveries, Inventions, Rationalizations and Industrial Designs, Section 13(9) (protection only under inventor's certificate);
— *France:* Patent Law, Section 7 (except breeds of animals and the plant varieties which can be patented under the plant variety protection law);
— *Germany (Federal Republic of):* Patent Law, Section 2.2 (except breeds of animals and the plant varieties which can be patented under the plant variety protection law);
— *Hungary:* WIPO document DMO/II/2; Law on the Protection of Inventions by Patents, Sections 6(2), 67 to 71;
— *Italy:* Law on Patents for Inventions, Section 13 (only plant varieties);
— *Romania:* Law on Inventions and Innovation, Section 14 (only State Socialist organizations);
— *Soviet Union:* Statute on Discoveries, Inventions and Rationalization Proposals, Section 22 (protection only under inventor's certificate);
— *United States of America: Diamond v. Chakrabarty, supra;* 35 U.S.C. Section 161 (cf. also Plant Variety Protection Act (Public Law 91-577)); only plant varieties);

Breeds of animals and/or plant varieties are not patentable in:
— *Algeria:* Ordinance Relating to Inventors' Certificates and Patents for Inventions, Section 5;
— *Denmark:* Patents Act, Section 1;
— *Finland: Ibid.;*
— *Israel:* The Patents Law, Section 7;
— *Luxembourg:* Patent Law, Section 1(3);
— *Netherlands:* Patents Act of the Kingdom, Section 3(2);
— *Norway:* Patents Act, Section 1;
— *Poland:* Law on Inventive Activity, Section 2;
— *South Africa:* Patents Act, Section 25(3);
— *Sweden:* Patents Act, Section 1;

— *Switzerland:* Federal Law on Patents for Inventions, Section 1a;
— *United Kingdom:* Patents Act 1977, Section 1(3);
— *Yugoslavia:* Law on the Protection of Inventions, Technical Improvements and Distinctive Signs, Section 23.

Although a positive answer has been given to the basic question of the patentability of technical living organisms, at least of microorganisms, in many countries, there still remain two arguments which, if followed, would in effect make product protection illusory or substantially weaken it.

3. Product Protection Only by Providing a Reproducible Description of a Process of Manufacture?

According to the first argument, a product claim is, in principle, only allowable if a reproducible process for the manufacture of the product, independently of the product itself, can be described, and a publicly available deposit of the living organism with an internationally recognized depositary, as, for example, established under the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, cannot substitute for such description.

This argument has been propounded mainly in the Federal Republic of Germany and Switzerland. In particular, it is invoked in the *"Rote Taube," "Bäckerhefe"* and *"Rosenzüchtung"* decisions referred to above, and in which, as we have seen, the patentability of the living organisms in question was recognized in principle, but the product claim was rejected by the courts in each case.

In the *"Rote Taube"* decision it is said (translation):

> "The problem is here, however, as the extensive conflicting literature shows, *inter alia* in the question to be discussed below under (B), whether the ability to replicate such results of breeding makes the requirement of reproducibility superfluous."

And in the decisions of the Federal German Supreme Court in *"7-Chloro-6-demethyltetracyclin"*[13] and *"Bakterienkonzentrat,"* [14] it is confirmed that the ability to replicate ensured by the deposit does not replace reproducibility. This is also expressed in the German Patent Office's Guidelines for Examination of June 24, 1981.[15]

In the *"Rosenzüchtung"* decision of the Swiss Supreme Court, *supra,* attention is drawn to this matter in a passage which follows on from that quoted previously above (translation):

> "However, in accordance with consistent case law, the invention in question must be capable of industrial exploitation, that is to say, the man skilled in the art shall be able to repeat it in accordance with the procedure disclosed in the description attached to the application."

[13] *GRUR,* 1978, p. 162.
[14] *GRUR,* 1981, p. 263.
[15] *Bl.f.PMZ,* 1981, p. 263.

Guidelines Z-100 of the Swiss Intellectual Property Office relating to "Inventions in the Field of Microbiology," para. 12.1, therefore require under the old law that, if a claim for a microorganism is made, the applicant must show in a credible manner that the method of obtaining the microorganism can be repeated any number of times and must indicate the means. The same applies under the new law (cf. para. 12.4).

The above-mentioned decision of the Patent Appeal Board and Commissioner of Patents in Canada,[16] in which a cell line, although deposited, was not considered as a "manufacture" because a reproducible method of manufacture was not disclosed, is based on the same line of argument. The guidelines in Japan also appear to require the description of the process of manufacture, which interestingly can also consist of a screening method.[17]

Therefore, according to the view expressed by these decisions, when claims are directed to a living organism per se, a deposit which is accessible to the public and guarantees replication shall not be able to satisfy the requirement of reproducibility.

This view is based on the situation prevailing in the field of classical chemistry, in which a new chemical compound, as subject matter of the invention, can of course only be made available to the public by means of a process for its manufacture and not by depositing this material, which is not self-replicating. Hence the requirement that availability must be ensured by describing a repeatable process was right. But if a new field emerges, in which the legitimate interest of the public in having the subject matter of the invention freely available to it for experimental purposes, or for any purpose after expiry of the patent, can be satisfied in another and—for the public—much simpler way, *viz.* by making a deposit of self-replicating material which is accessible to the public, then there is no reason to insist on the requirement of reproducibility of the process. Should opinion in a particular instance be that the new organism is only the result of a discovery of something already existing and not a true invention, the inventor can be required to explain why this is not so. The inventor can fulfill this requirement by showing what means he had to employ in order to obtain the living organism or how this living organism, in the form in which he desires to patent it, differs as a procduct from the existing starting materials used to obtain it, i.e., whether the product to be patented is a "product of manufacture." Making the invention available to the public is a requirement made of the description and is met by the deposit referred to in the description. The question whether there is only discovery is one that concerns the quality of the invention, such as the question concerning other attributes or qualities of the invention, e.g., inventive step or novelty. The achievement of the person who

[16] *Re Application No. 086556,* 35 C.P.R. (2d) 56.
[17] Guidelines Relating to Examination on Inventions for Microorganisms, Chapter I, 2(3) and 5(3).

has made a living organism is one of manufacture and therefore not a mere discovery, regardless of whether he is able to describe the procedure so that others can repeat it or not. What is important is that more is involved than the mere fact that a product has been brought to the attention of the public which unrecognized had been available to it previously in the same form.

The problem has therefore clearly arisen through the unnecessary and incorrect amalgamation of the concept of "availability" and "manufacture as against discovery" in the single concept of "reproducibility."

In addition, the view that the description of a reproducible method of manufacture in the application cannot be replaced by deposit is in obvious contradiction to the fact that, in the same countries, those processes that use a new microorganism as starting material have long been patented, and that the difficulties of identifying those microorganisms and ensuring their availability and, therefore, the reproducibility of their use by means of a description were obviated by depositing the microorganism with a recognized culture collection and making it available to the public from a specific date.

For example, in those countries, deposit of a host organism containing a plasmid would suffice to describe that organism as starting material in a process for extracting the plasmid, but would not suffice for this same organism if it were claimed as a product of the transformation of the host organism with the same plasmid.

The fact is that the voices of those who take the view that making a microorganism available by deposit ought to be able to satisfy the requirement of reproducibility are growing in number. Trüstedt[18] draws attention to the anomaly mentioned above that, while deposit suffices for the micoorganism employed in method of use processes and no description of its manufacture is required, such a description is necessary as soon as this microorganism itself is claimed.

Teschemacher[19] makes the same point and, in view of the availability of the deposit to the public, comes to the following conclusion (translation): "It seems therefore not justified to exclude from product protection microorganisms which the average skilled person cannot obtain for himself in reproducible manner."

Report has it that the European Patent Office too is inclining to this point of view.

The report of the working group of the Swiss Group of the International Association for the Protection of Industrial Property (IAPIP) on the question of "Industrial Property Rights in the Field of Microbiology" and on the partial question of "Protection of Microorganism by Product Claims"[20] is of the same opinion.

It would indeed be unrealistic to cling to the description of a reproducible process in the knowledge that, where a deposit is made and availability ensured, no one will ever repeat this process because the organism can be obtained more easlily.

In the United States of America the question of the necessity of a reproducible description of the process of manufacture did not arise in the decision *Diamond v. Chakrabarty, supra*, and in the dual decision *In re Bergy, In re Chakrabarty*.[21] It may be safely assumed that, in the United States of America, the deposit of a self-replicating organism suffices to support the product claim and a description of a reproducible process of manufacture is accordingly not necessary.

So long as the fulfillment of the requirement of reproducibility by deposit is not recognized, the possibility of product protection for microorganisms which are isolated and cultured from natural sources, in particular from soil samples, will usually be denied, because in the absence of the possibility of an exact identification, and hence of the availability of the natural source, it is hardly possible to repeat these processes by means of a description only. Exceptions are conceivable, for example, the decision *"Lactobacillus bavaricus"* of the Federal German Patent Court mentioned above; the isolation of hereditary material such as plasmids from defined available organisms would probably need to be dealt with in the same way.

As regards the new legal instrument of the deposit as substitution for an adequate description of a replicative material, there is a further but still controversial requirement to be taken into account, *viz.* that of an adequate safeguard, extending into the future, of the availability of such deposit.

In genetic engineering processes for obtaining new living organisms, other living organisms, especially microorganisms, are often used as starting material, whose production is not so unequivocally described in the literature that they can be obtained in absolutely identical form by every skilled person. They can, however, be purchased or obtained from culture collections or are available from scientists.

The question arises whether these organisms, perhaps many of which may be named in a patent application as starting materials or auxiliaries for obtaining the final products, are to be considered as available to the public, or whether each applicant using them has to make a fresh deposit for about 30 years,[22] a term laid down by the Budapest Treaty for microorganisms that are not available to the public. In the Federal Republic of Germany the courts seem to be adopting a conservative approach as in the question of reproducibility, and are dealing with availability in an abstract rather than in a pragmatic and realistic manner. For example, the Fed-

[18] *Op. cit.*

[19] *Op. cit.*

[20] *Revue suisse de la propriété industrielle et du droit d'auteur (Schw. Mitt.)*, 1979, p. 29.

[21] 201 USPQ 352.

[22] At least five years after the last sample has been requested, 30 years as a minimum.

eral German Supreme Court decision *"Erythronolid"* [23] requires the applicant to ensure the future availability of known organisms available to the public at the time of filing the application in the same way as new organisms not available to the public at the time of filing.

This decision is not in accord with the more liberal opinions which may be inferred from the decisions *"Typenbezeichnungen"* [24] and *In re Metcalfe and Lowe.* [25]

4. Is Product Protection in Accordance with the Strasbourg Convention and the European Patent Convention Process Dependent?

The second argument is that Article 2(b) of the Strasbourg Convention and Article 53(b) of the European Patent Convention, and the corresponding national laws, permit only the product claim for microorganisms in process dependent form, which is thus limited in its protective scope. This argument draws its sustenance from a restrictive interpretation of the second part of Article 2(b) of the Strasbourg Convention and Article 53(b) of the EPC, respectively. While the Guidelines of the EPC (C IV 3.5) do recognize the patentability of a microorganism, the opinion is nevertheless often expressed that this protection is "process related," as the Guidelines say, "if they are obtained by a microbiological process." Similarly, the Swiss Federal Council's message to Parliament of March 29, 1976, on the EPC declares that the product of a microbiological process can only be protected in process dependent form.

Such a restriction of product protection to the process is not to be inferred from Article 53(b) of the EPC. This—as previously remarked—not altogether felicitously worded Article merely confirms that inventions in the field of microbiology are excepted from the exclusion provision contained in the first part of the sentence.

Both Trüstedt and Teschemacher (see above) are in this regard in favor of absolute product protection and the previously mentioned report of the working group of the Swiss Group of IAPIP is also of the same opinion.

III. Peculiarities in the Field of Genetic Engineering from the Patent Point of View

1. Problems Relating to the Scope of Protection

In the traditional chemical industry, processes for the manufacture of starting materials always had to be carried out in quantitative correlation to the final products, and the starting materials prepared in the corresponding amount. Patent protection for these processes and products therefore always encompassed in practice the processes carried out and the products manufactured on an industrial scale.

In genetic engineering it suffices to prepare, for example, the desired hereditary material and the vector in the smallest amount sufficient for scientific purposes, to join them in a very small yield to recombinant DNA, to transfer them in a small, but practically sufficient yield to a bacterium and to select from its population a single clone with the desired properties in order to have available the starting material which, without repetition of the previous steps, suffices solely by its replication for the entire future production of the desired final product or result.

This problem is aggravated by the fact that these processes and materials, provided that the methods of carrying out the processes and the production of the materials cannot be described so that others can repeat them, are only patentable—if at all—if the starting materials or final products, respectively, can be deposited with a recognized culture collection in self-replicating form, whereby they are freely available to the public.

It can therefore happen that a first inventor protects, in a patent, the manufacture of a productive microorganism with a specific inventive recombinant DNA, the microorganism itself, and its use for the particularly useful production of a known polypeptide.

A scientist can then repeat experimentally the process described in the patent for obtaining the productive microorganism, or he can obtain this microorganism if it is deposited with a culture collection. He can isolate the recombinant DNA that codes for the production of the polypeptide and carry out further genetic modifications, so that the microorganism transformed with it contains further information that improves still more the production of the polypeptide, while retaining the original DNA sequence. The scientist deposits the new, improved productive microorganism. He has not committed any patent infringement, as the work he has done is purely scientific. A third party then procures this new, non-protected productive microorganism and with it produces industrially the polypeptide in substantially better yield, i.e., more cheaply than the initial inventor and patentee. In doing so, he uses neither the process for the production of the original microorganism claimed by the first inventor nor the protected original microorganism (protected per se or as the direct product of the process). Although the third party has based his entire production wholly on the use of the original protected process or of the protected original organism by the scientist, he has not actually used them himself.

Of course, there is the question whether the use of the improved microorganism for the production of the polypeptide infringes the claim in the patent of the original invention because the improved microorga-

[23] *Bl.f.PMZ*, 1981, p. 418.

[24] Federal Patent Court, *GRUR*, 1978, p. 709.

[25] 161 USPQ 789 (CCPA).

nism still contains, *inter alia*, the same DNA sequence.

Nevertheless, in view of this situation and of similar ones, it seems proper to grant the applicant, from the start, broad generic claims which do not include specific, limiting non-essential features and which do justice to his invention, *viz.*, the manufacture of a general group of production microorganisms containing the specific inventive DNA sequence.

In addition, it must be borne in mind that such inventions are clearly of the kind in which the inventive concept can be realized in a large number of embodiments, each individual realization, however, requiring an excessive amount of effort. It cannot be expected of the inventor, however, that he should put in a disproportionate amount of routine work simply to pack his patent application with further embodiments of the inventive concept.

The inventive concept should therefore be patentable in its application to higher classification units of production microorganisms characterized by their content of DNA comprising the specific DNA sequence on which the invention is based, regardless of the fact that it consequently relates to microorganisms of which perhaps at present only individual representatives are available to the public, or that it has been carried into practice only in one or some individual microorganisms and only with one or some DNA containing the specific DNA sequence. Accordingly, the inventor should be permitted to claim elements of the invention in a functional or general manner, as is not unknown in patent practice in connection with other fields.

Otherwise, in the event of infringement, only an extensive interpretation by the courts of the protective scope of product, process or use claims narrowly drawn to a specific DNA containing the new DNA fragment, to the fragment itself or to particular plasmids and microorganisms respectively containing them would cover other DNA sequences and artificially produced plasmids containing this fragment and expressing its functions, or other production microorganisms containing such plasmids, their production or use, and would thus do justice to the inventor. The reason for such an extension would be that each of those further embodiments of the inventive concept contains this fragment. In this same way, the protection deriving from claims relating to a new plasmid should then extend to all new production organisms designed to contain this plasmid, their production and use. This protective chain based on an essential partial DNA identity would only be interrupted when the metabolic products of the production microorganisms are at issue.

2. Problems with Regard to Publication Prior to Full Protection

As soon as a patent application for a process for producing a new or known productive microorganism is published without full protection, as unfortunately happens in a number of countries; for example, under the EPC and corresponding patent laws, a competitor can repeat the work and obtain the microorganism prior to full protection. For doing so, he is in many of these countries only obliged to pay reasonable remuneration, i.e., something less than damages. If he uses the microorganism and its progeny after the patent has issued, he may still argue that the process has been performed before and that therefore he cannot be prevented from using the particular microorganism clone and its progeny because they are not the product of an act done in violation of an enforceable claim.

If the competitor repeats the work prior to any protective effect of the application, for example, due to an early publication in a scientific paper by the inventor, he might try the same line of argument, i.e., that the particular clone was legitimately manufactured, and its progeny cannot be comprised by the later coming into force of the process protection.

3. Problems Relating to Proof of Infringement

In the instances illustrated above, patent infringement can be determined by analyzing the hereditary material of the infringing form for its content of essential DNA.

The going becomes more difficult for the patentee if he has only been able to patent a process in the field of genetic engineering by means of which either known DNA products, or production microorganisms containing them, are obtained, or which is a generally applicable process. As the third party has to carry out this process only once and with tiny amounts, and the use is not expressed in the hereditary material of the products, his use of the process can hardly be detected, especially as he is not subject to the reversal of the burden of proof provided for in some countries, because the patented process is not one for the manufacture of novel compounds, a prerequisite for such a reversal.

The owner of a patent for a generally applicable process is in an awkward predicament in another respect insofar as he does not enjoy patent protection worldwide. A general method, which is protected in one country, may be used in a patent-free country for the production of a new microorganism, and the product of the microbial fermentation may be imported into the country in which the process is protected. Only the microorganism is the direct product of the method, so that the importation of the fermentation product does not necessarily constitute patent infringement under any law corresponding to the EPC with respect to its Article 64. Also there does not seem to exist a fully applicable decision by the US authorities, clarifying whether such a situation is covered by 19 USC §§ 1337 and 1337a ("Unfair practices in import trade" and "Importation of products made, etc., under process covered by United States patent").

It seems that the "Saccharin doctrine" of earlier days, which developed in British law[26] and extended the protection of process and product claims for starting materials beyond those to the final products, if those processes or the starting materials, respectively, were of qualified importance for the manufacture of the final products, would meet the situations outlined above.

4. The Working Requirement

The special circumstance that genetic engineering methods no longer have to be repeated when exploiting their products industrially also creates problems in assessing whether a patent is being worked—a legal requirement in many countries. Is a patent for a genetic engineering process, or a corresponding product patent for the microorganism, being worked if the progeny of the microorganism once obtained by the process is industrially exploited? Presuming that this microorganism is modified further by a genetic engineering process and is only exploited industrially in this new form, would such exploitation be considered as working of the original patent? These, too, are questions that only the patent office and court practice of the individual countries concerned can answer.

5. Problems Concerning Proof of Utility

In contrast to the EPC as it is interpreted today, utility is required in some countries, especially the United States of America, as a prerequisite of patentability. Where the products of genetic engineering have been made in expectation of complex effects on humans, it will be difficult to prove actual utility in clinical tests already in the application stage. It should be sufficient if the applicant can show that, on the basis of certain in-vitro or in-vivo animal tests, his products are worthy of further investigation in view of their possible ultimate use (*cf. In re Krimmel,*[27] *In re Bergel et al.,* [28] *In re Jolles*[29]).

6. Requirements Made of the Reproducibility of Genetic Engineering Processes

Processes in the field of genetic engineering can often be termed reproducible only by applying a statistical standard. The question arises whether such a process can be regarded as having been described in such a manner that the skilled person can carry it out, i.e., that the process is reproducible. This question must be assessed in accordance with the views of the field of technology in question and not according to standards prevalent in other fields of technology. For example, a process which, statistically, proceeds in the desired manner only to a very small degree, still nonetheless constitutes a process which can be successfully performed by a person skilled in the field in question if a reasonable amount of starting material is large enough for success to occur as a statistical certainty, and if ways are available by means of which the desired product can be separated from the vast majority of unwanted product. In principle, this problem exists also in purely chemical processes, for in these too usually only a statistically determined part of the molecules reacts in the desired manner. However, the experiment is carried out with an amount of molecules such that the desired reaction, in addition to other reactions, takes place as a statistical certainty. The desired product is then separated from the unwanted products by a wide range of mostly physical methods, and success is expressed in terms of yield. A small yield, or the necessity of using large amounts of starting materials in order to obtain even only very small amounts of the desired substance, is normally not considered as evidence of the lack of reproducibility; why, therefore, should this be different in the field of microbiology? And all the more so as—in contrast to the situation in chemistry, where the desired product has to be obtained entirely by the process that affords perhaps only a very small yield—in microbiology it is often only a matter of obtaining a sole clone of the desired self-replicating organism once. This clone can then be selected, after which an amount suitable for further use is readily obtainable by replication.

This has the consequence that the processes of genetic engineering are often carried out in the framework of highly specialized scientific experiments that take place on a minute scale, yet are of great industrial importance. The description of these experiments is intended for suitably qualified scientists and a corresponding skill in experimentation and the requisite specialized knowledge may therefore be postulated. It would be wrong to apply to these descriptions the standards of conventional chemical examples as regards accuracy, for normally biological material is used which cannot be analyzed and standardized as accurately as chemical substances. From the patent point of view, in any assessment of the enablement of the description, greater value attaches in this field to the experimental skill of the expert and to the adaptation of the description that he may be reasonably asked to make to the facts of the particular situation with which he is confronted.

7. Patentable Subject Matter

7.1. New Metabolic Product of Production Microorganisms Obtained by Genetic Engineering

7.1.1. Products. Such metabolic products, for example, polypeptides, are eligible for product patent protection if they are inventive. There are, in principle, a number of possibilities for describing the manufacture of the products in the application.

[26] *Saccharin Corp. Ltd. v. Anglo-Continental Chemical Works Ltd.* (1900), 17 R.P.C. 307; *Wildermann v. F.W. Berk & Co.* (1925), 42 R.P.C. 79; *Beecham Group Ltd. v. Bristol Laboratories Ltd. and another* (1978), R.P.C. 153.

[27] 130 USPQ 215 (CCPA).

[28] 130 USPQ 206 (CCPA).

[29] 206 USPQ 885 (CCPA).

On the one hand, the entire cloning method, starting from known starting materials, may be described in such a manner that the skilled person can perform it. This also includes, *inter alia*, deposit with a recognized culture collection of starting materials which are used in the method and are not available to the public, provided that the preparation of these starting materials cannot be described so that others can repeat it, as, for example, a plasmid used as vector and/or the organism used to obtain the heriditary material to be spliced into the vector. Plasmids can be deposited in self-replicating host cells suitable for deposit.

On the other hand, however, it is also possible to describe only the last process step, i.e., the production of the novel substance by means of the novel production microorganism, in such a manner that others can repeat it, and to deposit the production microorganism with a recognized culture collection, as otherwise it would not be available to the public.

7.1.2. Processes. The process for obtaining a novel inventive metabolic product, e.g., a polypeptide, can be claimed with regard to its last step, *viz.*, fermentation and isolation. It should not be necessary to characterize the process by the use of a specific strain of production organism; it should be permitted to characterize the process generically by the use of a production organism characterized by its content of recombinant DNA which codes for the polypeptide. In this latter case, however, it will be necessary, besides a specific description of the manufacture of a suitable production microorganism or its deposition, to describe sufficiently a general process by means of which such production microorganisms with suitable recombinant DNA can generally be obtained, where this is not obvious to the skilled person as soon as he has knowledge of the necessary DNA sequences on the basis of the (degenerated) genetic code. Deposit of a single strain of microorganisms cannot replace a generic description of the process for obtaining such starting microorganisms since, proceeding from it, only a special embodiment of the process has been described in a repeatable way.

The same considerations apply also to processes for obtaining known products by fermentation of genetically engineered microorganisms, provided that their structure is unknown, so that the necessary DNA sequences, and consequently the microorganisms to be used, are not obvious.

Particular prominence may of course be given in subclaims to processes starting from organisms with special properties important for cloning and DNA sequences which are particularly useful for obtaining the final product.

7.2. Novel Production Microorganisms Obtained by Genetic Engineering

7.2.1. Production Microorganisms as Products. If the invention resides in the feature that it was recognized that a specific DNA sequence imparts to the production microorganism the ability to make a specific product, new or—without knowledge of the structure—known, or to obtain another result, new or—without knowledge of the necessary DNA sequence—known, and if the other requirements for patentability are fulfilled, then a general product claim to all novel production microorganisms which contain this DNA sequence may be justified in view of the opinions expressed in III.1, above.

In the light of the opinion expressed in II.3, above, for individual strains of microorganisms of this kind, a deposit ought to be able to replace the reproducible (repeatable) description of a process of manufacture. In any event, however, the description of a reproducible process of manufacture is probably necessary as regards general claims for such microorganisms which are characterized only by the content of the specific DNA sequence (cf., III.7.1.2).

7.2.2. Intermediates for Obtaining the Microorganisms. Each new DNA containing sequences of the kind referred to in 7.2.1, above, and suitable for insertion into a vector, as well as each and every recombinant DNA containing such a DNA, should be patentable as a chemical substance in accordance with case law on intermediates in the Federal Republic of Germany[30] and in the USA.[31] In view of the clear causality of these intermediates for the inventive property of the production microorganism, patentability should also be acknowledged under the EPC.

The parental vectors used for obtaining the recombinant DNA, which are in themselves genetically nonspecific with respect to the final product, can also be patented as substances, provided that they are novel and can be used in an unexpected manner or with unexpected success in the process for obtaining the productive microorganisms. Functional definitions as to their suitability to form recombinant DNA, with or without additional genes for later selectioning, are deemed to be appropriate.

Novel microorganisms obtained initially for isolating the desired DNA sequences may also be patentable, bearing in mind the points made above.

Particularly suitable embodiments of such subject matter may, of course, also be claimed in sub-claims.

7.2.3. Processes for Obtaining the Intermediates. Depending on case law concerning "intermediates," the processes for obtaining the intermediates described above can be patented individually or in combination with the final steps leading to the desired microorganism. Again it must be borne in mind that it should be

[30] *Bundesgerichtshof (BGH), Dilactame, GRUR*, 1970, p. 506; *BPat-Germ. Chlorepoxyde, GRUR*, 1971, p. 561.

[31] *In re Magerlein*, 202 UPSQ 473 (CCPA).

sufficient to characterize the starting materials by the desired nucleotide sequences or—in the case of the vectors—functionally by their suitability to form a corresponding recombinant DNA, with or without additional genes for later selectioning.

7.2.4. Generally Applicable Methods. Since genetic engineering is a new field, it is possible—more than in other, already established fields—to make inventions of generally applicable methods. Such methods are of course patentable. The important question is how far the claims can extend beyond the area experimentally covered. In answering this question, full credit should be given to the scope of the teaching and its meaning to the man skilled in this art, to a possible pioneering character and to the general considerations already set forth under III.1, above.

7.2.5. Specific Methods and Improvements of Known Methods. These are, of course, also patentable subject matter. Again the relation of breadth of claim to experimental description must be assessed on the basis of the teaching given and the prior art.

8. A Grace Period for Early Disclosures Affecting Patent Protection

In the new field of genetic engineering, progress is more than elsewhere based upon the work of scientists, many of them working in universities. Such scientists are, for understandable reasons, very eager to publish their research results or to communicate them to other scientists at the earliest possible moment. They may not be aware of the fact that their research results may contain patentable subject matter or that patent protection, for economic reasons, is an important factor in the further development of those results towards a practical utilization. Therefore, to ensure that development in this important field will profit from patent protection as much as possible, a grace period for premature disclosure should be provided in the various patent laws on an international basis. Such a grace period should have the effect that any disclosure of a patentable research result should not constitute prior art vis-à-vis a patent application filed later by the inventor or by a party having title to the invention, if that application is filed before the expiration of the grace period. The benefit of this grace period should extend to all applications in other countries which are entitled to the priority of the said application under the Paris Convention.

With respect to the general desirability of such a grace period, it should be remembered that grace periods of various types exist already in the United States of America,[32] in Canada[33] and Japan[34] and in the WIPO Model Law for Developing Countries on Inventions (Section 114 (3) and (4)). The desirability of a grace period was also affirmed in principle by the Congress of IAPIP in Buenos Aires[35] and has recently been advocated by various authors.[36] A meaningful grace period—apart from the case of misuse and exhibition at an international exhibition (Article 55(1) EPC)—was unfortunately not provided for under the Strasbourg Convention and the EPC, so that those countries which had broader savings provisions in their law, e.g., the Federal Republic of Germany, the United Kingdom and Italy, have abolished them and have adopted the EPC provision.

IV. Future Prospects

It is to be hoped that legislation, case law and patent office practice in the field of genetic engineering will take into account the importance of this field for solving urgent problems of our civilization, relating, for example, to medicine, nutrition and the environment, so as to promote this technology by making possible an effective patent protection that will encourage investment in research. In doing so, consideration will need to be given to the peculiarities of the field of genetic engineering and it will have to be borne in mind that applicants in this sector already carry a heavy burden as a consequence of the conditions on which deposited microorganisms are freely available to the public and which, while being very favorable to the public, are in no way commensurate with the material value represented by these microorganisms.[37]

[32] 35 U.S.C. §102 (a) and (b).

[33] Section 28(a) and (b).

[34] Section 30.

[35] *Yearbook*, 1981, p. 274.

[36] See von Pechmann, *GRUR*, 1980, p. 436; Bardehle, *GRUR*, 1981, p. 687; Pagenberg, *GRUR*, 1981, p. 690; and "Period of Grace for Invention Disclosure," *Industrial Property*, 1982, p. 279 (studies by Bardehle, Esaki, Mathély and Smegal, Jr.).

[37] Hüni, *IIC*, vol. 8, p. 499 (1977).

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