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WORLD INTELLECTUAL
PROPERTY ORGANIZATION

INTERNATIONAL UNION
FOR THE PROTECTION OF
NEW VARIETIES OF PLANTS

COMMITTEE OF EXPERTS ON THE INTERFACE BETWEEN PATENT PROTECTION AND PLANT BREEDERS' RIGHTS

Geneva, January 29 to February 2, 1990

COMMENTS RECEIVED BY THE INTERNATIONAL BUREAU OF WIPO
AND BY THE OFFICE OF UPOV ON DOCUMENT CAJ/XXIV/4

FROM THE Acting
COMMISSIONER OF PATENTS

PATENT OFFICE, PHILLIP OFFICES
CANBERRA, A.C.T. 2606
TEL. 83 2000

29 September 1989

Dr Arpad Bogsch
Director General
World Intellectual Property Organization
34 chemin des Colombettes
1211 GENEVA 20 SWITZERLAND

Dear Dr Bogsch

Under cover of your circular letter C.5034-457 dated 16 June 1989 you forwarded to the Australian Patent Office for comment a draft memorandum entitled 'The Interface Between Patent Protection and Plant Breeders' Rights'.

Your note to Governments which you sent on the same day in your capacity both as Director General of WIPO and as Secretary General of the International Union for the Protection of New Varieties of Plants (UPOV) indicated that comments would be considered and taken into account in preparing further documentation and taking such further steps as may be desirable in the preparation of a meeting to be organised by WIPO and UPOV to deal with questions of protection by patent and plant breeders' rights.

In Australia, as no doubt is the case in some other countries where both patent and plant breeders rights systems exist, different Offices and Government Departments have responsibility for patents and plant breeders' rights systems, respectively. The coordination and presentation of comments in the present case has made it seem preferable to the relevant authorities in Australia that the Australian Patent Office should forward to you comments which it has to make on a number of issues raised by the memorandum. In this regard, it is to be noted that the draft memorandum makes it clear that it is a discussion document. The Australian Patent Office comments are set out in the Attachment to this letter.

Insofar as the draft memorandum raises issues which impinge upon current revision proposals concerning the UPOV Convention it calls forth different considerations and competencies. To the extent that the comments made in the Attachment impinge on the current or future revision proposals they are without prejudice to the final position which the Australian Government may take on those revision proposals. An effort has been made to limit comments on the revision proposals but this has not always been possible since the proposals impinge on the patent system.

It may be useful for me to make some general observations on the draft memorandum. The document is not always an easy one to come to grips with and contains a good deal of material that is assertive

and/or argumentative. Also it proceeds very much from the European standpoint of a patent law that excludes plant and animal varieties etc. From the viewpoint of an Office that applies a patent law that does not contain limitations on patentability in relation to plants and plant varieties, there is a good deal of assertion and argument in the document that does not have a firm base. In addition, some of the argument proceeds on the basis of 'one opinion' or 'another opinion'.

The document seems to us to be lacking in clarity and one sometimes feels that it is obscure when important issues underlie what is being discussed. Also, it seems to us that it lacks transparency in that it fails to indicate what it expects will be the subject matter of plant breeders' rights under the current revision proposal. In this regard, we have some difficulty in understanding the full import of the definition of 'variety' particularly in conjunction with other proposals and in this context have looked at what was said in UPOV document CAJ/XXIV/2.

The document does not make it explicit if, and to what extent, what is at issue is the system of protection that should be provided for modern technological developments in the plant field. Uncertainty as to what is the possible subject matter of protection under the proposals for revision of the UPOV Convention compels one to question whether an alternative protection system is being proposed.

WIPO, has, of course, particular responsibilities in relation to the patent system and the protection of inventions. It has a unique position as the proponent of the values of the patent system as the appropriate form of protection for inventive activity taking into account both the private interests of inventors and the public interest in having a balanced system that serves the general cause of industrial development.

As regards protection of inventions, WIPO is accustomed, in general, to present a number of features of the patent system that serve either the private interests of inventors (and industries that rely on the protection of inventions) and the public interest in having a system of protection that promotes early disclosure of inventions, and dissemination of information about them as well as actual access to them. This is to increase the general pool of knowledge, to facilitate further technological advance and to enable competitors to operate in a more certain climate.

Any reference to issues of this kind (there are more, I am sure, than I have mentioned that the International Bureau puts forward when promoting the protection of inventions) seems to be completely absent from the document. This seems to me to raise questions about the document that the International Bureau needs to put to itself since it is responsible for input on patents issues (especially should it be the case that the UPOV Convention revision proposals lead to an alternative protection system for modern technological developments). Does the document (on that assumption) fail to raise the fundamental issues concerning the patent system and what that system seeks to achieve in the general public interest? If the consequence of what is being put forward was that inventions would be kept secret and enjoy prolonged periods of protection by other means, then that surely would be the kind of patents issue that WIPO must insist on being addressed.

If, on the other hand, the nature of the revision of the UPOV Convention does not raise questions of the kind indicated, it is equally as important that this be clearly stated.

Yours sincerely

Murray Haddrick

(E.M. Haddrick)

Attachment to letter dated 27 September 1989
to the Director General of WIPO
from the Acting Commissioner, Australian Patent Office

The Interface Between Patents and Plant Breeders Rights
Comments by the Australian Patent Office

This document identifies assertions regarding the patent system made in UPOV Document CAJ/XXIV/4, dated 3 April 1989, on the interface between patents and plant breeders' rights and subjects them to analysis and comment (referred to in the document as a response).

The analysis and commentary are directed to determining whether the picture of the patent system is balanced and accurate. To the extent that proposals are made to make the UPOV system coextensive with the patent system it will also become necessary to consider in particular those instances where the reach of the patent system is suggested as being wider than is, in fact, the case. This document does not attempt to do this.

Assistance in the preparation of this paper has been received from Dr. Noel Byrne, an expert in intellectual property protection for plants, from the Centre for Commercial Law, Queen Mary College, University of London. All analysis and comment contained within this paper is, however, the responsibility of the Australian Patent Office.

The Conditions for Patentability in Australia

The UPOV document, CAJ/XXIV/4, on the interface between patent protection and plant breeders' rights states at paragraph 30 that the conditions of patentability that must be fulfilled for grant of a patent are novelty, inventive step and industrial applicability.

It is important to note here that Australian law differs from these requirements in that for an invention to be patentable subject matter under Australian legislation it must be for 'a manner of new manufacture'. This term has been the subject of interpretation by the Courts and is understood to mean:

a. new in the sense of being not previously available to the public;

b. inventive in that it is not obvious to a person of ordinary skill in the particular art;

c. useful in economic affairs; and

d. involving the technical intervention of man.

Although these requirements differ from the European concept of novelty, inventive step and industrial applicability, the end results generally are the same.

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D: Impact of the Patent System on the UPOV System.

3. Comment by the Australian Patent Office on the Assumed Situations of Annex II

1. Assertions in UPOV Document, CAJ/XXIV/4 about Patents

A: Inventive Step In Relation To Plant Inventions

I. Assertion

It is asserted in paragraph 31(iv) of the UPOV Document that, historically, doubts existed in some countries as to whether 'the creation of a new plant variety involved an inventive step'. The assertion continues: 'it was sometimes considered to be obvious to a person skilled in the art that the progeny of a cross between variety A and variety B might include examples with improved yield' (emphasis added).

It is also asserted in paragraph 35 that the US Patent Office has difficulty applying its 'non-obviousness criteria' and that in practice it is ignored.

II. Response

A1 Even historically, as the heavily qualified assertion recognises, there were times when it would not have been obvious to a skilled plant breeder in the relevant art that the progeny of a particular cross might yield a particular result.

A2 But even if a particular result might be envisaged by the skilled person, Australian patent law has never predicated a lack of inventive step on the mere possibility of a particular result being a consequence of taking a particular step in the relevant art. That something might be obvious to try is not a ground for refusing to grant a patent, or for invalidating a patent after it has been granted.

A3 An objection to a patent application on the ground of obviousness (or lack of inventive step) cannot be taken by the Patent Office under the Patents Act 1952, although the provisions of the Patent Bill 1989 do allow the examiner to object to 'lack of inventive step'. The objection can, however, be raised in opposition or revocation proceedings. In assessing whether an invention is obvious or lacks inventive step the question is asked whether, having regard to the common general knowledge in the technology concerned, it would have been obvious at the priority date to a person of ordinary skill in the art to arrive at the claimed invention.

A4 The legal principles involved in determining the issue of obviousness are the same irrespective of the technical subject matter of the patent concerned. Determination of the issue is no more complex for plant patents than for other types of patents.

A5 An assertion that all traditionally bred new plants or plant varieties lack inventiveness cannot be accepted for many reasons.

For example:

A5.1 A new plant variety that meets a long identified need may well involve an inventive step. For example, if the creation of a variety of wheat that reaches maturity two days earlier than any other variety fulfils a long felt need in agriculture, it would be hard to deny the inventiveness of the step taken by the breeder of the variety.

A5.2 An inventive step could reside in the hypothesis that the crossing of two known varieties will produce a particular plant. It does not matter that, once the hypothesis has been formulated, it can be put into effect by the well-known technique of crossing and selection. It should be noted, however, that if a patent were granted, it would be granted not for the hypothesis but for the plant produced as a result of implementing the hypothesis.

A5.3 An inventive step can reside in the realisation that a particular flower colour, for example in a carnation, would be a useful product in the cut flower industry. The fact that the desired carnation is then produced by a series of standard crossing and selection techniques would not mean that the creation of the carnation lacked inventive step.

A5.4 An inventive step can reside in solving a technical problem in plant breeding where it was not obvious to breeders in the relevant art that the problem was amenable to solution at the time of invention. For example, a plant breeder working with sunflowers, and desiring to breed by conventional techniques a sunflower variety yielding seed with a particular ratio of linoleic acid to oleic acid, learns from the literature on the subject and common general knowledge in the art that the sunflower material he proposes to work with is unlikely to give that result. In fact, the knowledge that is publicly available says little about what determines at the genetic level the oleic acid content of sunflower seed. The breeder nonetheless achieves the desired result in a new sunflower variety bred by crossing followed by selection among the progeny of the cross (see U.S. Patent 4,627,192 dated 9 December 1986).

A6 The situation for plants has close parallels in other fields of technology where the patent system has functioned for many years. In the field of metallurgy, for example, experimentation occurs with mixtures of metals in different ratios to produce alloys having desired characteristics. An inventive step can lie in the recognition that a particular combination of metals, in the ratios specified, results in the desired characteristics. This can be so even though the individual metals comprising the alloy and the process of combining them to produce the alloy are well known.

B: Plant Varieties - Living Matter And Industrial Applicability

I. Assertion

It is asserted in paragraph 31(ii) and (iii) of the UPOV Document that, historically, there were doubts about the patenting of plant varieties because living matter was a 'product of nature', 'a mere discovery' or 'essentially biological' and as to whether plant varieties were industrially applicable.

II. Response

B1 An assertion that plants lacked 'industrial applicability', if made nowadays, would betray a complete misunderstanding of this criterion. Australian patent law does not expressly require an invention to be industrially applicable in order to qualify for a patent. But it does require that a patent application disclose 'a manner of new manufacture' and be useful in economic affairs.

B2 The High Court of Australia held in National Research Development Corporation v Commissioner of Patents [1959] 102 CLR 252 that an invention was a manner of manufacture if it offered some material advantage and belonged to a useful art, so that its value to the country was in the field of economic endeavour. This decision broadened the scope of statutory subject matter under the Patents Act 1952 to include horticultural and agricultural processes. It might be noted that this decision was followed in a number of Common Law jurisdictions, including the United Kingdom.

B3 The NRDC decision was followed by the Australian Patent Office in 1976 when it allowed a number of patent claims for specific variants of a microorganism: Rank Hovis McDougall's Application (1976) 46 AOJP 3915. That the claims were to living organisms was not a bar to their being regarded as statutory subject matter.

B4 In 1980 the Australian Patent Office issued an official notice to the effect that precisely the same criteria apply to applications involving living subject matter as apply to other subject matter. No distinction is made solely on the basis that the claimed product or process is, or contains, or uses, a living organism. The notice opened the way for the granting of patents for plants, plant varieties and plant components. It is entirely consistent with the NRDC judgment.

(See also paragraph N6 on the exclusion of plant varieties from patentability.)

C: Description of Plant or Plant Variety

I. Assertion

It is asserted in paragraph 31(v) of the UPOV Document that,

historically, there were doubts in some countries as to whether (a) living matter such as a plant or plant variety could be described fully and (b) living matter could be 'independently reproduced by a person skilled in the art without access to the actual living material, the subject of the invention'.

II. Response

C1 Paragraph 59 of the UPOV Document recognises that what historically may have been doubted can no longer be advanced as a general proposition against granting a patent for a plant or plant variety. Science has come a long way since such doubts were first expressed. The law has not remained still either.

C2 The purpose of a patent description is to ensure that the public has access to, and a clear understanding of, the invention. Firstly, it must clearly describe the advance made over the prior art so that interested parties are left in no doubt as to what is new and as to the monopoly covered by the granted patent. Secondly the best method of performance must be clearly and sufficiently described to ensure that the invention is repeatable (for public access purposes) from the written description given. There is no legal requirement for an invention to be 100% repeatable. Rather the repeatability must be such that it is acceptable to a person skilled in the art.

C3 Most chemical and biological processes, for example, are not 100% repeatable, yet this has not barred such processes from the grant of a patent. A fermentation process to produce a desired chemical may not reproduce the chemical every time the process is carried out. Patents for microorganisms, and for processes utilising the life processes of microorganisms, have been litigated before the courts of several countries, yet such patents have not been invalidated for insufficiency of description (the German courts aside until the recent Rabies Virus decision of the F.R. Germany Supreme Court in 1987).

C4 The standard in Australian patent law is clear. Australian patent legislation requires that an invention be described fully, and this description must disclose the best method of performing the invention. The requirement for a full description has been interpreted by the courts to mean that the application must include the best description known to the applicant when he files his application, as advances in technology will result in the availability of knowledge not available at the lodgement date.

C5 In the case of plant varieties, it is Patent Office practice to require an applicant to give a full taxonomic description and photographs of the variety to distinguish it from related varieties, together with an accurate history of the breeding involved, including the clear identification of the parents and any intermediate plants produced along the way. The results of scientific testing, such as, isozyme analysis, DNA 'finger printing' and other comparative means used to distinguish one plant variety from another can be, and are, used in patent

descriptions to further identify a plant variety. This further identification is, however, optional.

C6 For use to be made of the protected plant variety, e.g. for marketing or other purposes, it has to be reproducible in usable quantities. The patentee is entitled to achieve this by methods described in the patent document or by any other methods, not the subject of protection. It follows that the requirement of repeatability (for public access purposes) has no relevance to methods used to reproduce the plant variety for marketing or other purposes.

C7 Concern has been expressed in paragraph 22 of the UPOV Document that some plant varieties created by crossing followed by selection may not be reproduced with sufficient probability. A well known example popular among students of plant genetics is offered by way of support for this concern. It runs thus: if two plants that differ in only 21 gene pairs are crossed and a selection is made from the resulting progeny, the probability of repeating the selection is 2 in 4,399,046,511,104. In the opinion of many commercial plant breeders, this contrived example does not mirror the reality of commercial plant breeding. Moreover, for most sexually reproduced plants, a variety does not consist of a single genotype but of a range of genotypes which produce a phenotypic range characteristic of the variety. Therefore, the example is a gross over-estimate of the difficulty it seeks to support.

C8 Besides some new plant varieties can be recreated by a number of techniques. Some such techniques give a higher probability than others of being able to attain by their use the desired result. For example, the products of controlled mutagenesis or recombinant DNA engineering are reproducible at probabilities acceptable to a person skilled in the art.

C9 There also exists nowadays a well-developed system for depositing biological material (the Budapest Treaty) required for the performance of an invention where words will not suffice.

C10 As regards the patenting of microorganisms, the deposit system for biological materials assists the applicant in providing the best description available together with the requisite assurance. The availability of the deposit is taken as overcoming the problem of repeatability. In principle, there is no reason why a similar system should not be available for plant inventions.

C11 In fact, one is applied to plants. Deposits of plant material are currently accepted by depositories which operate under the Budapest Treaty. For example, the American Type Culture Collection (ATCC) readily accepts plant tissue cultures and seeds; and the Fermentation Research Institute, Japan, accepts plant cell cultures. However, it is not current practice in the Australian Patent Office to accept deposits of plant material to assist in meeting the

requirements of section 40(1)(a) as to the required description.

C12 Where a question arises about whether the deposited material is the same as the variety described and claimed or whether it differs from existing varieties an interested person may choose to grow the plant from a sample and compare it with the patent description and photograph provided, or compare the results of isozyme analysis or DNA 'finger printing' of the deposited material with that of existing varieties. This may be for the purpose of avoiding infringement or for challenging the patent in the courts.

C13 While deposit is not a complete substitute for the descriptive requirements of patent law (the deposited material still has to be distinguished from related biological materials), it has nevertheless been recognised widely as the best assurance possible against a patent issuing on a biotechnological invention without anyone being able to utilise the disclosure.

C14 Although Australia currently accept deposits under the Budapest Treaty for a limited range of biological material, the Australian Patent Office is currently looking at whether a wider range of deposits, for example to include seeds and plant cells, should be possible.

D: Exhaustion of Patent Rights

I. Assertion

It is asserted in paragraph 32 of the UPOV Document that according to one opinion because patent rights are exhausted when goods subject to a patent are placed into the market, this was 'considered to have the effect of nullifying the benefits of the patent when such goods freely reproduce'.

It is further asserted in paragraph 56 of the same document that 'the application of the exhaustion of right principle generally to self-replicating material requires clarification, as well as the rights of patent owners in relation to farm-saved seed, the so-called 'farmer's privilege'; and in paragraph 83 that 'Doubts exist under the patent system concerning the application of the doctrine of exhaustion of rights to plant varieties'.

II. Response

D1 There is no general principle of 'exhaustion of rights' in Australian patent law. It has been observed to us by one expert that in the jurisdictions where the principle applies, both its scope and application tend to be misrepresented unwittingly by advocates who ill-understand it. The UPOV Document, it was suggested, is not immune from this criticism, particularly where, in several places, it speaks of a right being 'revived'.

D2 The opinion referred to in paragraph 32 of the UPOV Document is quite evidently held in relation to Civil Law systems in Continental Europe, in particular Belgium, France, F.R. Germany. and Italy. The Australian legal system and its jurisprudence are part of the Common Law tradition.

D3 Insofar as the principle of exhaustion may need some clarification in the national laws of the Continental European countries just mentioned, the Australian Patent Office does not wish to offer an opinion on the matter at this stage, save to say that it would be surprising if such laws countenanced or encouraged depriving an inventor of reward for his inventive contribution.

D4 The history of patentees' monopoly rights under the Common Law has been of a purposive interpretation, in varying circumstances, of a general statutory formulation of those rights (see paragraph D7) to assure to the inventor adequate protection (for example, questions arising from the importation of products the subject of patents has been dealt with within the general concept of 'make, use, exercise and vend'). Third parties (who in other systems may rely on exhaustion of right principles) are, in general, protected against harsh consequences by the implication of a licence to do those acts which come within the natural contemplation of what a reasonable person would regard as normal in a business environment, in which both the patent system and the normal principles of law, such as those governing the sale of goods, co-exist. An attempt at comprehensive and prescriptive rules generally proves inadequate to provide a more certain basis for commercial relationships.

D5 The paragraphs that follow apply the existing law to the case of self-replicable material, for example, seeds. It needs to be emphasised that the exposition that follows is hypothetical to the extent that, so far as is known, there are no actual cases where patent rights are in existence that are being exercised in the way suggested. The exposition is to exemplify how it is thought that the present law could without change, resolve emergent issues. Also the exposition leaves out of account possibilities affecting the exercise of patent rights that could well emerge were patent rights to be exercised in respect of, for example, field crops. For example, one would imagine a general agreement between farming and seed producing interests that would establish standard conditions of sale applicable to the initial sale of seed which would cover the reproduction of seed for re-use as seed by the purchaser.

D6 Such general conditions could provide an acceptable basis for individual contracts. (Such conditions are, of course, a feature of many commercial spheres of activity.) The conditions in such a standard agreement could well pay regard to the sorts of considerations that have led to the so-called 'farmers privilege' in plant breeders rights legislation, perhaps with some additional reward to the seller either by an additional initial payment or by a subsequent payment.

D7 Under Australian law, the patentee has the exclusive right to 'make, use, exercise, or vend' the claimed invention. If the claims of a patent claim the seeds of a plant variety, that patent is infringed when a third party, without the licence of the patentee, 'makes, uses, exercises or vends' the seeds of that plant variety. However, as a general rule, when any patented article, including patented seed, is sold by a patentee, or with his consent, the purchaser will take it together with a full licence to deal with that article as if it was not patented. This licence is implied by the Common Law and it can be expressly restricted by the patentee at the time of sale. The Common Law could also, in the light of the circumstances of the sale or established usages in the particular trade concerned, imply a licence which differs from the usual implied licence.

D8 The application of the general principles of the previous paragraph require a consideration of the particular circumstances of both the relevant sale and of any established usages in the particular trade. For example, where there is an established trade in grain between producers and millers, if patented seed is sold by a patentee (or with his consent) to a miller, the Common Law would imply that the miller is free to use the grain in the way grain is usually utilised by millers - i.e. for grinding into flour. If, on the other hand, patented seed is sold to a farmer, the Common Law would imply that the farmer is free to utilise the seed in the way that seed is usually utilised by farmers. The farmer would accordingly be able to plant the seed and sell his crop. In Australia it is the established practice of wheat farmers to retain some of the crop for replanting; and the Common Law would (in the absence of an express exclusion by the patentee at the time of sale) imply that the sale of patented seed to wheat farmers would carry an implied licence to follow this established practice.

E: Experimental Use of Protected Varieties

I. Assertion

It is asserted in paragraphs 56 and 83 of the UPOV Document that there is uncertainty as to the application of the experimental use principle of patent law. Two opinions are advanced. First, that any use other than that involved in genuine enquiry to see 'how it works' would infringe the rights of a patent owner to a patented plant or plant variety. Second, that a patented plant or plant variety could be used to breed new plants although commercialisation of a new variety derived from the patented one would require the patent owner's consent.

II. Response

E1 It is clear under Australian law that the use of a patented product or process for genuine experimentation, for example for the purposes of producing a new improved product, does not infringe the patent. Freedom to experiment on and, if possible, improve patented inventions is a cornerstone of Australian

patent law. If the new product satisfies the criteria of patentability, the owner of the improvement can seek a patent for it. A new plant variety derived from the patented variety, under these circumstances, would be expected to have a different genetic profile and taxonomy from the patented variety and be capable of patent protection.

(See also the comments in Item F: Genes as Patentable Subject Matter, paragraphs F3 and F4.)

E2 Where genuine experimentation produces a new variety from a patented variety but the patented variety is not used repeatedly to reproduce the new variety, for example, by reproducing the new variety using asexual reproduction techniques and consequently no impermissible use is made of the patented variety, infringement will not occur. If, however, the commercialisation of the new variety involved the repeated use of a patented variety, a licence would be needed to avoid infringement.

F: Genes as Patentable Subject Matter

I. Assertion

While accepting that a gene or gene construct which satisfies the criteria of patentability should not be denied the benefit of a patent, paragraph 84 of the UPOV Document asserts that a 'general concern exists in relation to genes that are known to be present in a crop species or which are present in existing varieties' (even though they are not known to be present there). Plant breeders, it is asserted, 'could hardly accept that a person cloning and sequencing a gene of this nature could thenceforth claim a total monopoly on its use in the species concerned'.

II. Response

F1 A gene is a chemical compound that has no independent identity in the absence of human intervention. As a chemical compound it is subject matter capable of patent protection.

F2 Under Australian patent law a patent for a new gene per se would only afford protection for the gene that was isolated and/or for that gene when inserted into a host organism. In other words, the patent would not extend to the gene where it occurs naturally in an organism. If, for example, a gene which is responsible for dwarfness in a plant is isolated and patented, the patentee's rights would encompass only the isolate and a host organism wherein the isolate is expressed. This result is attributable to human intervention of a technical nature. The patent right would extend only to such host organisms as the patent specification provides descriptive support for. If, therefore, a patent specification only supports the insertion of a gene into a limited range of plants, then the scope of the patent would extend only to plants within the limited range.

F3 There is no question of a total monopoly being granted under Australian patent law. The extent of a patentee's monopoly is governed by the claims of the patent specification. See also paragraph R2.

F4 An improvement which comes within the claims of an existing patent, however, could not be exploited commercially without the licence of the owner of that patent. Thus the patentee is not able to block further research, but his licence would be required before the improvement could be commercialised.

F5 When it has been characterised, isolated, and sequenced, for the first time, the isolated gene is new. It has not been present in nature prior thereto as an isolate. The mere fact that an observable characteristic in a plant must be due to a gene residing within that plant is insufficient to render the newly identified gene unpatentable by reason that it must be known to have existed.

F6 Where a gene has been previously characterised and is known to exist within a genome it cannot be claimed per se. However, the process of its sequencing, isolation and cloning may be very far from being an obvious step in the relevant art as problems may exist in this process for particular genes. The grant of a patent on the basis of such a step should not be foreclosed on the basis of a concern that, as paragraph 84 of the UPOV Document admits, 'could perhaps be non-existent in practice'.

F7 As paragraph 84 itself recognises, the concern is unwarranted because in practice an examiner would limit a patent claim to what had actually been invented. A patent is granted for what has been invented, no more and no less, and this principle applies as much to genes as to any other invented subject matter.

F8 The requirements in the Australian Patents Act relating to description are satisfied in the case of a gene by detailing the manner of its isolation from the natural source and disclosing the full sequence of nucleotides or the complete sequence of amino acids of the polypeptide and its function coded for by the gene.

F9 Meeting the requirements for a sufficient description of a gene is, therefore, no more difficult than for a chemical compound. Procedures for synthetically producing a sequence of nucleotides are well known and rely on standard techniques. Reproducibility of a gene is not therefore a problem within the parameters of the techniques of genetic engineering.

F10 Moreover, the requirement that an invention must be useful in economic affairs (this is similar to 'industrial applicability' in other countries) could only be met under Australian law by showing the gene applied for can be expressed in a host, whereby a useful product may be produced. The product could be a protein, encoded for by the gene, or a plant

which expresses the characteristic encoded for by the gene, for example, herbicide resistance (resistance to glyphosate).

G: Patents and Plant Characteristics

I. Assertion

It is asserted variously that it is possible to patent a plant characteristic per se. For example, in paragraph 104 of the UPOV Document the suggestion is made that 'the patenting of the characteristics of plants would permit any party establishing a higher level of expression of any one such characteristic in a plant, to make claims in relation to that characteristic which will block further development in that species'.

Further in paragraph 105 it is asserted that 'the issue of claiming 'characteristics' in this way seems to arise in circumstances where the claims in a product patent or in a process patent include what is in effect a plant variety. Plant variety in this context is given a broad general meaning of plant breeding usage which is reflected in the definition set out in paragraph (iii) of the proposal for Article 2 in the UPOV Convention revision proposals'. (This should be a reference to proposed Article 2(ii))

In addition, in paragraph 87 it is also asserted that 'a patent permits claims so that the exclusive right would cover not just the claimed, not yet fixed, material but all future varieties with any characteristic claimed for the non-fixed material'

II. Response

G1 It is asserted in paragraph 105 and elsewhere that a patent claim to a plant is in effect a claim to a plant variety and plant breeders would normally define a variety in the broad terms of proposed Article 2 (ii). This is then put forward as one reason why plant breeders rights should be extended to cover the same scope as a patent claim to a plant.

G2 This reasoning is obviously not supportable. Consider, for example a tomato plant having herbicide resistance (to glyphosate) through insertion of an isolated gene. The term 'tomato plant' would be seen by the breeder as encompassing a large number of individual and distinct tomato varieties. One has only to look at breeder's catalogues to see the large number of varieties commercially available.

G3 It is not possible simply to patent a plant characteristic per se. A characteristic resulting from the insertion of a gene into a plant is a characteristic of the plant itself. It is not a characteristic in isolation. The patent is to the plant having the characteristic resulting from the inserted gene. Accordingly, the assertion, so far as understood, does not represent the scope of patent protection available under Australian patent law. Since the document does not indicate to what patent law the statement is referable, the Australian

Patent Office remains to be convinced as to the validity of the assertion.

G4 Under Australian law, a patent claim to a plant variety per se, with desirable characteristics, is a claim to that plant variety as defined by its particular taxonomy. The patent monopoly does not extend to these desirable characteristics where they occur in other distinct plant varieties, either resulting from plant breeding techniques or occuring in nature.

G5 A patent for the gene encoding for a particular phenotypic trait or characteristic, however, ensures the patentee protection against unauthorised insertion of the isolated, protected gene into plants. The patent would not extend to the characteristic where it occurs naturally in an organism. A patentee has the right to obtain protection corresponding to the inventive contribution made by the invention. To suggest more is to misunderstand the patent system and to misrepresent it.

(See also the comments under Item E: Experimental Use of Protected Varieties and Item F: Genes as Patentable Subject Matter.)

H: Impact of the Patent System on the UPOV Convention

I. Assertion

It is asserted by some plant breeders, according to paragraph 82 of the UPOV Document, that, if patents are granted for plant varieties or for parts of plants which amount, in effect, to plant varieties, this might impair the legal certainty afforded by the UPOV system.

Paragraph 88 of the Document asserts that the availability of patents for plant varieties would have a negative impact on the integrity and reliability of the UPOV system. It would make the work of plant variety protection offices more difficult. It asks whether these offices should amend their practices to take into account what is already happening in the patent system. Should these offices take into account patent applications involving plants, plant varieties and plant components when testing a variety for distinctness under the UPOV system?

II. Response

H1 The authors, in paragraph 88 appear to have overlooked the fact that some countries, the United states and Australia, for instance, already allow patents for plant varieties. In Australia where applicants for patents for plant varieties are required to include a full taxonomic description of the plant, an accurate description of the breeding process and colour photographs of the variety claimed. The Plant Variety Office makes use of patent literature in processing its applications. The Patent Office regularly supplies details of appropriate patent applications. Copies of patent specifications and photographs are supplied upon request.

H2 It is suggested that the concern of the plant breeders is that the availability of patents for plants, plant varieties and other biological material will force them to take account of patents and patent applications before applying for plant breeders' rights. It must be doubted whether entitlement to obtain plant breeders' rights will be affected. But should plant breeders have a claim to privilege in the legal system in respect of monopoly rights? Other innovators cannot proceed in ignorance of existing rights. Indeed, as paragraph 88 of the UPOV Document properly concedes, an applicant for plant breeders' rights needs to take into account all prior art even if it has been disclosed through the patent system. This can only strengthen the criteria applied under the UPOV system, particularly the distinctness and no-prior-marketing requirements.

H3 The paragraph 88 assertion, and the various questions associated with it, might be taken as suggesting that plant variety rights offices do not already take account of patents and patent applications when deciding whether to grant plant variety protection. It is therefore hardly appropriate for paragraph 88 to question whether patent offices have considered or availed themselves of data in plant variety protection offices when examining and granting patents in the plant field. The practice of the Australian Patent Office is set out in paragraph H1.

H4 The question betrays a misunderstanding of the concept of 'prior art' in patent law, and ignores the rule that, if a patent is granted for subject matter already available to the public (either on paper or by prior use) at the priority date of the application on which the patent issues, the patent can be invalidated in infringement proceedings or revoked. That said, patent examiners at the Australian Patent Office have available to them copies of the Australian PVR Journal, since this may be relevant information in the context of applications involving plants.

(See also the comments in the Addendum, Item D)

J: Subject Matter Capable of Protection under the Patent System

I. Assertion

It is asserted implicitly in paragraph 42 of the UPOV Document that, while the UPOV system affords protection only for a physical reality, a plant variety, the patent system allows ideas (albeit ideas of a technical nature) to be claimed as the subject matter for protection. In other words, that a plant variety without reality could be patented. As a consequence, the UPOV Document in paragraph 87 alleges that it would be possible to cover 'not just the claimed, not yet fixed, material but all future varieties with any characteristic claimed for the non-fixed material'. This, it is said, would deter plant breeders from attempting to create a variety with such claimed

characteristic.

It is also asserted in paragraph 86 that the patent system allows incomplete and unrealised inventions to be protected thus enabling claims to characteristics where there is no certainty that a useful variety would emerge.

II. Response

J1 The assertion makes assumptions which do not reflect commercial reality, since one would have to assume that there would be some advantage to be gained from a patent for a 'paper' variety. Although the patent examination process does not require the examiner actually to view the invention, the grant of a valid patent for a hypothetical variety is most unlikely since the application would not be able to meet patent law requirements relating to description including the best method of performance. Such an application would be open to opposition and a patent if granted would be liable to revocation. It is hard to envisage a rational person embarking on such a worthless venture.

J2 If a patent were to be granted for a non-existent plant or plant variety, the patentee could not claim rights to any particular plant. He would therefore be unable to prevent a plant breeder from actually producing a plant or plant variety with the desired characteristic(s).

J3 All areas of inventive activity are potentially open to the patenting of 'paper' ideas, yet it has never been an issue in other areas or industries in Australia. (Defensive publication is generally utilised to cover technology adjoining the area covered by a patent). The plant industry is such that it seems to be not susceptible to this kind of activity which would only be justified by some commercial advantage being obtained.

(See also the comments under Item F: Genes as Patentable Subject Matter, Item G: Patents and Plant Characteristics, Item D: Exhaustion of Patent Rights and the Addendum, Item C.)

K: <u>Scope of Patent Protection</u>

I. Assertion

It is implicitly asserted in paragraph 42 of the UPOV Document that a patent with claims to a plant or plant variety, plant material and plant products would allow the patentee to exact multiple royalties from growers, users or processors.

II. Response

K1 This assertion misrepresents the position at least as it exists under Australian patent law. In the case, for example, of a patent with claims to an orange tree, oranges produced by the tree and the juice obtained from such oranges, the patentee

on selling the orange tree to a grower would take his royalty then or at some later point with the buyer's agreement (e.g. based on how many oranges the tree produced). 'Double taxation', in effect, is not possible under Australian patent law.

K2 The reason why a patent would claim the fruit and the juice is to gain protection against unauthorised propagation of the fruit tree and the sale of the fruits of the infringing act. Otherwise, a propagator could buy a patented orange tree, take it out of Australia, propagate it, and then import the fruit or the juice into Australia thereby robbing the Australian patentee of his proper entitlement. The claims available to the patentee would support an infringement action against the importer, but that in no way amounts to a statement that a patent facilitates multiple royalties.

K3 The availability of this wider protection is what marks the patent system out for many plant breeders as a more desirable way of protecting plant varieties in some countries than under the plant variety protection system there.

L: Problems Perceived by Plant Breeders in Relation to Patents for Plant Innovations

I. Assertion

It is asserted in paragraph 79 that plant breeders as a group have historically had little familiarity with the patent system and for the time being still perceive problems in relation to patents for plants. The assertion forms the basis for discussion of a range of issues, in paragraphs 80 to 88, directed to supporting the assertion.

II. Response

L1 Notwithstanding the fact of continuous activity in the plant field over an extended period, it is insufficient to ignore the impact of modern biotechnological developments in the plant field. Indeed, the assertion first endeavours to tie up into a single group plant breeders using quite different technologies and then attribute to the single group the perceived attitudes of persons who are in fact only a part of that group (which for convenience one might call those following traditional plant breeding methods).

L2 It is not the role of the Australian Patent Office to dissuade plant breeders from using a system with which they feel comfortable. But the Office has, in its contacts with both private enterprises and public institutions using modern biotechnological methods, been left in no doubt that they regard access to the patent system as essential. Those plant breeders oriented towards traditional breeding methods are also, in general, interested in having access to the patent system even if, as a general proposition, they see the UPOV system as one designed to meet their situation.

L3 The kind of discussion provided by paragraphs 80 to 88 tends to require two kinds of response. One is an examination of assertions directed against the patent system and the other is a critical examination of the UPOV system itself. Similarly changes to the UPOV Convention currently proposed would have to be examined to see what weight to attach to the kinds of consideration (e.g. legal certainty) mentioned in Section B, Chapter IV of the UPOV Document. The Australian Patent Office sees its primary task as being to provide a response of the first kind. This is not to say that it is unaware of matters pertaining to the second kind of response which it has included in an addendum to this document.

M: Legal Certainty

I. Assertion

It is asserted variously in paragraphs 80 to 82 of the UPOV Document that, whereas the UPOV system promotes legal certainty, the patent system involves relative uncertainty.

II. Response

M1 The Australian Patent Office has not heard, from Australian plant breeders, arguments of the kind advanced in paragraphs 80 to 82. Indeed, in Australia a significant range of plant breeders have indicated a desire to have the option of using the patent system or the plant variety rights system. While the plant field is not a new field of technology, those breeders who wish to take advantage of modern technological methods are particularly concerned to have access to patents. Breeders using traditional methods also (with some dissentients) want access to the patent system.

M2 If the paragraphs mentioned perceive correctly the advantages of the UPOV system to the plant breeder one would expect the usage of the UPOV system to reflect them without the need to exclude access to the patent system. In the event that the paragraphs mentioned do not perceive all the needs of plant breeders, access to the patent system may enable these needs to be reflected by the use of the patent system.

M3 The Australian Patent Office is wary of the use of generalised propositions of the kind put forward in the paragraphs mentioned as the basis for reaching conclusions to limit the free exercise of decisions by plant breeders such as are possible in Australia at present.

N: Exclusion of Plant Varieties from the Patent System

I. Implication

There is an implication in various parts of the UPOV Document that plant breeders are served better by the exclusion of plant varieties from their patent systems (see, for example,

paragraphs 46 and 47 of the Document). It is stated, moreover, in paragraph 14, Annex I, of the UPOV Document that all UPOV member states are bound by Article 2(1) of the UPOV Convention with the exception of the USA.

Further in paragraphs 101 to 106 it is implied that the scope of plant breeders' rights should be extended to provide the breeder with the scope of protection available to an applicant under the patent system if patents were to be granted for plant varieties per se.

II. Response

N1 Of the 56 countries given in paragraph 47 as having excluded plant varieties from the ambit of their patent systems, only 13 are member countries of UPOV (Austria, Belgium, Denmark, France, F.R. Germany, Israel, Italy, Netherlands, South Africa, Spain, Sweden, Switzerland and the United Kingdom).

N2 Included in the list of countries with the exclusion in their patent laws are a number of developing countries. When these developing countries enacted their present patent laws, they most likely based these laws on the model law prepared by WIPO and this model includes a provision on the exclusion of plant varieties and essentially biological processes. It would not appear that the evolution of events that has occurred has been of advantage to the developing countries in most of which access to a patent office is available.

N3 In the developed countries of Western Europe, several UPOV Member States still afford patent protection for new plant varieties (e.g. France, F.R. Germany). In the United States of America, the position following the Supreme Court decision in 1980 in the Chakrabarty case is that three systems of intellectual property protection are available for plant inventions in the United States. The U.S. Plant Patent Act 1930 (now incorporated in the Patents Code) affords plant patent protection for new varieties of asexually propagated plants, the Plant Variety Protection Act 1970 caters for new varieties of sexually reproduced plants and, following the Chakrabarty dictum that everything under the sun is potentially statutory subject matter, the utility patent provisions of the Patents Code extend to any plant variety that meets the ordinary criteria of patentability'(novelty, non-obviousness, utility and an enabling description).

N4 Hungarian patent law is an example where the legislator states positively that plant varieties and animal varieties are patentable. Prior to the United Kingdom enacting the provisions of the UPOV Convention in the Plant Varieties & Seeds Act 1964, the British Patent Office had no stated position relating to the patenting of plant varieties.

N5 The position within the European Community is such that, because of different interpretations being placed on the exclusion in the national patent laws of the member states, an

amending Directive is currently being discussed. The aim of this Directive, by correcting the existing disparities between the patent laws of the Member States as regards biotechnological inventions, is to remove the barriers to trade in the internal Community market that arise from such disparities.

N6 While it is not for the Australian Patent Office to comment on European patent law, nonetheless it holds the opinion that it would be highly detrimental to Australia and Australian industry if the confusion and problems associated with the exclusion of plant varieties from the ambit of the European Patent Convention system, and national patent laws based on the EPC, were to be imported into Australian patent law through the adoption of a similar exclusion.

N7 The Industrial Property Advisory Committee (IPAC) appointed by the Australian Government to report on 'Patents, Innovation and Competition in Australia' in considering whether to codify patentable subject matter under Australian patent legislation recommended 'that the present threshold of patentability "by reference to section 6 of the Statute of Monopolies" and to the expression "manner of new manufacture" should be retained, without specific legislative inclusions or exclusions'. The Australian Government, in a formal policy response, accepted the recommendation.

(See the Australian Official Journal of Patents, 18th December 1986, pp 1462 - 1480, in particular p 1470.)

N8 As part of its consideration IPAC looked at the approach adopted in Article 53(b) of the European Patent Convention (cf. paragraph 46 of the UPOV document). The Committee rejected codification in the European manner (i.e. Articles 52 and 53) as 'likely to produce more problems than it would solve'. Thus Australian patent law draws no distinction between inventions involving or comprising plants or other biological material, on the one hand, and all other invention on the other.

N9 Where a particular plant variety satisfies both patent and plants variety rights requirements, protection under either or both regimes at the election of the inventor/plant breeder is possible in Australia. There are cases where both sets of criteria can be satisfied. No evil or adverse consequences have resulted from the provision of both forms of protection and, as noted, in paragraph M1 above, a number of plant breeders have expressed the wish that no change be made.

N10 Such multiple protection is not novel in concept. It arises, for example, in the area designs and patents.

N11 As to the assertion that all UPOV member states are bound by Article 2(1), with the result that member states cannot grant patents and plant breeders' rights for one and the same botanical genus or species, the authors of the UPOV Document must have overlooked the fact that, when the Council of UPOV advised that Australian law was consistent with the UPOV

Convention and Australia was accepted as a member state of UPOV on 1 March 1989, the Council had taken a view inconsistent with that put forward in the document.

P: Doubts Concerning the Exercise of Patents for Genes Incorporated into Plant Varieties

I. Assertion

It is asserted in paragraph 73 of the UPOV Document that the UPOV Convention confers a positive right to produce and sell the new plant variety and on this basis the enforceability of patents for genes is questionable.

II. Response

P1 This assertion involves so serious a misunderstanding of the nature of property, including intellectual property, at least in Common Law jurisdictions that it needs to be reconsidered by the authors of the UPOV Document.

P2 Interestingly in the course of argument, the authors refer to Article 1 (which in Document CAJ/XXIV/2 the UPOV Office describes as being 'declarative' rather than 'binding') and to Article 9 which refers to the breeder's right as being an exclusive right.

P3 In Australia intellectual property, whether in the form of a patent or plant variety rights, is the exclusive right to do certain acts. An exclusive right gives the holder no positive right to do anything. Rather it gives him a right to exclude others from doing what falls within the scope of his right of exclusion. This legal principle has been stated throughout Common Law jurisdictions on occasions too numerous to mention. Indeed, paragraph 73 itself refers to 'The free exercise of the exclusive right ...'.

P4 Where a gene is patented and a plant breeder incorporates the patented gene in his variety, assuming the breeder is not also the patentee, he will need the patentee's consent to exploit commercially the patentee's property. This is not open to doubt. It is implicit in the very notion of property. You may not reap where another has sown.

P5 Australian biotechnology companies are adamant on the absolute necessity of patent rights.

Q: Dependency

I. Assertion

In paragraph 95 the authors discuss Article 5(3) of the revision proposal 'that where a variety is 'essentially derived' from a protected variety, the owner of the protected variety may prevent all third parties not having his consent from exploiting the derived variety' without reference to any possible effects

on the patent system. The authors offer the vague assertion that the 'objective of the provision is to reduce the attractions of breeding approaches totally based upon the 'structure' of an existing variety and so remove the most criticised aspect of the present breeders' exemption'.

In discussing the 'collision norm' the authors assert in paragraph 100, that 'if a system of mutual dependence were to evolve it would then be a matter for further discussion whether a dependent party should be able in all circumstances to acquire a compulsory licence under a dominant right' and that ' the parties involved may be the best arbiters of what is reasonable and any interference with their freedom of contract should perhaps be limited to the protection of public rather than private interests'.

II. Response

Q1 The term 'essentially derived' is neither clearly defined nor qualified in the text of Article 5(3) which is not clearly distinguished from the provisions of Article 5(2) and leaves room for more confusion. It is therefore not clear what limits apply to the scope of the term, if any, and when the dependency clause can be invoked.

Q2 It is clear that holders of plant breeders' rights should be able to prevent unlicensed exploitation of a variety where 'derivation' involves mere 'cosmetic' changes in the protected variety and may be used as a means of avoiding the existing breeders right.

Q3 A clear line must be drawn, however, between, this situation and cases where the difference between the original and the derived variety results in a distinct variety with improved characteristics, even where this may simply involve the insertion of one gene into the plant. Where the derived plant variety is quite distinct and involves an inventive step then a new right should be available.

(See also the comments in Item E: Experimental Use of the Protected Variety and paragraphs F3 and F4.)

Q4 The possibility of conflict between patent and plant breeders rights is often raised in the context of patent protection for genes, and there is a tendency to discuss this possibility as though a plurality of property rights was somehow unique to this context. While patent law has various means for resolving conflict that might arise out of the exploitation of a patented monopoly, nonetheless it leaves to the parties involved the resolution of conflicts of interest; it intervenes, in the public interest, very much as a last resort where there is proof of an abuse of monopoly (sections 108 to 112 Patents Act 1952).

Q5 As a general principle, it is preferable that the law should be slow to interfere in commercial negotiation, and it should interfere only where there is clear evidence of an abuse of the

monopoly rights. In patent law practice, as in other areas of intellectual property law, it is rare where there is a conflict of economic interests for the parties to be incapable of resolving it through negotiation.

R: Patent Claims

I. Assertion

It is asserted in paragraph 42 that the patent system allows inventors to specify the scope of protection by the free formulation of claims whereas the UPOV Convention exhaustively determines the scope of protection and in paragraph 101 that the ' potential extension of protection to the product of the variety will cover a significant portion of the scope that might typically have been the subject matter of claims'.

II. Response

R1 The vague reference to 'potential extension of protection to the product of the variety' is presumably a reference to a proposed new Article 5(1) in which protection is extended to 'material of the variety'. The meaning of 'material of the variety' depends on whatever is determined in relation to the definitions in proposed Article 2 of 'variety' ('any plant ..... for the purposes of ..... any form of use') and 'material'. The term material is particularly unclear. It seems that it may include 'harvested material' or even products obtained - directly or indirectly - 'from harvested material'. The scope of the term 'material' could therefore include parts of a plant (e.g. leaves, cells, chromosomes and even individual genes) as well as chemical compounds isolated from the plant or produced from products (including other chemical compounds) of the plant.

R2 The alleged freedom of the patentee to specify the scope of protection has to be understood in a highly qualified sense. The scope of protection is always limited by the inventive step that the inventor has made and this may be a broad step or a narrow step. This is a particular advantage of the patent system in its own context and has the result that the scope of the protection obtained may be broad or narrow in scope, and is dependent on the inventive step described. It is open to question how far it can be used as the basis for change in the UPOV system, a quite different system of protection.

R3 The assertion made in the sentence in square brackets in paragraph 101 would require that a patent for a plant variety should afford to the patentee rights governing the products derived - directly or indirectly - from the protected variety. This follows from the fact that the extended protection suggested for a 'plant variety' under the UPOV system would cover, for example, the products of plant cell in a fermenter such as alkaloids or essential oils.

R4 By comparison a patent for a plant variety would permit claims to be made for the variety, for its reproductive

material, for known (if specified) consumption material that may be directly obtained from the plant variety.

R5 To obtain protection in respect of the products of plant cells in a fermenter, for example, alkaloids or essential oils, a patentee would have been required to have made an invention pertaining to them. For example, the invention would have had to have involved isolation from the plant material a previously unknown alkaloid, essential oils and/or have developed a new process for the extraction or preparation of the alkaloid or essential oil.

R6 The invention of the plant variety and of the new alkaloid mentioned above would be quite separate inventions and separate patents would need to be obtained. (It would be quite exceptional to invent a plant variety having a characteristic which is the source of an unknown product; one would perhaps have to speculate on a eucalypt tree that produces a new form of rubber!!).

R7 What this illustrates is that what is suggested in paragraph 101 not only misrepresents the patent system but on that basis seeks to justify the creation of new monopoly system of a kind hitherto unknown for the purpose of protecting industrial property. As a reward system, the patent system confines the reward to the contribution made by the inventor whereas under the proposed new system there is no such relationship between the reward proposed for the plant breeder and the breeding contribution. Indeed, this extensive reward would be provided even where the breeding contribution was of the most mundane and pedestrian character.

S: <u>Application of the Patent Cooperation Treaty</u>

The following assertions are made regarding the PCT:

It is asserted that the PCT:	Where made
- is not relevant	Appendix 1; UPOV member State excluding Plant Varieties etc., Examples A and B, Column 4.
- might not be fully available if the whole plant is considered to be a plant variety	Appendices 1 and 11; UPOV member State excluding Plant Varieties, etc. Example B, Column 3; UPOV member State without exclusions, Example A and B, Column 3.
- might not be fully available in the case of a plant variety	Appendix 11; UPOV member State without exclusions, Example B, Column 4.

- is not available in the case of a plant variety	Appendices 1 and 11; UPOV member State excluding Plant Varieties, Example A, Column 3. UPOV member State without exclusions, Example A, Column 1.

It is asserted in paragraph 47 'that Rule 39 of the PCT Regulations establishes that no International Searching Authority shall be required to search an international application if and to the extent to which its subject matter is ..... plant or animal varieties'.

II Response

S1 There is nothing in the PCT to exclude its application in relation to plants or plant varieties. Given that the PCT is a vehicle by which nationals and residents of PCT Contracting States may file applications in or for those States, there is no Contracting State for whose nationals the PCT is 'not relevant' in an absolute sense in relation to plants and plant varieties, i.e. as a vehicle for protection in those Contracting States where it is available. PCT Articles 17(2)(a)(i) and 34(4)(a)(i) specify two conditions in relation to exclusion of international search and preliminary examination:

(i) subject matter not required to be searched or examined under the regulation;

(ii) a decision by the relevant authority not to search or examine in the particular case.

S2 PCT Rule 39.1 to which reference is made in paragraph 47 (and PCT Rule 67 to which reference is not made) specify plant varieties in this context. It follows that it is open to all authorities to search or examine in any particular circumstance. Failure to search or examine has no consequence as regards patentability in any designated PCT Contracting State.

S3 While the various references to the PCT may not be wrong <u>per se</u>, the body of the document fails to deal with the PCT in an adequate manner to reflect when it is available in respect of plants and plant material.

T: <u>General Comment on Annex II</u>

T1 In paragraph 3 of the document it is said that 'Annex II analyses examples of possible assumed situations concerning the protection of innovations in the plant field ..... with indications, for the purposes of discussion, of possible consequences'.

T2 Each of the 4 so-called 'Assumed Situations' does not comprise a factual situation but consists of a list of possible changes to the patent system or the plant breeders' rights

system or both and the 'Possible Consequences' that are identified do not solely consist of a description of factual consequences having a casual relationship to the 'Assumed Situations' but include what can only be taken as the arguments of the authors of the document as to the merits, or lack of them, flowing from the changes included in the lists. The merits, or lack of them, are in some instances based on assertions made in the main body of the UPOV document so that the reasoning of the 'Possible Consequences' is only tenable to the extent that the assertions are sustainable. It will be seen from the comments made above that many of the assertions are regarded as questionable.

T3 It appears that the 4 Assumed Situations have as their origins:

First Assumed Situation: current proposals for the revision of the UPOV Convention;

Second Assumed Situation: "Suggested solutions' put forward in WIPO document BioT/IV/3 (with the addition of the converse of the 4th change listed under the First Assumed Situation');

Third Assumed Situation: 'All the changes mentioned in the First and Second Assumed Situations' (the authors of the document appear to have resolved the apparent conflict between the first part of the 4th change listed under the First Assumed Situation and the 1st change listed in the Second Assumed Situation in favour of the latter: see comments appearing under the heading 'Consequences').

Fourth Assumed Situation: Not obvious but one assumes that the changes listed represent the view prevailing amongst the authors as to what they would like to see happen. (Certainly the 'Consequences' suggest that 'all in the garden would be roses'.)

T4 The main body of the UPOV Document contains little if any discussion of issues bearing directly on the 'suggested solutions' put forward in the WIPO document BioT/CE/IV/3. This gives rise to difficulties in dealing with the 'suggested solutions' in Annex II.

T5 Set out below is a table which generally relates assertions made in the main body of the UPOV document and the corresponding comments of the Australian Patent Office to the comments appearing under the 'Consequences' sections of each of the 'Assumed Situations'.

TABLE

See also the comments made in the Addendum to the Australian Patent Office text.

Assumed Situation	**Australian Patent Office Text**
First Assumed Situation	Item F: Genes as Patentable Subject Matter Item G: Patents and Plant Characteristics Item M: Legal Uncertainty Item N: Exclusion of Plant Varieties from the Patent System Item P: Doubts Concerning the Exercise of Patents for Genes Incorporated into Plant Varieties Item R: Patent Claims
Second Assumed Situation	Item B: Plant Varieties - Living Matter and Industrial Applicability Item C: Description of Plant or Plant Variety Item D: Exhaustion of Patent Rights Item F: Genes as Patentable Subject Matter Item G: Patents and Plant Characterisatics Item M: Legal Uncertainty Item Q: Dependency
Third Assumed Situation	See comments for the First and Second Assumed Situations.
Fourth Assumed Situation	See comments for the First Assumed Situation, and Item D: Exhaustion of Patent Rights. Item E: Experimental Use of Protected Varieties. Item H: Impact of the Patent System on the UPOV Convention. Item J: Subject Matter capable of protection under the Patent System. Item L: Problems Perceived by Plant Breeders in Relation to Patents for Plant Innovations. Item Q: Dependency.

2. Addendum: Comment about the Interaction of the Patent and Plant Breeders Rights Systems.

(see paragraph L3 above)

A: General

A1 The two systems should be seen as complementary with a small degree of overlap rather than as competing for the power to grant intellectual property rights for plant varieties. A small degree of overlap is not unknown in other areas of intellectual property law, as witnessed by patent law and the law relating to the registration of novel designs.

A2 The more strict criteria of patent law, particularly as regards novelty, would exclude from the patent system many plant varieties that would qualify for a grant of breeders' rights under the UPOV system. The additional requirement for inventive step in the patent system represents a hurdle that more pedestrian results of plant breeding will not be able to overcome. Such results will be protectable, if at all, under the UPOV system. Thus, while a few varieties may qualify for protection under both the patent system and the UPOV system, others will be confined to one system.

A3 Paragraph 80 lists desirable features of an intellectual property system, and claims that the plant breeders' rights system emerges well from a review based on these criteria. One European expert has suggested to his audience at a lecture in Australia that the arguments put forward in this paragraph ignore the beneficial impact that the seed laws in the countries of the European Community have on the breeders' rights system there. UPOV does not of course recognise this impact when it debates the breeders' rights system, but it remains the view of many European plant breeders that without the seed laws (National Lists and EEC Common Catalogue) far less success could be claimed for the UPOV system.

B: Legal Certainty

B1 The Australian patent system has operated for over 80 years to the satisfaction of its users. The patent systems of some other countries have operated for at least 200 years, again with a considerable degree of user satisfaction. No system of the type that concerns us here will totally satisfy all of the users all of the time. The UPOV system could not claim such a record.

B2 It has been suggested to the Australian Patent Office by one expert that the uncertain scope of plant variety protection in some countries, arising in no small part from the distinction that is made between reproductive material and consumption material, involves considerable uncertainty as regards the legitimacy of certain activities. This has been a matter of serious concern for some plant breeders.

B3 The same expert has commented that the relative absence of

litigation in relation to plant variety protection may be explained in terms of the cost of mounting infringement proceedings and the low values involved in many aspects of plant breeding. Many users of the plant breeders' rights system tend to be small enterprises in business in a small way employing only a handful of people. Even the largest plant breeding enterprises are small in comparison with, say, a typical medium-sized engineering firm. Put simply, the cost of mounting litigation against infringers is prohibitive for a majority of plant breeders who use the UPOV system. But that does not imply user-satisfaction or indeed legal certainty.

B4 Uncertainty about any legal system must be expected until users become familiar with how to operate the system. The plant variety protection system is no different in this regard from the patent system. The patent system has a virtue of being more widely known , its rights are better understood and it has a flexibility to adapt to changing technological conditions in order to provide adequate protection for technological developments (witness how the patent system has adapted to cater for developments in biotechnology), thereby providing incentive for future developments.

C: Time Scales/Subject Matter Capable of Protection under the Two Systems

C1 The possibility of 'paper' varieties is discussed under Item J: Protectable Subject Matter under the Patent System. Under the UPOV system it is possible for an applicant to apply for protection for a non-existent variety. Between the filing date of an application and the time when material is made available to the authorities for testing, the applicant is often working on the material to bring it up to the standard required for the grant of protection. So, in that sense, the UPOV system could entertain applications for non-existent varieties.

D: Impact of the Patent System on the UPOV System.

D1 The granting of patents for plant varieties might also strengthen plant variety rights in ways yet to be seen. For example, the UPOV system has a standard of universal novelty in the distinctness and no-prior-marketing criteria, but it has been said that in the practice of plant variety protection offices this standard is rarely applied. Universal novelty is the norm for most patent systems.

D2 In Australia, the patent and plant variety rights systems have co-existed for a short period without there being any evident weakening of either system.

3. Comment by the Australian Patent Office on the Assumed Situations of Annex II (See Item T above)

A. First Assumed Situation.

a. Proposed change 1.

This change is acceptable.

b. Proposed change 2

This change is acceptable on the understanding that, although undefined, 'variety' retains its present meaning under the UPOV Convention, i.e. that variety, as limited by Article 4(1), Article 5(1) and Article 6, is in effect limited to distinct plant variety in the botanical sense (a rank subordinate to species but above the category form in the taxonomic hierarchy).

(See also comments under Item G: Patents and Plant Characteristics and Item R: Patent Claims.)

c. Proposed change 3

This change is acceptable on the understanding that the term 'essentially derived' clearly relates to protection against using the protected variety as the basis for new varieties which represent insignificant developments of the protected variety and, further, that such a change would be compatible with the provisions of proposed Article 5(2), in particular proposed Article 5(2)(iv). It is not at all clear as to what is meant by this term and it is also difficult to see how it would work in practice. It would be necessary to define the term in a precise and clear manner.

(See also comments under Item Q: Dependency)

d. Proposed change 4.

It must be questioned whether Article 2(1) in its present form has the effect indicated in the UPOV document in the light of the circumstances surrounding the acceptance, by the Council of UPOV, of the compliance of Australian law with the UPOV Convention.

(See also the comments under Item N: Exclusion of Plant Varieties from the Patent System, in particular paragraph N8.)

The 'collision norm' is without justification, at least in its present form.

(See also comments under Item M: Legal Uncertainty, Item P: Doubts Concerning the Exercise of Patents for Genes Incorporated into Plant Varieties and Item Q: Dependency.)

B. The Second Assumed Situation.

a. Proposed change 1

Plant varieties and essentially biological processes are already allowed patent protection in Australia.

(See Item B: Plant Varieties - Living Matter and Industrial Applicability, Item C: Description of Plant or Plant Variety and Item N: Exclusion of Plant Varieties from the Patent System.)

b. Proposed change 2 and 3

Under Australian patent law these proposed changes are unnecessary and undesirable. No objection is held, in principle, to other systems achieving by other means the same result as can be achieved under Australian patent law.

A claim to a process, under Australian patent law, only provides protection for the process itself and not to the product per se. Where the invention is to a process, it is normal to include a claim to 'the product whenever produced by that process'. This then provides protection for the product of the process.

These proposed changes would appear to include the case where a known plant is produced by a new process. To extend protection in this way would give a patentee rights to what is old. This is obviously unacceptable. If the process results in a new plant variety then it would be normal to claim the new variety per se. If the new process resulted in a known variety, then there is little reason to give the patentee a right to protection for future generations of the variety.

(See also Item D: Exhaustion of Patents Rights.)

c. Proposed change 4.

This proposed change appears to be directed to the patent protection of genes and their expression in plants.

It is not clear why it is seen necessary to extend present patent law, as the principle is quite clear under Australian law which allows the patenting of new isolated genes per se and plants containing these genes.

This change therefore appears to be unnecessary.

(See also comments under Item F: Genes as Patentable Subject Matter and Item D: Exhaustion of Patent Rights.)

d. Proposed change 5.

A change of this kind would not appear to be relevant in the Australian context. So far as understood, the change would achieve a result consistent with our understanding of Australian law.

(See Item D: Exhaustion of Rights.)

e. Proposed change 6.

The subjection of patent rights to compulsory licences (even in the guise of dependency licences) is considered unacceptable.

While Australian law has various means for resolving conflict that might arise out of the exploitation of a patented monopoly, nonetheless it leaves to the parties involved the resolution of conflicts of interest; it intervenes very much as a last resort where there is proof of an abuse of monopoly (sections 108 to 112 Patents Act 1952).

As a general principle, and this applies to conflict between plant breeders rights and patent rights as well, it is preferable that the law should be slow to interfere in commercial negotiation, and it should interfere only where there is clear evidence of an abuse of the monopoly rights. In patent law practice, as in other areas of intellectual property law, it is rare where there is a conflict of economic interests for the parties to be incapable of resolving it through negotiation.

C. The Third Assumed Situation

The Australian Patent Office is of the opinion that the 'Third Assumed Situation' is closest to the Australian situation as it accepts the patentability of plant varieties. The comments made in respect of the 'Changes' listed in the First and Second Assumed Situations would need to be accommodated.

D. The Fourth Assumed Situation

a. Proposed change 1

See comments under Part A - First Assumed Situation.

b. Proposed Change 2.

This change is unacceptable to the Australian Patent Office as Australian law currently allows patenting plant varieties *per se*.

c. Proposed change 3.

On the understanding that proposed change 2, above, is unacceptable the same comments apply here as to Part B.b.

d. Proposed change 4.

Again, on the understanding that proposed change 2 is unacceptable, the same comments apply here as to Part B.c.

e. Proposed change 5. See the comments under Part B.d.

f. Proposed change 6. See the comments under Part B.e.

PLANT VARIETY RIGHTS OFFICE

L88/2776

Mr B Greengrass
Vice Secretary-General of UPOV
34 Chemin des Colombettes
1211 Geneva 20
SWITZERLAND

18 October 1989

Dear Mr Greengrass

In the joint WIPO/UPOV memo of 16 June 1989 comments were sought on the document CAJ/XX1V/4 The Interface Between Patent Protection and Plant Breeders' Rights.

The position on the interface question has not been finalised in Australia. The comments in this paper are those of the Plant Variety Rights Office and are for discussion to assist with the development of future policy. The Australian Patents Office has commented separately through the International Bureau of WIPO.

Yours sincerely

K ADAMS
Registrar of Plant Variety Rights

Department of Primary Industries and Energy,
GPO Box 858, Canberra 2601 Telephone: 062 716472; Fax: 062 723650
Printed on Australian Recycled Paper

THE INTERFACE BETWEEN PATENT PROTECTION AND PLANT BREEDERS' RIGHTS

GENERAL COMMENTS

The Interface paper outlines the benefits of the breeders' rights systems and the difficulties of applying patents to varieties per se. This has drawn strong rebuttal from proponents of the patents system, providing a detailed analysis of both sides of the debate.

While recognising the early stage of the debate it would seem appropriate to clearly define the objective of a joint UPOV/WIPO meeting and to examine the range of options arising from the diverse views presented so far.

It is now generally accepted by various legal systems that living material is the proper subject matter of a patent if it meets the usual criteria. Many proponents of the patents system for plant varieties take the view that the patents legislation should not be limited except by the courts and should be available to give breeders the widest choice. Many also wish to limit the scope of the breeders' rights scheme irrespective of new technologies in variety development. These arguments seem inconsistent with an objective of giving the user as wide a choice as possible.

The interface paper raises several basic issues:

1. Should patents be available for plants or more specifically, plant varieties per se?

2. Can breeders rights and patents coexist to provide protection to meet the differing needs of users? If so should breeders rights be strengthened and expanded to all aspects of the plant variety to provide choice to a wider range of users?

3. Is it more effective to have an integrated system for protection of different aspects of plants rather than separate systems; if so how is the interface defined?

The ultimate aim is to stimulate rather than stifle plant breeding and this should not be lost in the academic debate about what each system may or may not be able to do.

In assessing the answers to the above questions the reasons for the original introduction of breeders rights must be examined for continuing relevance. Breeders rights laws exist because of a perceived failure of the patents system to take into account specific policy issues relating to plants. Such failure is also seen in relation to integrated circuits where special legislation is being developed to provide a more limited form of protection.

The interpretation of "invention", "repeatability", "new manufacture" and "non obviousness" to plant varieties, have not been extensively tested, as utility patents have not been widely available for varieties in most countries.

Many expert plant breeders (cf genetic engineers) consider that if the criteria were applied in the strict sense very few varieties per se would be eligible for a patent.

In Australia there have been 16 patents granted on varieties per se since 1983 and 28 breeders rights granted between February and October 1989. Many of the PVR applicants are from other countries where breeder's rights are the norm and the system is understood. In addition many of the varieties may not have met the patent criteria. A patent attorney indicated at a recent Workshop that many of the early patent applications were lodged in the absence of PVR, and the latter may have been used if it had been available.

This experience can either support the argument that there is no problem with the two systems coexisting as applicants will choose the most appropriate means of protection, or that there is no need for the two systems and an integrated approach to intellectual property for plants would be more efficient.

The debate hinges on the inherent advantages of the breeders rights systems in terms of certainty of scope and criteria, preciseness of description, the advantages of an international network using the same criteria and the relevance of the policy issues which resulted in the introduction of breeders rights in the first instance. These must then be compared with the possible advantages and disadvantages of two coexisting forms of protection for the same entity.

Many of theses issues have been addressed by the interface paper and in some cases are being modified by the proposed changes to the UPOV Convention.

OPTIONS

There are two extremes in relation to future directions

1) breeders rights and patents develop independently to the fullest extent possible providing alternative systems to meet the perceived differing needs of plant breeders.

1) total differentiation between the two systems, with plants being excluded from patent law.

Between the extremes there are several options. There is general agreement in most circles in Australia that genes processes and processed products which meet the patent criteria should not be excluded from patents. Similarly the breeders rights system would not be extended to cover these areas. The main area in doubt remains the plant varieties per se.

Options include:

a) retaining the current situation in Australia where varieties are eligible for a patent if they meet the normal criteria,

b) excluding varieties developed using known techniques from patentability under the definitions of inventions, new methods of manufacture or non obviousness.

c) excluding sexually reproducing plants from eligibility under the repeatability or enablement provisions of patent law - even deposit may be hard to justify for sexual reproduction.

d) including in patents varieties per se if they form part of the manufacturing process of a new product but only when used in that way.

e) excluding varieties per se as the subject of a patent.

There may be other options or a combination of the above.

This issue cannot be resolved without considering the policy factors that induced Governments to introduce breeders rights' legislation.

These factors include the need for:

- farmers exemption
- use of protected variety for private purposes
- free exchange of germplasm
- clearly defined scope of the right
- applicability of DUS criteria
- exhaustion of right
- international compatibility
- areas of perceived failure of the patents system in relation to plant varieties

In Australia these issues are again being considered now that breeders' rights legislation is operational.

SPECIFIC COMMENTS

SECTIONS 1 & 11

The first sections of the document deal with the nature of plant breeding and highlight the concept that existing plant varieties provide the basic tools for the development of new varieties. It also emphasises that the phenotype of a plant variety is not fixed and varies with environment and management practice. Therefore the only true method of determining whether a plant variety (ie the combination of genetic characters) is different is in comparative field trials under the same conditions.

It should be emphasised that written descriptions have limited meaning when distinguishing between two varieties unless the exact growth parameters are described or the new variety has been compared with existing varieties growing under the same conditions.

However new methods of genetic characterisation will allow valid descriptions based on genome rather than phenome in future and this may be sufficient to distinguish varieties for legal purposes. Policy decisions in relation to interpretation of the results and minimum distances will need to be made.

SECTION 111

This deals with the reasons why governments took the policy decisions to establish separate intellectual property rights for plant varieties based on difficulties meeting the patent criteria.

The USA introduced plant patents for asexually reproduced plants. It is interesting that it was limited in this way and can be used to support the argument that it is difficult to meet the patent repeatability criteria for sexually reproduced plants due to segregation. It is also important to recognise that this is not a true patent system as distinctness is the major criterion and the scope is limited to the plant variety per se.

When addressing sexually reproduced plants the USA introduced specific plant variety protection legislation. Since that time the industrial patents system has accepted plant varieties per se and it would be interesting to know to what extent it is used.

Some countries exclude plant varieties from patent law and the reasons given in the European Patent Convention were that the plant variety protection laws already existed in many countries and that at that time it was considered that patenting living material would be too difficult for the new European system.

These would hardly seem to be valid reasons for excluding plant varieties from patent laws and more emphasis could be given to reasons individual countries had the exclusions prior to the Patent Convention.

Emphasis should also be given to the reasons why governments felt that the patent system was not applicable to plant varieties and whether those policy considerations are still valid, particularly in the light of the proposed UPOV revisions.

The use of the patent system in France and Germany is only for species not covered by breeders rights and has not been used extensively. Reasons for this could be explored and expanded.

In Hungary plant varieties are patented using simlilar criteria to the UPOV system and in fact Hungary is a member of UPOV on this basis.

Para 53 establishes that countries could grant patents for varieties of species not covered by the breeders rights system. Presumably this was to fill the gap and ensure that at least some form of intellectual property was available for these species (usually of lesser commercial importance). The breeders rights systems were limited to commercially important species due to the expensive trial ground infrastructure. This issue is now being addressed by the increased use of applicant testing.

Para 51 (a) states that if "variety" is limited to the genetically fixed form and patents are available for other plant components and forms, breeders may find it impossible to distinguish between a plant and a variety. If this is the case then the default should be that it is a variety. Such a situation would be unusual if the normal disciplines of plant breeding and taxonomy are followed even if biotechnological process are used.

SECTION 1V - CURRENT DEBATE

GENERAL COMMENTS

Inventive Step in Relation to Plant Inventions

In most cases the outcome of traditional plant breeding can be predicted by anyone skilled in the art as long as they play the numbers game. The uncertainty is how long it will take to reach the desired result. It has

been stated that it would be hard to deny the inventiveness of the breeder who develops a wheat variety maturing two days earlier; many plant breeders would question the true inventiveness of such a development. It is usually incremental progress using well established techniques and procedures that would be obvious to anyone skilled in the art.

Repeatability

This is an issue that many expert plant breeders do not believe is clearly established. It is stated that repeatability must be acceptable to a person skilled in the art. With many out crossing species the probability of reproducibility is such that it would not be accepted by a person skilled in the art. Therefore it appears to be misleading to state that there is not a problem with the use of patents for plant varieties in this respect. The example given in the UPOV paper may overstate the odds but even the chance of 1 in 1000 would be a low rate of repeatability for someone skilled in any art form.

Microorganisms reporduce asexually as do many plants. Such cases are more likely to meet the criterion than sexually reproduced plants and this is one reason why the USA limited its plant patent law to the former and saw fit to introduce plant variety protection laws for the latter. Engineered plants may also have a higher probability of repeatability.

Description and Distinctness

Written descriptions of plant varieties have little meaning for precise identification unless the growth parameters are specified and the characteristics are described relative to comparative varieties grown under the same conditions. The PVR Office uses descriptions supplied by the Patent Office for initial screening and still requires the inclusion of the patented variety in comparative growing trials. Our experience is showing that there is often variation from the description in the patent.

The major concern is the lack of scientific certainty with the patent description compared with the comparative data supplied for PVR. There will always be some difficulty in repeating the precise characteristics but relativities under specified conditions usually remain constant.

Applicants for breeders rights would need to take account of patents granted for plants as the chances are that the varieties are now common knowledge and if similar to the PVR applicant variety would need to be distinguished. Similarly applicants for patents on a plant variety would need to take account of applications for breeders rights.

The deposit of a sample of material may meet the "enablement" provisions but does not describe the variety for the public at large. If a tissue culture is deposited, how is it determined whether this is the same as the variety described in the patent claim and whether it differs from existing varieties. This issue is raised throughout the UPOV paper.

Experimental Use of Protected Varieties

Many plant breeders see the need to make genetic material available without restraint for use in the development and commercialisation of further new varieties. Germplasm is the basic tool of plant breeding and breeders claim that availability for experimentation is not sufficient if commercialisation of the final product can be limited by the original patent holder.

Limited dependence as proposed by UPOV may be acceptable if the definitions can be clarified.

Extension of the Breeders Rights System

The extension of the scope of breeders rights as proposed by UPOV would still result in clearly defined scope, based on the DUS characteristics rather than the more open ended and arbitrary criteria for patent description based on individual claims. The essential elements that make the breeders rights systems specifically applicable to plants would still exist.

The use of "utility" patents for plant varieties per se is a matter of policy and a decision for indivisual governments, rather than a question of law.

Doubts Concerning the Exercise of Patents for Genes

Patenting of genes is generally accepted in Australia and it is important that there is mutual dependence between plant breeders rights and patents.

Farmers' Exemption

The farmers' exemption is still an important issue in Australia for sexually propagated varieties. The government believes that it is necessary to retain the exemption until breeders rights have been in place for sufficient time to assess the implications of the exemption. If any change is made, it will be after full consultation and probably on a genus by genus basis.

INSTITUTE OF INVENTIONS AND RATIONALIZATIONS INRA

1156 SOFIA G.A.NASSER 52b PHONE 71291 TELEX 23412 INRA BG

99-07-243/21.09.89

Dr. A. BOGSCH
Director General, WIPO
Secretary General, UPOV
World Intellectual Property
Organization
34, chemin des Colombettes
1211 Geneva 20
SWITZERLAND

Dear Dr. Bogsch,

Reference is made to your letter of June 16,1989 whereby you invited our country to express its opinion on the Memorandum concerning "The Interface Between Patent Protection and Plant Breeders' Rights" prepared by UPOV Office and the International Bureau of WIPO.

To begin with, the Bulgarian side expresses its satisfaction with the Memorandum. This is really a very competently worked out document which gives an overall and perfect picture of the current situation in the field of protection of new varieties of plants. The Memorandum contains an analysis of the substance of the problems treated and a historical review of the development of new varieties of plants protection. It treats also the merits and drawbacks of the present forms of protection, the problems arising during their application, especially those regarding the new development of the biotechnological science and researches, as well as the possibilities and the advantages of the different forms of legal protection of new varieties of plants.

Undoubtedly, such an extensive research as the Memorandum will be very helpful to all UPOV countries or those that are not members of UPOV in analyzing the problems of legal protection of new varieties of plants. Therefore, we express our gratitude for the preparation of the Memorandum to Dr. A. Bogsch, Director General of the World Intellectual Property Organization and Secretary General of the International Union for Protection of New Varieties of Plants, and through him to all [illegible] who participated in working out the Memorandum.

In our country, the operative Inventions and Innovations Law provides for legal protection of new varieties of plants through granting author's certificates to the breeders who have created them, i.e. they are excluded from legal protection through patents. This situation causes many difficulties to a great number of Bulgarian breeders working at different research institutes and organizations in our country, who are engaged in scientific researches and experiments for creating new varieties of plants in all branches of agriculture, e.g. cereals, fruits, vegetables, tobacco, etc. Our country encounters the same difficulties in the lawful use of original foreign varieties of plants.

On account of the above-recited reasons during the past years discussions have been carried out in Bulgaria for an amendment to the national patent legislation, as well as for a possible adherence of our country to the UPOV Convention.

At present, it is being worked intensively on the preparation of a new Inventions Law which will provide for the introduction of legal protection of new varieties of plants through patents. At the same time, the possibility is discussed of acceding to the UPOV Convention. The Memorandum of UPOV Office and WIPO International Bureau will be very helpful to us in solving the problem of legal protection of new varieties of plants in our country by giving us extremely useful information and orientation on the experience of the other countries in the field of the legal protection of new varieties of plants. Based on the analysis

in the Memorandum of the different forms and systems of legal protection of new varieties of plants, we will probably adopt a combined form of legal protection, i.e. through patents on one hand and protection of the breeders' rights on the other hand. Thus we aill use the merits of the two systems and their scope of protection for a most comprehensive legal protection of all varieties of plants created in a different way, including the methods of the biotechnological science.

Sincerely yours,

T. Toshev
Deputy Director General

The Permanent Mission of Canada to the United Nations

La Mission Permanente du Canada auprès des Nations Unies

NOTE NO 5684

The Permanent Mission of Canada to the Office of the United Nations at Geneva presents its compliments to the World Intellectual Property Organization (WIPO) and has the honour to acknowledge receipt of its Note No C.5033/U.1456 of June 16, 1989 concerning the Interface Between Patent Protection and Plant Breeders' Rights.

The Permanent Mission of Canada wishes to inform the World Intellectual Property Organization (WIPO) that its request has been forwarded to the appropriate Canadian authorities who have made the following comments on the UPOV Doc. CAJ/XXIV/4 :

" Regarding paragraphs 14 and 15 on pages 3 and 4 of Annex 1, Canada does not provide explicitly in its Patent Act for the exclusion of either plant varieties or essentially biological processes, although both have been held unpatentable.

The Fourth Assumed Situation described on page 4, Annex II, covers many of the concerns which have been raised in Canada regarding the interface between patent protection and plant breeders' rights. However, it would be helpful to set out in detail all of the situations of concern and then explain how this option would affect such situations. Similar detail on the other assumed situations in Annex II would also be useful. The ultimate objective should be to establish a system which balances the needs of plant breeders, genetic engineers, variety sellers and variety users so that no sector is disadvantaged ".

The Permanent Mission of Canada avails itself of this opportunity to renew to the World Intellectual Property Organization the assurances of its highest consideration.

GENEVA, September 27, 1989.

DER BUNDESMINISTER FÜR ERNÄHRUNG, LANDWIRTSCHAFT UND FORSTEN

Der Bundesminister für Ernährung, Landwirtschaft und Forsten
Postfach 14 02 70, 5300 Bonn

An das Büro des
Internationalen Verbandes zum Schutz
von Pflanzenzüchtungen
34, chemin des Colombettes

CH 1211 Genève 20

Ihre Nachricht	Mein Zeichen	Tel. (0228) 529-1 Durchwahl 529-	Bonn
	312-1850	3644	03.10.1989

Überschneidungsmöglichkeiten zwischen Sortenschutz und Patent;
hier: Einzelne Fragen zum Verhältnis zwischen Patent und Sortenschutz

Sehr geehrte Damen und Herren!

Im Einvernehmen mit dem Bundesminister der Justiz übersende ich als Anlage eine Aufzeichnung der deutschen Delegation hinsichtlich einzelner Fragen zum Verhältnis zwischen Patent und Sortenschutz, die in offener Weise Probleme aufzeigt, ohne schon Lösungsvorschläge zu enthalten.

Ich wäre Ihnen dankbar, wenn Sie eine erste Erörterung der Fragen in der Sitzung des Verwaltungs- und Rechtsausschusses vom 11. bis 13.10.1989 ermöglichen könnten.

Mit freundlichen Grüßen
Im Auftrag

Burr

Dienstgebäude
Rochusstraße 1, Bonn-Duisdorf

Telex
8 86 844

Teletex
2 28 36 55

Telefax
529-42 62

Telegrammanschrift
bundesernährbn

Einzelne Fragen zum Verhältnis zwischen Patent und Sortenschutz

1. Allgemeine Fragestellung

Das Patentrecht und das Sortenschutzrecht sind voneinander unabhängige Formen des gewerblichen Rechtsschutzes, die zwar gemeinsame Prinzipien aufweisen, hinsichtlich des Schutzgegenstandes, der Schutzvoraussetzungen und der Schutzwirkungen aber unterschiedlichen Regelungen unterliegen (siehe dazu im einzelnen UPOV-Dokument CAJ/XXIV/4).

Das Sortenschutzrecht beschränkt sich auf den Schutz von Pflanzensorten im Sinne von Beständen belebter botanischer Materie. Das Patentrecht erfaßt dagegen allgemein Erfindungen, üblicherweise als Lehren zum technischen Handeln bezeichnet, und schließt nach inzwischen überwiegender Auffassung auch solche Erfindungen nicht von der Patentierbarkeit aus, die sich auf belebte Materie beziehen. Lediglich Pflanzensorten (und Tierarten) sowie im wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren sind nach Artikel 53 b des Europäischen Patentübereinkommens und dem nationalen Recht einer Anzahl von Staaten von der Patentierung ausgeschlossen.

Der trotz des vorgenannten Ausschlusses bestehende rechtliche Berührungsbereich zwischen beiden Schutzsystemen warf keine Probleme auf, solange die Schaffung von Methoden und Ausgangsmaterial für die Züchtung von Sorten im wesentlichen z.T. in der Hand der Wissenschaft und im übrigen vor allem in der Hand der Züchter lag, die für das Ergebnis ihrer Arbeit, die Sorte, den Sortenschutz erhalten können.

Neue Entwicklungen auf dem Gebiet der Biotechnik, einschließlich der Gentechnik, werden zunehmend dazu führen, daß in Wirtschaftsbereichen außerhalb der Züchtungsunternehmen Erfindungen gemacht werden, die für die Züchtung und die Nutzung von Pflanzensorten relevant sind. Soweit für solche Erfindungen Patente erteilt werden, stellt sich die Frage, in welcher Weise sich solche Patente auf die Ausübung der im Sortenschutzrecht

...

geregelten Befugnisse auswirken und inwieweit sich daraus das Bedürfnis nach einer präziseren Abgrenzung der Anwendungsbereiche beider Systeme ergibt.

Dabei wird davon ausgegangen, daß beide Systeme für ihren jeweiligen Anwendungsbereich spezifische Vorteile haben und deshalb so aufeinander abgestimmt sein sollten, daß sich möglichst ohne Überlappungen aber auch ohne Schutzlücken ein Gesamtsystem des gewerblichen Rechtsschutzes für belebte Materie (im Pflanzenbereich) ergibt.

Versuche zur Klärung dieser Fragen werden sowohl in der WIPO (siehe die Suggested Solutions des Committee of Experts on Biotechnological Inventions and Industrial Property) als auch in der UPOV (siehe Vorschlag des Verwaltungs- und Rechtsausschusses für eine Revision des Internationalen Übereinkommens zum Schutz von Pflanzenzüchtungen, im folgenden UPOV-Übereinkommen genannt) unternommen.

Einzelne Fragen, die noch nicht befriedigend gelöst zu sein scheinen, werden nachfolgend zur Diskussion gestellt. Die Darstellung der Überschneidungsbereiche erfolgt dabei vor dem Hintergrund des bestehenden Doppelschutzverbots des UPOV-Übereinkommens sowie des derzeit geltenden Patentierungsausschlusses für Pflanzensorten.

2. <u>Schutz von Pflanzen oder Pflanzenteilen (außer Pflanzensorten)</u>

Da das Sortenschutzrecht im Pflanzenreich nur "Pflanzensorten" schützt und das Patentrecht nur diese von der Patentierung ausschließt, wird die Auffassung vertreten (siehe Suggested Solution Nr. 6) und auch zum Teil von den Patentämtern praktiziert, daß Pflanzen und Pflanzenteile dem Patent zugänglich sind, wenn sich der Patentanspruch nicht ausdrücklich auf eine Pflanzensorte bezieht.

In diesem Zusammenhang sind folgende Fragen zu erörtern.

...

2.1 Begriff der Sorte

Für die Handhabung der genannten Ausschlußregelung stehen die Patentämter vor der Frage, unter welchen Voraussetzungen sie einen Pflanzenbestand als "Sorte" ansehen müssen. Hier wird seit einiger Zeit teilweise die Voraussetzung des Begriffs "Sorte" nur dann angenommen, wenn der Pflanzenbestand die Voraussetzungen des Artikels 6 des UPOV-Übereinkommens erfüllt, also im konkreten Falle nach dem Sortenschutzrecht schützbar ist. Das Sortenschutzrecht selbst enthält eine solche Festlegung nicht. Ebenso wie im Patentrecht der Begriff der "Erfindung" nicht erst dann erfüllt ist, wenn feststeht, daß für sie ein Patent erteilt werden kann, geht auch das Sortenschutzrecht davon aus, daß eine Sorte nur unter bestimmten Voraussetzungen geschützt werden kann und Pflanzenbestände nicht deshalb die Eigenschaft einer "Sorte" verlieren, weil sie im konkreten Fall eine Voraussetzung für die Erteilung des Sortenschutzes nicht erfüllen und daher nicht schützbar sind.

Akzeptiert man, daß für Patentierungszwecke der Sortenbegriff anders gesehen wird als im Sortenschutzrecht, so stimmen der Anwendungsbereich des Sortenschutzrechts und der genannte Ausschluß von der Patentierbarkeit, die nach der legislativen Absicht aufeinander bezogen sein sollen, möglicherweise nicht mehr überein. Es kann dann der Fall eintreten, daß für Pflanzensorten zwei Schutztitel zur Wahl stehen und zwar für solche, die die Voraussetzungen des Artikels 6 des UPOV-Übereinkommens erfüllen, der Sortenschutz (mit dem - bislang - eingeschränkten Verbietungsrecht) und für diejenigen, die hinsichtlich dieser Voraussetzungen bestimmte schutzhindernde Mängel aufweisen, das Patent (mit dem weitergehenden Verbietungsrecht).

Für Pflanzensorten hat der Gesetzgeber aber im Sortenschutzrecht bislang aus agrarpolitischen Gründen bestimmte Benutzungshandlungen (z.B. die allgemein freie Nutzbarkeit der Sorte als genetische Ressource für die Züchtung neuer Sorten und die grundsätzlich allgemein freie Verwendbarkeit von Erntegut der Sorte für Konsum- und Verarbeitungszwecke) von den Schutzwirkungen ausgenommen. Diesem legislativen Zweck könnte es zuwiderlaufen, wenn auf dem Wege über das Patent bisher schutzfreie Räume für bestimmte Sorten doch dem Verbietungsrecht aus einem Patent unterworfen würden. Andererseits stellt sich die Frage, ob die möglicherweise

...

hohen Aufwendungen für den Erfinder oder Züchter im Bereich biotechnologischer Forschung nicht eine Erstreckung des Patentschutzes oder eine wesentliche Verstärkung der Schutzmöglichkeiten durch den Sortenschutz erfordern.

In diesem Zusammenhang entsteht folgendes besondere Problem:

Auf Pflanzenmaterial gerichtete Patentansprüche können so formuliert sein, daß ihnen nicht zu entnehmen ist, ob die betroffenen Pflanzen in sortenspezifischer Weise genutzt werden sollen, also faktisch eine Pflanzensorte darstellen. Häufig werden sich Pflanzen überhaupt nur in sortenspezifischer Weise praktisch nutzen lassen, insbesondere durch fortlaufende Vermehrung zu einem Bestand von Pflanzen mit gleichen Anbau- oder Verwertungseigenschaften. Wenn man vermeiden will, daß durch entsprechende Anspruchsformulierung trotz des Patentierungsausschlusses praktisch Patente für Pflanzensorten erlangt werden können, stellt sich die Frage, ob und inwieweit die Wirkungen eines etwa erteilten Patents nicht eintreten, soweit das Material sortenspezifisch genutzt wird, und somit faktisch ein Patent für eine Pflanzensorte erteilt worden wäre.

2.2 Schutz von Pflanzenteilen

Pflanzen werden üblicherweise derart genutzt, daß ihre Teile jeweils einer spezifischen Verwendung zugeführt werden (z.B. Vermehrungsmaterial zum Anbau, Erntegut zum Verzehr oder zur weiteren Verarbeitung, Restmaterial, wie z.B. Stroh, zur technischen oder betriebsinternen Verwendung).

Das UPOV-Übereinkommen regelt in Artikel 5 derzeit mit verbindlicher Wirkung nur das Erzeugen, Feilhalten und Vertreiben sowie in gewissem Umfang das Verwenden des Vermehrungsmaterials. In Artikel 5 Absatz 4 werden die Verbandsstaaten aber ermächtigt, einen weitergehenden, also auch auf andere Teile oder Erzeugnisse der Pflanzen der Sorte erstreckten Schutz vorzusehen. Einige Verbandsstaaten haben von dieser Möglichkeit bereits Gebrauch gemacht. Im Vorschlag für eine Revision des UPOV-Übereinkommens ist vorgesehen, den Schutz unter bestimmten Voraussetzungen obligatorisch auf weiteres Material der Sorte zu erstrecken.

...

Die - von einem Teil der interessierten Kreise zur besseren Amortisation ihrer Aufwendungen mit Nachdruck geforderte - Patentierung von Pflanzenteilen könnte zu der Situation führen, daß entweder einzelne Pflanzenteile einer Sorte einem weitergehenden Schutz unterworfen werden, als ihn das Sortenschutzrecht - bislang - vorsieht, oder daß trotz der Tatsache, daß nur die für die Nutzung einer Sorte vorrangig wichtigen Pflanzenteile (z.B. Saat- oder Erntegut) zum Gegenstand des Patentanspruchs gemacht werden, praktisch ein Patent für die ganze Sorte erlangt wird. Hier stellt sich dann ebenfalls die Frage hinsichtlich der Erteilbarkeit und der Wirkungsweise eines Patents für den Fall, daß die Pflanzenteile in einer Weise genutzt werden, die für sortenspezifisches Material typisch ist.

3 Schutz von Verfahren

3.1 Schutzform

Es ist anerkannt, daß "technische" Verfahren zur Züchtung von Sorten dem Patentschutz zugänglich sind. Auch Verfahren zur Nutzung pflanzlicher Materie sind grundsätzlich patentierbar. Insoweit dürfte unstrittig sein, daß ein Patent erteilt werden kann für eine Lehre, vermittels der

- ein neues Taxon geschaffen werden kann
- Pflanzen eines an sich bekannten Taxons in bisher nicht bekannter Art gewonnen, genutzt oder mit neuen Eigenschaften versehen werden können.

Ein Sortenschutz wird dagegen nur für das Ergebnis eines Züchtungsprozesses, die Pflanzensorte, unabhängig von der Art und Weise ihres Zustandekommens, nicht für das Verfahren erteilt

3.2 Patente für Züchtungsverfahren

Ein Verfahrenspatent erstreckt sich in einer Reihe von Staaten auch auf das durch das Verfahren unmittelbar hergestellte Erzeugnis. Bei Anwendung der herkömmlichen Patentgrundsätze wäre im Falle eines Züchtungs-

...

verfahrens wohl nur die erste aus dem Züchtungsprozeß hervorgehende Generation von Pflanzen oder Pflanzenteilen als "unmittelbares" Verfahrenserzeugnis zu betrachten. Die rein biologische Vermehrung des Erzeugnisses dürfte dagegen dazu führen, daß die zweite Generation und weitere Generationen nicht mehr als unmittelbares Verfahrenserzeugnis angesehen würden.

Dies bringt bei selbstreplikabler Materie Probleme für den Patentinhaber. Anders als bei technischen Gegenständen muß zur fortlaufenden Gewinnung des Verfahrenserzeugnisses das geschützte Verfahren nicht ständig erneut angewandt werden. Weitere Erzeugnisse der durch das Verfahren hervorgebrachten Art (Pflanzen und Pflanzenteile) können vielmehr durch Nutzung der biologischen Vermehrungsfähigkeit des botanischen Materials gewonnen werden, die Anwendung des patentierten Verfahrens ist hierfür entbehrlich.

Es ist deshalb der Vorschlag gemacht worden (siehe Suggested Solution Nr. 8), daß sich ein Verfahrenspatent auf alles Material erstreckt, das auf Material zurückgeht, das ursprünglich aus dem patentierten Verfahren hervorgegangen ist.

Hinsichtlich solchen Materials, das die begrifflichen Voraussetzungen einer Pflanzensorte erfüllt, würde eine solche Handhabung im Ergebnis faktisch eine Möglichkeit zur Patentierung von Pflanzensorten über den Schutz des patentierten Verfahrens - gleichfalls mit der in Nr. 2.1 Absatz 3 aufgezeigten Wirkung - eröffnen.

Es stellt sich die Frage, ob die berechtigten Interessen des Erfinders eines Züchtungsverfahrens eine solche Erweiterung der Schutzwirkungen erfordern oder ob die für die Entwicklung des Verfahrens aufgewandten Kosten auf andere Weise amortisiert werden können.

3.3 Patente für Verfahren zur Nutzung von Pflanzen

Patente für Verfahren, durch die die Nutzung von Pflanzen generell oder von Pflanzen einer bestimmten botanischen Art für bekannte Zwecke allge-

...

mein verbessert wird (z.B. neue Konservierungs-, Extraktions- oder Backverfahren), dürften ebenso unproblematisch sein wie solche, durch die allgemein für Pflanzen einer botanischen Art neue Verwertungsbereiche (z.B. die Gewinnung technischer Rohstoffe) erschlossen werden.

Eine spezielle Fragestellung kann aber dann entstehen, wenn die Anwendbarkeit des Verfahrens davon abhängt, daß die Pflanzen oder Pflanzenteile spezifische Eigenschaften haben (z.B. einen Inhaltsstoff in einer bestimmten Konzentration), die nicht allen Pflanzen der betreffenden botanischen Art gemeinsam ist. In diesem Falle würden vom Patent nur bestimmte Pflanzenbestände innerhalb einer botanischen Art, also u.U. auch Pflanzensorten erfaßt.

Die Handlungen, die hinsichtlich einer Pflanzensorte dem Schutz unterliegen, sind im Sortenschutzrecht unter Berücksichtigung der Interessen des Züchters und der Allgemeinheit abschließend, ohne die Möglichkeit der Anspruchsformulierung durch den Züchter, aufgezählt. Alle anderen Benutzungshandlungen sind - bisher - für jedermann frei. Diesem legislativen Zweck könnte es zuwiderlaufen, wenn es möglich wäre, bestimmte, vom Sortenschutzrecht bislang nicht erfaßte Handlungen hinsichtlich der Benutzung einer Sorte (z.B. Benutzung als genetische Ressource zur Züchtung neuer Sorten, Verwendung des Erntegutes für Konsum- oder Weiterverarbeitungszwecke) dem Verbietungsrecht aus einem Patent zu unterwerfen.

Es ist deshalb die Frage zu prüfen, ob der in der Suggested Solution Nr. 1 aufgestellte Grundsatz der Patentierbarkeit von Verfahren zur Benutzung von Pflanzen - wie von einigen beteiligten Kreisen gefordert wird - auch dann gelten soll, wenn sich das Verfahren auf die Benutzung von Pflanzenbeständen mit spezifischen Eigenschaften (Sorten) bezieht.

4. <u>Schutz genetischer Informationen</u>

Das Sortenschutzrecht schützt einen Pflanzenbestand, der durch die Kombination seiner genetisch bedingten Eigenschaften gekennzeichnet ist, also insofern die Summe der Expressionen der im Genom der Pflanzen angelegten genetischen Informationen.

...

Für die Anwendung des Patentrechts auf "genetische Informationen", wie in der Suggested Solution Nr. 9 vorgeschlagen, ist daher zu prüfen, welche Tatbestände patentierbar sind.

Für die Abgrenzung ist von Folgendem auszugehen:

Eine "Eigenschaft" (z.B. die genetisch bedingte Fähigkeit von Pflanzen, bestimmte Inhaltsstoffe zu bilden) ist keine "Lehre" und damit schon begrifflich keine Erfindung.

Die Feststellung, daß in einem Genom ein bestimmtes Gen vorhanden ist und bestimmte Eigenschaften in den Pflanzen exprimiert, ist ebenfalls noch keine Lehre im Sinne des Patentrechts, sondern zunächst nur eine (wissenschaftliche) Erkenntnis.

Unstrittig dürfte aber sein, daß eine dem Patent zugängliche Erfindung vorliegen kann, wenn eine Lehre gegeben wird z.B. für

- ein Verfahren, durch das Pflanzen zur Ausbildung einer bestimmten genetisch verankerten Eigenschaft veranlaßt werden,
- die Herstellung eines Stoffes, der in Pflanzen die Ausprägung bestimmter genetisch verankerter Eigenschaften hervorruft,
- die Schaffung eines bisher nicht existierenden Gens
- die Operabilität (z.B. Isolierung, Transfer) eines existierenden Gens.

Hier stellt sich die Frage, wie weit der Schutz eines solchen Patentes reicht. Nach den herkömmlichen Grundsätzen des Patentrechtes würde das Patent seine Wirkung wohl nur dann entfalten, wenn

- das patentierte Verfahren als solches angewandt wird oder
- der Stoff, der unmittelbar durch das patentierte Verfahren gewonnen wurde oder als solcher Gegenstand eines Patents ist, benutzt wird, bevor er vom Patentinhaber oder mit seiner Zustimmung erstmalig in den Verkehr gebracht wurde.

...

Bei selbstreplikabler Materie muß aber zur Gewinnung weiterer Erzeugnisse mit gleichen genetisch bedingten Eigenschaften weder auf das Verfahren noch auf den Stoff unmittelbar zurückgegriffen werden.

Auch hier stellt sich die Frage, ob die berechtigten Interessen des Erfinders eine Erweiterung des Schutzumfangs erfordern oder ob er die für die Erfindung aufgewandten Kosten anderweitig angemessen amortisieren kann.

Unstrittig dürfte folgender Fall sein: Wer ein in pflanzlichem Material enthaltenes Gen, das Gegenstand eines Patents ist, als solches benutzt (z.B. indem er es aus dem Material isoliert und in anderes Material transferiert), unterliegt dem Verbietungsrecht aus dem Patent.

Schwieriger zu beantworten ist die Frage des Schutzumfangs, wenn nicht speziell das Gen, sondern insgesamt das Material benutzt wird, in dem es enthalten ist oder in das das Gen transferiert wurde. Dabei ist in Betracht zu ziehen, daß in diesem Falle ein einzelnes Gen, das nicht selbst replikabel ist, sondern nur als Bestandteil des Gesamt-Genoms an der Replikationsfähigkeit etwa einer Pflanze teilnimmt, nicht unabhängig vom übrigen Genom, sondern nur als dessen Teil benutzt werden kann. Eine Erstreckung des Patents an einem Gen auf alles Material, das dieses Gen <u>enthält</u>, würde die Benutzung des gesamten (z.B. aus 60.000 Genen bestehenden) Genoms, also etwa der Pflanze insgesamt, dem Verbietungsrecht aus dem Patent unterwerfen.

Von daher wird die Erstreckung des Schutzumfanges eines Patents auf genetisches Material wohl nur auf solches (Pflanzen-) Material in Betracht kommen, in das das patentgeschützte Erzeugnis oder dessen genetisch (praktisch) identische Folgeprodukte durch menschliches Zutun <u>eingefügt</u> wurde.

Die zu klärende Frage ist dann aber, ob die Wirkungen des Patents beim Erstanwender oder Erstbenutzer, also etwa dem Züchter, enden und allein dieser eine entsprechend bemessene Vergütung an den Patentinhaber zu zahlen hat, die Handlungen der folgenden Nutzer (Anbauer, Verarbeiter des Erntegutes, weitere Verbraucher) von den Wirkungen des Patents jedoch frei bleiben.

...

Ein besonderes Problem stellt sich in diesem Zusammenhang für den Weiterzüchter, der eine am Markt erhältliche Sorte als Ausgangsmaterial für die Weiterzüchtung verwenden will:

Eine durch Sortenschutz geschützte Sorte kann grundsätzlich frei von jedermann als genetische Ressource für die Züchtung neuer Sorten und deren wirtschaftliche Verwertung benutzt werden. Hinsichtlich patentierten Materials gilt dies nicht.

Ließe man die Wirkungen eines Patents für ein Gen bei dem ersten Züchter enden, der das Gen in seine Sorte transferiert hat, so wäre die ohne unmittelbaren Zugriff auf das Gen unter Benutzung der vorgenannten Sorte neu gezüchtete Sorte, auch wenn sie ebenfalls das Gen enthält, in gleicher Weise von den Wirkungen des Patents freigestellt, wie die sonstigen Folgeerzeugnisse der erstgenannten Sorte. Hier ist zu diskutieren, ob die berechtigten Interessen des Erfinders an der Amortisation seiner Aufwendungen in diesem Fall sichergestellt wären, also etwa die Lizenzzahlung des ersten Züchters ausreichen kann, oder ob der Schutzumfang des Patents hier gezielt zu verbessern ist.

5 <u>Abhängigkeit</u>

Das Sortenschutzrecht kennt bisher keine Abhängigkeit; im Rahmen der Revision des UPOV-Übereinkommens wird ihre Einführung für bestimmte Fälle erwogen.

Im Zusammenhang mit der Frage des Verhältnisses zwischen Patent und Sortenschutz sind folgende Fragen zu prüfen:

Ein Erfinder kann aufgrund des im Sortenschutzrecht verankerten Züchtungsvorbehalts bislang eine geschützte Sorte frei zur Schaffung einer neuen Sorte durch genetische Veränderung benutzen, nicht aber umgekehrt ein Züchter patentiertes Material. Außerdem kann innerhalb des Sortenschutzsystems die schon erwähnte Frage auftauchen, daß ein Züchter besondere Aufwendungen für die Züchtung einer Sorte aufzubringen hat, deren Vorteile von anderen Züchtern aufgrund des Züchtungsvorbehalts bei der Züchtung weiterer Sorten frei genutzt werden können.

...

Es ist daher zu erwägen, ob der Züchtungsvorbehalt aufgegeben oder aber unter seiner grundsätzlicher Aufrechterhaltung ein konsistentes System entwickelt werden kann, das über den in der Suggested Solution Nr. 11 abgehandelten Fall hinaus einen angemessenen Ausgleich sowohl zwischen Patentinhabern und Züchtern (und umgekehrt), als auch zwischen verschiedenen Züchtern sicherstellt.

PERMANENT MISSION OF FINLAND
IN GENEVA

No. 2593

The Permanent Mission of Finland presents its compliments to the Secretariat of the World Intellectual Property Organization and has the honour to transmit to the Secretariat the comments of the Finnish Authorities as regards the draft memorandum prepared by the Office of UPOV in cooperation with the International Bureau of WIPO entitled "The interface between patent protection and plant breeders' rights".

The Permanent Mission of Finland avails itself of this opportunity to renew to the Secretariat of the World Intellectual Property Organization the assurance of its highest consideration.

Geneva, 15 September 1989

Secretariat of the
World Intellectual Property Organization
34, chemin des Colombettes
1211 G e n e v a 21

THE NATIONAL BOARD OF PATENTS AND REGISTRATION

Helsinki September 11, 1989

No
Ref.

World Intellectual Property
Organization,
International Bureau
34, chemin des Colombettes
1211 Genève 20
SUISSE

Re Note C 5033/U 1456
dated June 16, 1989

A Draft memorandum has been "prepared by the Office of UPOV in cooperation with the International Bureau of WIPO. It remains subject to review in the light of deliberations in the 24th session of the Administrative and Legal Committee (of UPOV) and in the light of any decision to be made by the Governing Bodies of WIPO".

The document was first presented as a UPOV document. It still is, because the facts and views essentially bear a UPOV flavour. Patent protection is given little attention in the document. To the extent it is dealt with, the text contains a number of misconceptions.

A major short-coming of the document is its failure to address constructively a common UPOV-WIPO approach. In particular, we consider that any further version of the document ought to include a proposal to the effect that the prohibition against double protection in the UPOV convention be deleted. Furthermore, the new definition of the term "variety" appears to include plant material presently being patentable subject matter in many countries. Thus, such a definition would unduly restrict the applicability of patent protection.

A final common memorandum ought to strike a balance between the two systems of protection. In order to accomplish this, patent experts ought to assist in the preparation of a revised document.

These comments are based on negotiations between the Directors general of the Patent Offices of Denmark, Finland and Sweden.

ADDRESS: Albertinkatu 25
00180 Helsinki 18

TELEPHONE: 641 811
Director General: (640 980)

1882010530—22

The National Board of Patents and Registration shares the opinions of the Patent Department as stated in the enclosed, more detailed comments.

Martti Enäjärvi
Director General

Juhani Rainesalo
Head of Patent Department

THE NATIONAL BOARD OF PATENTS AND REGISTRATION

Helsinki

No September 11, 1989

Ref.

World Intellectual Property
Organization,
International Bureau
34, chemin des Colombettes
1211 Genève 20
SUISSE

Re Note C 5033/U 1456
dated June 16, 1989

Comments on the memorandum entitled "The Interface Between Patent Protection and Plant Breeders' Rights"

According to the circular, comments are invited on the memorandum to be used in preparing further documentation for a meeting jointly organized by WIPO and UPOV to deal with the question of protection by patent and plant breeders' rights. The memorandum remains subject to review in the light of deliberations in the 24th session of the Administrative and Legal Committee (of UPOV) and in the light of any decision to be made by the Governing Bodies of WIPO.

The memorandum bears a distinct UPOV flavor and does not give a clear picture of whom it is intended for.

If the intention has been to give the plant breeders a clear description of the patent system and its use as a form of protection for the inventions in plant breeding, it has not achieved the aim. The memorandum contains misconceptions and unnecessary presumptions when dealing with patent matters (cf. paragraphs 30-31, 42, 46, 48, 51, 59-60, 65, 68, 74-75, 80-84, 86-88, Appendix I Examples; please note e.g. that patents are not granted to inventive ideas or characteristics as such!).

ADDRESS: Albertinkatu 25
00180 Helsinki 18

TELEPHONE: 641 811
Director General: (640 980)

1882010930—2

Again, if the intention has been to present the UPOV form of protection to those more familiar with patent protection it has failed because it does not describe clearly all the important amendments that are proposed in the draft of the UPOV revision. Neither does the memorandum specify which of the merits belong to the present UPOV protection and which to the stronger, more patentlike protection as proposed in the draft of UPOV revision.

As the major short-coming of the memorandum is its failure to address constructively a common UPOV-WIPO approach, it ought to be redrafted using the assistance of patent experts in the preparation. The valuable expertise used in preparation of the EC directive on the legal protection of biotechnological inventions (COM 88 496 final-SYN 159) dated 17 October 1988 should also be taken into consideration when redrafting the memorandum. The following aspects are proposed to be considered in the redrafting, too.

- The general discussion parts of the present Annex I paragraphs 7 to 28 should be transferred to the main part of the memorandum in order to give in this part a fair and somewhat better balance between the descriptions of patent and UPOV protection systems.

- Instead of excluding the reflection of "the special situation existing in the United States of America" as it is noted in Annex I page 2, footnote, the present practice in the US where the inventor/breeder has a free choice between three forms of protection should on the contrary be described more in detail in the memorandum. This is of utmost importance because in many states, e.g. in Finland, the industry stands in opposition to the "double protection inhibition" of UPOV. The present paragraph 56, which probably is meant to reflect the US situation, is totally

confusing. It sets forth quite wrongly the patent system as such and totally neglects the real facts of the practice in the US where utility patents have been granted to plants (already long before the Hibberd case).

- The numerous paragraphs giving the historical review of how UPOV convention was created in 1961 could be shortened, as well as the history of US plant patents from 1930. Instead of reflecting the plant breeding techniques 28 years ago the memorandum should give a more detailed (cf paragraphs 67, 63, 57, 29) review of the modern plant breeding techniques - with or without the use of genetic engineering - above all in order to prove why the products of these modern, most often repeatable methods are not fit to be protected by patents!?

- The main concept "variety", its historical background and the proposed new broad definition <u>needs a chapter of its own</u>. The reason for the deletion of the definition of variety in the present UPOV is surely also worth clarification (paragraphs 29 and 37).

  The split information concerning "varieties" among many paragraphs e.g. 36-37, 51-52, 105, should be collected together and be supplemented with the views of those parties who are against even the protection of the varieties as they are restrictively defined at present, cf paragraphs 63, 83. The influence of the modern back cross techniques to the variety manipulation should also be mentioned in this connection.

  The new variety definition also needs a more profound argumentation because it includes

"plant material" which already has been patentable subject matter according to many patent laws. As examples could be used artificial seeds (cf EP patent 107141) or tissue and/or cell cultures. The last mentioned may find no use outside small scale factories as e.g. when producing shikonin, flavors etc.

- The numerous inexact expressions like "the view is taken...", "it seems unlikely", "in opinion of some" etc. in presenting doubts about the suitability of the patent system as a protection form for inventions in modern plant biotechnology should be grounded better - or deleted.

- In order to make the memorandum an efficient working paper for a short time meeting of UPOV-WIPO experts, the critics against the present UPOV and patent system should be collected to an easily readable list- or tableform. The same should be done with the proposed amendments to the UPOV system and their comparison with the patent system.

- At present the proposed UPOV revision is referred to incompletely in paragraphs 89-106, e.g. article 2 giving the new definition to variety has not been referred to under chapter IV C.

  The short reference to article 4 in paragraph 96 should be complemented with information from e.g. paragraphs 39, 78, 93-94, Appendix I, examples, which clearly show that even in the future the UPOV system cannot be used to the <u>whole plant kingdom</u> (and all the plant cells). One can then ask why the UPOV experts insist on not deleting the double protection inhibition in the UPOV revision, too? An opportunity to

choose between two protection systems would also be in the interest of inventors and innovators.

The text concerning the most important question of dependency between patent and UPOV protection should be rewritten to make it possible to find the best balanced dependency between the two systems. The present reference to Art 5 and its interpretation e.g. in paragraphs 92-95, 98-106 does not seem to represent a fair and balanced dependency.

- The two theoretical examples as presented too broadly in the tables in Appendix I could be restricted to one example only. Instead, one or two real examples of the patent applications dealing with modern plant biotechnology could be described and analysed in order to show which protection form, patent or UPOV, is the most suitable for them (see e.g. EP patent documents 10393, 44723, 90033, 107141, 122791, 170904, 209882).

- The Finnish Patent Office at the moment considers it unnecessary to comment in detail the paragraphs, the errors in them and the many parts unfair to patents in the text. However, it should be mentioned that paragraph 50 need to be complemented with the abstract of the EP case T 320/87 where the Technical Board of Appeals has taken a decision as to how the "essentially biological processes" and "plant variety" of EPC Art. 53(b) have to be interpreted.

The Finnish Patent Office agrees with the memorandum in that the patent system is not easy to understand for those classical plant breeders who historically have had little

familiarity with patents (cf paragraph 79). This should not, however, be an obstacle in the reevaluating of the legal protection forms for modern plant biotechnology - the plant breeding included. Therefore the Finnish Patent Office wishes success for and good cooperation in the future meetings of experts on patents and UPOV in order to be able to offer the inventors and innovators of today the best legal protection for their creations and this way stimulate the development and research in this important, partly high-tech field.

Hely Lommi

H e l y L o m m i
Head of Division
Patent Department

HIL/mh

GERMAN DEMOCRATIC REPUBLIC

Ministry for Agriculture, Forestry,
and Food Processing and the
Office for Inventions and Patents

AMT FÜR ERFINDUNGS- UND PATENTWESEN
DER DEUTSCHEN DEMOKRATISCHEN REPUBLIK
Der Präsident

Director General
of the World Intellectual
Property Organization
Dr. A. Bogsch
34, chemin des Colombettes
CH - 1211 G e n e v a 20
Switzerland

Berlin, 09 Jan. 1990

Dear Mr. Director General,

Enclosed please find the common position of the Ministry for Agriculture, Forestry and Food Processing and the Office for Inventions and Patents of the German Democratic Republic on the memorandum prepared by WIPO and UPOV "The interface between patent protection and plant breeders' rights".

Sincerely yours,

Prof. Dr. Hemmerling

Enclosure

POSITION

of the Ministry for Agriculture, Forestry and Food Processing and the Office for Inventions and Patents of the German Democratic Republic on the memorandum prepared by WIPO and UPOV "The interface between patent protection and plant breeders' rights"

The problems dealt with, and proposals made, in the memorandum are of special interest to us because they refer to essential questions of differentiating between patent protection and variety protection.
Also in the GDR, there is, apart from patent protection, a legal protection for new plant varieties under the Decree on the protection of plant varieties of March 22, 1972. According to Section 5, Paragraph 6, of the Patent Law of the GDR of October 27, 1983, plant varieties and animal breeds as well as breeding methods are not patentable. That is why a double protection under both the plant variety and patent protection is not possible for the same object.

We can not see any reasons to stop prohibiting such a double protection because it sufficiently considers the interests of plant breeders and owners of patents and clearly differentiates between their rights.

In principle, we support the direction in which the revision of the UPOV Convention is to be made. The effects of the various amendments can be evaluated only when the draft text and the explanations are available.

Among the four assumed situations as to both the patent and breeders' rights, situation no. four is of special interest because it accounts the justified interests of both plant breeders and genetic engineers in the best way.
The proposed extension of patent protection is also the subject matter of further discussion on the draft treaty on the harmonization of patent law (Article 204).

According to the GDR patent law, plant protection is not granted for a product derived from material initially obtained by a patented process. The same holds true for matters containing a patented product or obtained from a patented product. We have no principal objections against the proposed mutual dependency of breeders' rights and patents if it is formed in a way that the breeders'

rights, when using a new variety for selection purposes, are not essentially limited to the patent owners' advantage. Plant breeders have fears that there will be not a "mutual" dependency but a mostly partial dependency to the patent owners' advantage. A strong monopoly position of patents owners should not be allowed especially in the field of human nutrition.

ORSZÁGOS TALÁLMÁNYI HIVATAL
ELNÖK

PRESIDENT
OF THE NATIONAL OFFICE OF
INVENTIONS OF THE HUNGARIAN
PEOPLE'S REPUBLIC

ПРЕДСЕДАТЕЛЬ
ГОСУДАРСТВЕННОГО ВЕДОМСТВА
ПО ДЕЛАМ ИЗОБРЕТЕНИЙ
ВЕНГЕРСКОЙ НАРОДНОЙ РЕСПУБЛИКИ

Budapest, September "6", 1989

500-UP/CAJ-157

Dr. Arpad Bogsch
Director General of WIPO
Secretary General of UPOV
G e n e v a

Dear Mr. Director General,

In compliance with your request I wish to make the following remarks on the memorandum entitled "The interface between patent protection and plant breeders' rights".

As a whole, the memorandum is a high-level and comprehensive material revealing the problems and possible solutions from many aspects. As to the Hungarian legislation, it is well known that innovations concerning plant breeding may be protected in two ways: within the framework of the general patent system (e.g. genetic engineering or other processes and devices) or within the framework of patents of UPOV system (plant varieties).

Hungary supports all the efforts which are aiming at strengthening the breeders' rights within the framework of the revision of the UPOV Convention, mainly by approaching the contents of the right to the patent system, delimiting the farmers' privileges and research exemption, practically determining the rights relating to the variety derived from the protected variety, furthermore by extending the protection to all botanical genera and species. As to the collision of patents for genes and plant breeders' rights, the removal of collision should be left first of all to the agreement of the parties involved and compulsory licenses lifting mutual dependence may be granted only for lack of this.

./.

The Hungarian delegation will be ready in the future, too, to participate in the discussion of the questions raised in the memorandum both within the framework of the Administrative and Legal Committee of UPOV and the joint UPOV/WIPO committee of experts meeting envisaged for January 1990.

Sincerely yours,

Dr. Gyula Pusztai
President

MISIÓN PERMANENTE DE MÉXICO

103005 La Misión Permanente de México ante los Organismos Internacionales con sede en Ginebra saluda muy atentamente a la Organización Mundial de la Propiedad Intelectual y a la Unión Internacional para la Protección de las Nuevas Variedades de Plantas y en relación con la nota C. 5033/U. 1456 anexa a la cual se envió el memorándum titulado "The Interface Between Patent Protection and Plant Breeders' Rights", se permite transmitir los comentarios del Gobierno de México:

"La Ley de Invenciones y Marcas de México establece que las especies vegetales, sus variedades y los procesos esencialmente biológicos para su obtención, no pueden ser patentables.

Asimismo, la protección por patente en esta área será permitida para 1997. Solamente podrán ser patentables los procesos genéticos para obtener especies vegetales y sus variedades, y cuando sea el caso, los productos con actividad biológica y sus procesos de obtención (como semilla, células, enzimas y plásmidos que pueden ser utilizados en ingeniería genética).

La protección de las plantas y sus variedades se circunscribe en un marco más amplio y complejo que es el de la biotecnología. Los sistemas de protección para estos objetos todavía no están bien definidos, por lo que el sistema más apropiado estará en función de los intereses nacionales de cada país.

.../.

A la Organización Mundial de la
Propiedad Intelectual,
Ginebra

103005

Dado las características de las plantas y sus variedades, en un gran número de países industrializados y en desarrollo se encuentran excluídas de la protección por patente. Sin embargo, en virtud del progreso tecnológico se plantea frecuentemente la necesidad de una protección más completa y efectiva en el área de los vegetales. Algunos países, como se puede observar en el documento de que se trata, han establecido cierta protección como la que se lleva a cabo por medio de la UPOV o la patentabilidad de procesos, los cuales pueden ser reproducidos invariablemente y así cumplir con las condiciones para la protección por patente.

En consecuencia, las distintas características de los sistemas de protección han impedido el desarrollo de un marco adecuado para la protección de las plantas y sus nuevas variedades. Por lo tanto, el documento preparado por la OMPI y la UPOV representa una buena base para los debates en una reunión común de estos organismos, que sean útiles para definir un sistema o sistemas complementarios de protección.

Las situaciones hipotéticas contempladas en el Anexo II del documento, plantean cuestiones muy concretas sobre las modificaciones de algunas disposiciones legales y sus consecuencias, ofreciendo aportes importantes para los debates. El cuarto caso de figura, señalado en dicho Anexo, merecerá una especial atención, ya que de acuerdo con las características de las invenciones y las condiciones para la protección, los sistemas complementarios podrían representar la solución más apropiada para la protección de las plantas y sus variedades".

La Misión Permanente de México aprovecha la oportunidad para reiterar a la Organización Mundial de la Propiedad Intelectual las seguridades de su más atenta y distinguida consideración.

Ginebra, a 21 de septiembre de 1989

ESTADOS UNIDOS MEXICANOS

DELEGACION
PERMANENTE DE MEXICO
ANTE LOS ORGANISMOS
INTERNACIONALES CON
SEDE EN GINEBRA
GINEBRA, SUIZA

OCTROOIRAAD (Netherlands Patent Office)

2 Patentlaan • P.O. Box 5820 • 2280 HV Rijswijk • The Netherlands • Postbank account 17300
Telephone 070-986655 • Telex 33265-OCTRD-NL • Telefax 070-900190

Your letter and ref.	Our ref.	Encl.
June 16, 1989, C. 5034/-457	S89.327 DS/cp	4

Date: September 8, 1989

Subject: Memorandum "The interface between Patent Protection and Plant Breeders' Rights" (CAJ/XXIV/4)

Mr. A. Bogsch
World Intellectual Property Organization
34, chemin des Colombettes
CH-1211 GENEVA 20
Switzerland

Dear Mr. Bogsch,

With reference to Circular 5034/-457 dated June 15, 1989 we herewith send the asked comments on the above-mentioned Memorandum.

Yours sincerely,

i.o. MCJ Perizonius-Ritman,
secretary.

J.C.H. Perizonius,
Vice-President

Also sent by fax
on September 8, 1989.

Mevr. M.C.J. Perizonius
Octrooiraad
Patentlaan 2 (kamer 02-51,
Postbus 5820, 2280 HV Rijswijk
Tel.: 070 - 986655 tst. 306

OCTROOIRAAD (Netherlands Patent Office)

2 Patentlaan • P.O. Box 5820 • 2280 HV Rijswijk • The Netherlands • Postbank account 17300
Telephone 070-986655 • Telex 33265-OCTRD-NL • Telefax 070-900190

COMMENTS ON THE DRAFT MEMORANDUM "THE INTERFACE BETWEEN PATENT PROTECTION AND PLANT BREEDERS' RIGHTS" (CAJ/XXIV/4)

GENERAL

Recently the National Council for Agricultural Research in the Netherlands (NRLO) published a report on this subject, prepared by an ad hoc Study Committee (NRLO-study 89/23). This report is added as Annex 1.

Very shortly after this report was presented to our Minister for Agriculture and Fishery, this Minister, together with the Under-secretary for Economic Affairs, sent a letter on this subject to our Parliament; this letter is added as Annex 2 O (Original); a translation of the summary is added as Annex 2 T (Translation).

The above-mentioned report of the Study Committee, in which many points mentioned in the Draft Memorandum under discussion have been elaborated, was accepted unanimously by the members of the Committee; being one of its members and so agreeing with it, my opinion did not change up to the present. So I can restrict my comments on many paragraphs in the Draft Memorandum to referring to Annex 1.

Apart from this, I do not consider it appropriate to give comments on points in which the Minister and the Undersecretary mentioned before have already taken a position. So, on paragraphs of the Draft dealing with such points, I can only refer to Annex 2 O and 2 T.

Comments on specific paragraphs

36. (The second paragraph 36, beginning with "A particular feature . . ") It is proposed to replace "contains" on line 6 by "contained" and to add after "Article 6(1)(c)

provides" and after "Article 6(1)(d) provides": "in the text as amended in 1978 (in the original text the word 'new' was not present)."

50. and 51. Here a reference is to be made to the interpretation given by the Netherlands Government in para. 2 of the summary in the letter, referred to above: "Varieties or groups, higher than varieties, can not be patented as such."
In the part of para. 51. starting on line 13, the problems arising with on the one hand individual plants or parts of plants and on the other hand with categories of plants higher than that of variety, are dealt with together. Because the problems in those two groups may be totally different, it is better to deal with these groups under separate heading.

51(a) One of the requirements for a protectable variety is homogeneity. Because the expression "homogeneous" can only be used in relation to a group of plants, a "plant" (singular!!) can never form a protectable variety.

51(b) A "characteristic" can never be an acceptable claim; I assume that here is meant a claim directed to plants or parts thereof, having a characteristic, . . .".
It is a basic rule in Patent Law that if a certain subject within a group is not patentable, any group that includes that subject, is also not patentable; the consequence hereof is that no patent of the type discussed in this part of para. 51 can be granted.

52. A gene, being as such a chemical compound, would be patentable if the normal requirements i.e. novelty, inventive step, industrial application and sufficient disclosure are fulfilled. Up till now, as far as I am aware, no gene has been synthesized, resulting in expression of a valuable property in a plant; on the other hand practically all

genes available at the moment have been obtained from plants being present in nature, which plants were selected because one wanted to have a gene leading to a desirable property, present in the selected plant. It will be clear, that in such a situation there is great doubt whether the requirements of novelty and inventive step can be fulfilled.
But even if a gene would be invented, that satisfies the requirements mentioned above, it has to be discussed whether the claim may include plants or parts of plants containing that gene. In my opinion this ought not to be allowed, because such a claim would give exclusive rights on all the plant varieties containing this gene. Here a reference is made to the paragraphs dealing with "Patents on genes per se" on page 19 and 20 of Annex 1 and to Annex 2 T, point 2.

59. Even a complete description of living material is not sufficient for making the grant of a patent possible, because the requirement is that the disclosure must enable a person skilled in the art to carry out the invention and this is for living material not the case when only a description, even a "complete" one, is available.

60. The last sentence of this paragraph is not clear: for microorganisms the combination of deposit and description is possible and acceptable without any doubt. Why should then a combination of deposit and description for a plant be not sufficient or even not possible?

69. In my opinion the problems mentioned here are not inherent to the plant breeders rights system as such, but a consequence of the "farmer's privilege". If this did not exist, it would only be possible to produce the products meant in this paragraph, when the propagating material,

necessary every time again, is produced by the owner of the plant breeders right or with his consent.

70. Here is the situation in fact the same: if there were no "farmer's privilege", the actions mentioned in this paragraph would not be allowed without consent of the owner of the plant breeders right.

73. In my opinion the problem is not whether a patent for a gene incorporated in a plant is enforceable. If a patent is granted and considered valid by the Court, it is of course enforceable. The real question, however, in my opinion is whether such a patent may be granted, when plant varieties are not patentable. It will be clear that my opinion - and, when reading point 2 of Annex 2 T, probably also the opinion of our Minister - is, that such a patent ought not to be granted.

74. Here two, quite different exclusions having a totally different background, are dealt with together. Splitting this paragraph is advisable.

75. Another explanation for this exemption could be that microbiological processes exist already for many centuries and were always considered as being of a technical nature. Apart from this the criterion in my opinion is not whether microorganisms are involved, but which "actions" are taken in the process under consideration. So it is quite understandable that processes using plant cells are microbiological processes. However, is it possible that a <u>process</u> results in a plant variety? I wonder because I assume that, at least theoretically, there will always exist other processes, leading to the same type of plants. A comparison can be made with the situation existing in chemistry, where no protection for a substance as such can be reached via the "product for process" protection

principle. Also claims directed to a process for production of plants could only result in protection for a variety as such, if the claim would have the form: "Process for the production of plants, characterized by producing a plant, having the following properties .....". Such a claim, however, could in my opinion not be granted, because then in fact a patent application for a plant variety was filed.

76. The first sentence is incomplete: only the product directly obtained by the process is protected by a process claim and how could one consider later generations as such?

77. If a patent were granted for a plant variety, then producing such a plant forms an infringement irrespective whether the parents were put in a permitted way on the market or not. I, however, assume that such a patent will not be granted in e.g. the EPO.

78. Reference is made to point 2 of Annex 2 T.

81. It is true that a patent is based on an inventive idea; the subject of the property right, however, is always a product or a process, as described in a claim.
With respect to the criterion of non-obviousness for varieties, one should be aware that in most cases it is obvious that one wants to reach certain combinations of properties in a new variety. The difficulty, and often this is the real problem, is how to reach the desired goal.

84. I miss here a paragraph on the question whether, within the existing patent system, a valid patent for a gene can be granted: At the moment genes are produced from material known in nature; the starting material in most cases selected because one knows from the properties of the starting materials that there must a gene, responsible for a desirable property, present in the selected material. How

can in such a situation the requirements for novelty and non-obviousness be fulfilled? Apart from this: I assume that it will take still a very long time before man will be able to produce synthetic genes, that after introduction in a plant, result in desirable and unexpected properties of a plant, and this is necessary before a patent can be granted for a gene not present in nature.

86. It is rather unlikely that a particularly desirable combination of properties is nevertheless non-obvious. Apart from this also in patent law an idea, a wish, is not patentable at all. It is always necessary that the wish or the idea is brought into the concrete form of a reproducible product or process.
A same remark could be made with claims directed to characteristics (page 24, lines 8 and 9): either the characteristics are known to be desirable and then there will be no invention at all or the characteristics are really new and then I wonder whether the state of the art in this field is already that far that such an idea could be brought into practice.

87. It is very unlikely for the moment that the plants falling within the field of a claim of the type "Plants, characterized by the following characteristics ..." will be new <u>and</u> can be considered as non-obvious <u>and</u> have been produced de facto, but all these requirements have to be fulfilled before a valid patent can be granted.

88. Reference is made to Annex 2 T, point 2.

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ANNEX 1

PLANT BREEDERS' RIGHTS AND PATENT RIGHTS IN RELATION TO PLANT GENETIC ENGINEERING

Second Report

NRLO-study 89/23

National Council for
Agricultural Research
P.O. Box 20401
2500 EK The Hague
Netherlands
telephone: 070 - 793654/793653

June, 1989

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PREFACE

In 1984 a Study Committee of the National Council for Agricultural Research in the Netherlands (NRLO) published a report on Plant breeders' rights and patent rights in relation to plant genetic engineering (1). An English translation of this report was issued in 1985 (2).

Recently important proposals have been put forward (3), (4), (5) which have led to a further intensification of national and international discussions.

The Study Committee, under the auspices of NRLO, decided to analyse some of the main questions.
The outcome of the study is recorded in this report.

Attention is given to the fundamentals of exclusive rights and the extension and strengthening of plant breeders' rights.
Furthermore an analysis is made of the legal consequences of the exclusion of plant varieties from patent protection in the European Patent Convention (6).

The members of the Study Committee, who participated in a personal capacity, are:
Ir. J.D. Bijloo (chairman)
Ir. R. Duyvendak (secretary)
Ir. J.S.W. van Gennip
Prof.Dr. B. de Groot
Drs. P. Mars
Dr.Ir. C. Mastenbroek
Drs. J.C.H. Perizonius
Prof.Dr. R.A. Schilperoort

SUMMARY

This study deals with intellectual property rights in plants.

Legal systems relating to patent rights and plant breeders' rights are systems established to stimulate research and make innovations available to the public.
There should be no gaps or overlapping between the systems.
They should guarantee a clear and firm protection of breeding results, but they should never allow an absolute blockade.
Both patent rights and breeders' rights lose their justification if the underlying conditions are not respected.
The main patentability requirement is non-obviousness, while the main requirement for breeders' rights is distinctness.
The principle of a fair balance underlying property rights must be respected by everybody, first of all by the granting authorities.

Improvement of the plant breeders' rights system by revision of the UPOV Convention should be supported, in particular with respect to the proposals

- to open plant breeders' rights for all varieties of all cultivated plants,
- to make 'material of a variety' clearly include all reproductive material from which the variety with its distinctive characteristics can be reproduced, including protoplasts, cells, etc.,
- to restrict the freedom of a grower to multiply a protected variety on his own premises to multiplications for non-commercial purposes,
- to let the scope of protection cover material of a variety that is imported and commercialized after multiplication in a foreign country,
- to implement a system of dependency.

In relation to this last point an analysis is made of some technical background and terms.
The concepts 'original variety' and 'genetic modification' are used in a proposal for a possible set of rules for dependent plant breeders' rights.

In the European countries that have ratified the European Patent Convention plant varieties are excluded from patent protection by the provisions of art. 53b of that Convention.
The specific exclusion of patents for plant varieties involves the generic exclusion of patent claims that might block a group of varieties.

A patent may be granted for a gene or genetic component per se, if it is an invention.
The patent cannot cover (parts of) living plants defined by the specific character(s) expressed by the gene, because this would block (future) varieties and thus violate the exclusion of the European Patent Convention.
The exclusion should be made explicitly clear by inserting a disclaimer in the patent grant stipulating that (parts of) plants containing the gene fall outside the scope of the patent.
If the inventor wants protection for plant material containing the gene he must apply for plant breeders' rights or seek remuneration in an other way.
Since the scope of a patent for a gene cannot cover living (parts of) plants, it cannot reach the use of (parts of) plants as genitors for further breeding.

A patent may be granted for a new and inventive genetic manipulation process applicable to different genes or genotypes.
If, at least in principle, the result of the process can be achieved with other processes as well, the patent cannot lead to an absolute barrier for a variety or a group of varieties. There is no conflict with art. 53b of the European Patent Convention and the granting authority cannot require the inclusion of a disclaimer for plants or parts of plants in the patent.
A process patent only gives exclusive rights for the direct product of the process.
A patent claim formulated as a chain of sequential steps may not be prolonged ad libitum, but ought to stop at the point where the 'embodiment of the invention' ends, e.g. the first protoplast, cell or plant tissue harvested.

The holder of a patent on a genetic manipulation process is not entitled to exercise exclusive rights either on further multiplications of the initial plant material, or on plant material of other varieties developed therefrom.
This plant material can be subject matter of plant breeders' right protection.

1. WHY PROTECTION BY PATENT; WHY PROTECTION BY PLANT BREEDERS' RIGHTS?

The purpose of protection of inventions by patent rights and protection of plant varieties by plant breeders' rights is, simultaneously,

- to stimulate research, development and commercialization of innovations by granting exclusive rights during a limited period and
- to facilitate the participation by everyone in the further development of the state of the art.

The aim is to create the best possible balance between

- the interests of the inventor (or plant breeder) who will try to get a return on his investments in research and development and
- the interests of the public in securing the availability of something that would not have existed without the efforts of the inventor or plant breeder.

The last words in the preceding paragraph are essential.
Exclusive rights may never be granted for something that was already available to the public in some way, so <u>novelty</u> is required.
(The definition of novelty in the patent system differs from that in the plant breeders' rights system).
Equally rights may not be granted for something that does not become completely available to the public, so <u>availability</u> is required in the patent system through publication of a full description, coupled with an unconditional deposit in the care of material for which an enabling disclosure by description cannot be guaranteed.
Protected plant varieties must be available to the public; furthermore the requirement of <u>stability</u> is added.

Furthermore in the patent system, <u>non-obviousness</u> is required: a patent may only be granted for something that could not have been achieved by obvious further development of the state of the art.
For granting a plant breeders' right <u>distinctness</u> is enough, a much lighter requirement than non-obviousness.

A final condition in the patent system is that the granted exclusive rights, as laid down in the claims, should not be too broad in relation to the invention made.

The most important consequence of the foregoing is that both a patent system and a system of plant breeders' rights lose their justification if the conditions mentioned above are not taken respected.

The bodies granting exclusive rights should therefore examine meticulously whether all conditions are fulfilled.

If exclusive rights are granted too easily or too broadly one or more interested third parties or organisations should avail themselves of the possibility of opposing the grant in order to correct the situation.

2. PLANT BREEDERS' RIGHTS

Plant breeders' rights have been developed as a system of intellectual property rights tailored to protect newly bred varieties.

It is generally agreed that the system as a whole has proved to work well, though some improvements are needed.
Plant breeders' rights are obtainable by a relatively cheap and simple procedure.
The subject matter of protection is clear: a concrete variety. There is no free formulation of claims, open to interpretation and dispute.
The criteria for granting plant breeders' right protection (see chapter 3) differ from the patentability criteria and they are, as time has proved, well chosen.
All this is in the interest of both breeders and growers.

The desired improvements relate to both the extension and the strengthening of the plant breeders' rights.
The majority of them already form part of the present proposals for the revision of the UPOV Convention. Some of them are summarized briefly here, some are discussed in more detail.

The legal systems for the protection of breeding results should permit neither gaps nor overlaps.
This means that since all plant varieties are excluded from patent protection by the provisions of article 53b of the European Patent Convention all types of varieties of all cultivated plants should be made eligible for protection under the plant breeders' rights system.
The plant breeders' rights testing authorities hesitate to take the step from the present restricted lists to such an open ended system.
For society as a whole, however, plant breeders' rights protection for concrete varieties is easier to cope with than patent protection for freely formulated claims.

It should be made perfectly clear in the plant breeders' right legislation that the expression 'material of a variety' includes all material from

which the variety with its distinctive characteristics can be reproduced, viz. whole plants and parts of plants such as protoplasts, cells, cell aggregates, cell lines, plant tissues, specific organs, artificial seed, etc.
Due to their genetic identity they are 'the material' of the variety.
In fact this is not an extension of breeders' rights protection, but a clarification.

The freedom of the grower to multiply a protected variety on his own premises, should be restricted to multiplications for non-commercial purposes only.

Material of a variety that is imported and commercialized after multiplication in a foreign country should be brought within the scope of protection by plant breeders' rights.

A system of dependency, comparable to that existing in the patent rights system, should also be introduced in plant breeders' rights legislation. The technical and legal aspects are surveyed in the chapters 3 and 4.

3. TECHNICAL BACKGROUND AND TERMS

Taxon

Living organisms are arranged by science in a hierarchical system of classes: species, genus, family, etc.
A general word for such a class is: taxon.
A taxon is defined by a relatively arbitrarily chosen type-specimen and a short description.
Each taxon is formally identified by a Latin name according to the rules of the 'International Code of Botanical Nomenclature'.
Within a taxon one can observe genetic variants.

Variety (=cultivar, F: varieté, D: Sorte, NL: ras).
A variety is not a taxon.
A variety is defined by the totality of its characters.
A variety is formally identified by a fancy name according to the rules of the 'International Code of Nomenclature for Cultivated Plants' often abbreviated as the 'Cultivated Code'.
The criteria for the addition of varieties to official catalogues and for granting plant breeders' rights fit in the general framework of the Cultivated Code, but they are formulated in a little more detail.

A variety must be stable. Any sample grown under a given set of conditions must exhibit the typical varietal characters.

A variety must be sufficiently homogeneous with due regard to its actual mode of reproduction (true breeding or hybrid, vegetatively propagated, self or cross fertilized) and the practicability of selection of the character under consideration.
In practice there will always be found some residual variation, but on closer investigation this must be of a random nature.
A variety cannot exist in genetically different forms.

A variety must be distinct from all other varieties.
In principle any reproducible character can be used for establishing distinctness.

At present in the granting of plant breeders' rights only differences are noted, the degree of resemblance is not taken into consideration.
This has led to dissatisfaction, first with respect to 'easy mutations' in ornamental and fruit crops, but latterly on a wider basis.
Terms like 'plagiarized varieties', 'near-duplicate varieties' and 'cosmetic breeding' reflect the feelings of the breeders concerned.

Nowadays there is general agreement among both producers and growers of varieties that in view of the advances in biological sciences the situation needs reconsideration.

Several proposals are under discussion to remedy the situation.
Some proposals suggest the enlargement of the minimum distances or the restriction of the list of distinctness characters to the agronomically important ones.
Acceptance of these suggestions would mean a drastic deviation from current practices in the recognizing and naming of cultivars, which practices have a much wider scope than the field of breeders' rights alone.

It is a much better suggestion to maintain the rules for establishing distinctness as they are, but - as a new element - to group and treat the varieties according to their resemblance.

Modification

In biological science the following definitions have long been accepted:
modification - a non-genetic variant expression, e.g. due to environment,
mutation - a change in genotype.

Recently the term modification is coming into use in the following two ways:

1. Non-genetic modification (hitherto a pleonasm!) e.g. caused by
   - light spectrum: shadow and mountain forms,
   - nutrition: dwarf and giant forms, stained flowers,
   - virus: Rembrandt tulips, Harlequin pelargoniums,
   - differentiation: plagiotropic growth.

Some non-genetic modifications cause confusion as they may remain present after vegetative propagation, but they can always be induced and removed by specific treatments, e.g. light, chemicals, infection, meristem culture, etc.
Plant breeders' rights are not granted for these non-genetic modifications.
They are not furhter considered.

2. Genetic modification (hitherto a contradiction!) e.g. due to
   - spontaneous mutation,
   - induced mutation: by chemicals, radiation, etc.,
   - transformation: recombinant DNA techniques, micro injection, etc.,
   - selection for variants in an established variety,
   - repeated back-crossing if carried to its extreme (rarely observed!).

   A genetic modification fulfils the requirement of varietal stability and cannot be reversed by treatment.
   Each genetic modification is a new variety *in statu nascendi*.

Information given by the breeder concerning how a modification was obtained will be helpful to save costs of laboratory, greenhouse and field assessments, but this information is not decisive.
The degree of resemblance between varieties should be deduced on the basis of morphological, physiological and biochemical reactions of plant material, including electrophoresis patterns of e.g. storage proteins, enzymes and DNA restriction fragment length polymorphisms (RFLP's).

The term genetic modification indicates: a restricted change in a variety with the preservation of the character pattern of that variety as a whole.
This notion should always be kept in mind.
Only those varieties that unmistakably are a genetic modification of an earlier established variety should be identified as such.
In case of doubt we should not use the predicate.

Whether, how and by whom a genetic modification may be commercialized should be governed by the plant breeders' rights dependency rules.

4. DEPENDENCY BETWEEN VARIETIES PROTECTED BY PLANT BREEDERS' RIGHTS

Generally speaking varieties are created by crossing, combining or modifying existing plants in some way or another.
At present there is no legal dependency relationship between plant varieties.
Existing varieties may freely be used for the development of a new variety and one may commercialize such a new variety unconditionally.

The principle of free availability of genetic resources in plant breeding has always been regarded as a precious principle.

As can be seen in the relevant reports, already during the founding of the UPOV Convention it was acknowledged that in some specific cases a restriction of this general principle was desirable.
The repeated use of a protected variety for the production of an hybrid variety was brought under the scope of protection.
For other cases, however, like the 'easy' selections and mutations, no provisions were made since it was found difficult to establish satisfactory definitions and rules.
Accordingly, apart from the repeated use mentioned above, the Convention was executed in 1961 with no limitations on the freedom of use of protected varieties for further breeding purposes and no limitations or obligations on the commercialization of any resulting varieties.

Since that time both the number of cases that were felt to be unjust and the techniques to detect close relationships have multiplied.

Also the insight has gained ground that plant breeding must be directed towards the creation of varieties with different genetic backgrounds.
Plant breeders' right protection can be instrumental in addressing this goal.
Plant breeders must be stimulated to continue to rearrange polygenic characters and to test their breeding products under practical conditions.
The situation must be avoided where the range of varieties in a crop narrows down to a few clusters of varieties with a common genetic

background.
Such a narrow range is very vulnerable, as was proven by some notorious examples, e.g. the Helminthosporium blight attack on maize in the U.S.

Both the planned revision of the UPOV Convention (3) and the new EEC Draft Council Regulation on Community Breeders' Rights (4) contain proposals to introduce a system of dependency in plant breeders' rights.
The aim is to develop a system with limited applicability and effects.
The use of varieties in breeding programs in general will remain free, just as it is today.
The principle of dependency will be restricted to specific cases.

For this purpose both in the proposed revision of the UPOV Convention and in the Draft Council Regulation on Community Breeders' Rights the terms 'original variety' and 'derived variety' are coined.
In the texts accompanying the proposals for the revision of the UPOV Convention examples are given and attempts are made to explain the concepts.
Precise definitions are avoided since even if they were valid at the present time they might be too restrictive in future.

In our view the concept of a 'derived variety' coincides with the concept of a 'genetic modification' in the former chapter.
In legal terms an 'original variety' then simply is any variety which is not a genetic modification.

How are varieties to be compared?
Two plants will never be fully identical and varietal characters will always show a certain range.
The question whether two groups of plants belong to the same variety or not must be answered by assessment and comparison of samples.
If the differences between the two groups grown under the same conditions are random, then the two groups belong to the same variety.
If the differences are of a systematic nature, then the groups must be considered as different varieties, however small the differences might be.
Whether differences are either random or systematic can easily be

established: random differences decrease with enlargement of samples, whereas systematic differences become statistically more significant in larger samples.

Since the size of a systematic difference is irrelevant, the growing technological potential for the identification of differences, e.g. in the detailed structure of genes increases the opportunities to distinguish new varieties.
Under the UPOV system, in theory, any reproducible difference, however small, suffices to obtain plant breeders' rights.
It will become progressively easier to create a new variety by selection for or the introduction of an identifiable piece of DNA.
The new creation will ride piggy-back on the original variety without remuneration of the breeder who performed the major breeding work.

The introduction of a dependency system for genetic modifications of protected varieties will remedy the situation.
The following is a proposal for a set of rules for such a system:

The plant breeders' rights protection of original varieties is broadened; the 'broad' right shall apply to all original varieties, regardless whether the protection was granted before or after the entry into force of the revised system.

During the term of plant breeders' rights in an original variety the protection covers the original variety, as well as genetic modifications of that variety not marketed before the date of entry into force of the system.

During the term of the rights in an original variety, genetic modifications may not be multiplied or commercialized, unless their creators have applied for and have received grants for dependent plant breeders' rights and have reached agreement with the holder of the right in the original variety with respect to multiplication, commercialization and remuneration.
The agreement should be reached, either directly or via arbritation, with due consideration of the contributions of each party.

The holder of a plant breeders' right may not at present withhold a variety from the market if the availability of the variety is required for reasons of public interest.
In order to prevent plagiarization with trivial modifications the holder of the right in the original variety should only be obliged to grant licenses for modifications that fulfil the same condition of public interest.

A genetic modification will never become an original variety.

Plant breeders' rights protection for genetic modifications is granted for the normal period, during a part of which it may be a dependent right.

For the sake of clarity it is reiterated that in the proposed system the restrictions made in case of the repeated use of a protected variety for the production of a hybrid variety and those made in case of a dependent plant breeders' right will be the only exceptions on the principle of free availability of varieties in plant breeding. In all other cases the general principle is maintained that new varieties may be multiplied and commercialized without any obligation (financial or otherwise) to the holders of plant breeders' rights in the varieties used in the preceding steps of the breeding program.

5. PATENT RIGHTS

The holder of a patent has the legal right to prevent others from performing certain acts in relation to the process or product for which the patent was granted.

No patents on varieties

In the European countries that have ratified the European Patent Convention plant varieties are excluded from patent protection according to art. 53b of that Convention.

This specific exclusion of patenting plant varieties involves the generic exclusion of all patent claims that directly or indirectly lead to a right to prohibit any acts with respect to a variety or a group of varieties during the term of a relevant patent right.

Patents on genes per se

The word 'gene' when used here means any genetic component or construct. The word may refer to synthetic genes as well as to natural genes that are identified, isolated and made suitable for transfer.

A patent may be granted for a gene *per se* if it is an invention.
The holder of the patent may use the gene exclusively for his own transformation purposes or offer it to others under licence.
Plant breeders who would like to build a patented 'portable gene' into a new variety will have to direct themselves to the patent holder since this is the only legitimate source for this patented 'portable gene'.

The scope of a patent for a gene cannot cover any living plant or part of a plant defined by the specific character(s) expressed by the gene, because this would cause an absolute blockade for (future) varieties and thus violate the basic exclusion of the European Patent Convention.

A gene patent should therefore contain a disclaimer stipulating that plants or parts of plants carrying the gene fall outside the scope of the patent.

If the inventor wants protection for plant material containing the gene he must apply for plant breeders' rights or seek remuneration otherwise.

Since the scope of a gene patent cannot cover living plants or parts of plants it cannot reach the use of these plants or parts thereof as genitors for further breeding.

Patents on genetic manipulation processes

A patent may be granted for a new and inventive genetic manipulation process.
What is meant here by 'process' are acts which are not defined by or bound to a gene per se, but which are applicable to different genes or genotypes.

If, at least in principle, the result of a genetic manipulation process can be also achieved with other processes, then the patent cannot lead to an absolute barrier for a variety or a group of varieties. There is no conflict with art. 53b of the European Patent Convention and the granting authority cannot require the inclusion of a disclaimer for plants or parts of plants in the patent.

From the foregoing one may not conclude, however, that the holder of a patent on a genetic manipulation process is entitled to exercise exclusive rights either on further multiplications of the initial plant material or on plant material of other varieties developed therefrom.

The reason is that a process patent only gives exclusive rights for the direct product obtained with the process.

The formulation of the claim in the patent will define what is to be understood as the 'direct product'.
The applicant may propose a set of claims with a series of subsequent steps, e.g.:
.. process for introducing a genetic component in plant cells,
.. followed by the multiplication of the component by the cells
.. and multiplication of the cells,
.. followed by raising of plants from the cells,

.. which plants can be multiplied
.. and used as such,
.. or used for the development of other plants or varieties,
.. which can be multiplied,
.. etcetera,
and call all this 'the direct product' of the process.

A set of claims ranging so widely should not be granted in its entirety, since a chain of steps, starting with the invented process, may not be prolonged ad libitum.
The chain ought to stop at the point where the 'embodiment of the invention' ends. In the example given above one can think of the first protoplast, cell or tissue that is harvested.
All that is done afterwards are acts that have nothing to do with the invention made.
Supporting evidence for this line of thought can be found in the existing jurisprudence about 'Embodiment of the invention'.

Plant material resulting from later acts can be subject matter of plant breeders' right protection.

Here again the legislators, granting authorities and courts of justice should see to it that the domains of protection by patent rights and protection by plant breeders' rights fit properly together, without gaps or overlaps.

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Tweede Kamer der Staten-Generaal

2

Vergaderjaar 1988–1989

19 744 Biotechnologie en het octrooi- en kwekersrecht

Nr. 4

BRIEF VAN DE MINISTER VAN LANDBOUW EN VISSERIJ

Aan de Voorzitter van de Tweede Kamer der Staten-Generaal

's-Gravenhage. 23 juni 1989

Zoals door de Vaste Commissie voor Landbouw verzocht, zend ik u bijgaand, mede namens de Staatssecretaris van Economische Zaken, de heer A. J. Evenhuis, een notitie inzake octrooi- en kwekersrecht.

De snelle ontwikkelingen op het gebied van biotechnologische technieken in de plantenveredeling en de ontwikkelingen in internationaal verband maken het noodzakelijk thans een standpunt voor de verschillende overlegkaders te bepalen. Deze notitie beoogt daaraan richting te geven.

Ik merk daarbij op, dat deze notitie zich toespitst op plantenveredeling en de relatie tussen octrooi- en kwekersrecht. Ethische aspecten van genetische manipulatie – die in mijn wijze van zien overigens veeleer bij de genetische manipulatie van dierlijk materiaal een rol zullen spelen – blijven buiten beschouwing.

Teneinde daaromtrent duidelijkheid te verkrijgen heb ik onlangs de Commissie van Advies inzake ethiek en biotechnologie bij dieren, onder voorzitterschap van prof. dr. E. Schroten ingesteld, welke commissie vóór 1 januari 1990 zal rapporteren.

Tenslotte vermeld ik, dat de Nationale Raad voor Landbouwkundig Onderzoek (NRLO) zojuist een studie over dit onderwerp het licht heeft doen zien. De Raad stelt in zijn aanbiedingsbrief dat het rapport slechts beschrijvend is en geen uitspraken beoogt te doen over de te kiezen afstemming tussen octrooi- en kwekersrecht.

Ik heb er kennis van genomen, dat in de pers berichten zijn verschenen, als zou de Raad van oordeel zijn, dat geen octrooien op planten behoren te worden verleend. Daarbij zij opgemerkt, dat zulks voorbijgaat aan de praktijk in de USA en Japan en aan die van het Europees octrooibureau, dat immers – na een aanvankelijk negatieve beslissing – in beroep is overgegaan tot het verlenen van een octrooi op een biotechnologische werkwijze, uitmondend in een door octrooi

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beschermde plant (zie: zaak T320/87-3.3.2, Lubrizol Genetics inc. beslissing van de afdeling van beroep dd. 10 november 1988).

Zoals echter in deze notitie wordt aangetoond, is een evenwichtige afstemming tussen octrooi- en kwekersrecht zeer wel mogelijk indien de lijn van het Europees octrooibureau, op de voet van het Europees octrooiverdrag en de ontwerp-EEG-richtlijn inzake de bescherming van biotechnologische uitvindingen wordt gevolgd en mits in de Rijksoctrooiwet en in de Zaaizaad- en Plantgoedwet de in de notitie aangegeven voorzieningen worden getroffen.

De Minister van Landbouw en Visserij,
G. J. M. Braks

Huidige stand van zaken

a. Biotechnologisch onderzoek

Het biotechnologisch onderzoek heeft zich in een snel tempo ontwikkeld. Tot enige jaren geleden beperkte dit onderzoek zich in hoofdzaak tot onderzoek naar praktische toepassingsmogelijkheden van micro-organismen. De resultaten van dat onderzoek, nieuwe en inventieve werkwijze en produkten, zijn octrooieerbaar. Maar het onderzoek naar praktische toepassingsmogelijkheden van ander levend materiaal – waaronder planten, delen daarvan en in het bijzonder die delen die kenmerkende eigenschappen bezitten, het genetisch materiaal – neemt een steeds hogere vlucht. Nederland neemt daarbij een vooraanstaande plaats in. De bevordering van onderzoeks- en ontwikkelingsactiviteiten op het gebied van de biotechnologie is één van de aandachtspunten van het technologiebeleid. Uitgangspunt daarbij is dat Nederland op die onderzoeksterreinen waar het een voorsprong heeft weten op te bouwen in staat moet blijven die positie te behouden. Belangrijke overweging daarbij is dat de resultaten van dat onderzoek een wezenlijke bijdrage kunnen leveren aan de volksgezondheid (bijvoorbeeld geneesmiddelen), het milieu (vermindering van de afvalproblematiek, zowel door het langs natuurlijke weg doen afbreken van afval als door het verminderen van dierlijk afval) en aan de agrarische sector (nieuwe, hoog produktieve plantenrassen, hogere resistentie tegen ziekten – hetgeen overigens ook de toepassing van chemische bestrijdingsmiddelen kan terugdringen – en meer in het algemeen een snellere ontwikkeling van nieuwe plantenrassen die aan de eisen van de teler en consument voldoen). Het is van groot belang dat Nederland voor de voordelen die biotechnologisch onderzoek levert niet afhankelijk wordt van buitenlandse bedrijven. De internationale concurrentie-positie van niet alleen het bedrijfsleven dat biotechnologisch onderzoek verricht, maar ook van de daarop voortbouwende agrarische sector, dient te worden behouden en waar mogelijk versterkt.

De bescherming van onderzoeksresultaten door middel van intellectuele eigendomsbescherming vormt daarbij een onmisbaar sluitstuk.

b. Het octrooirecht

Het octrooirecht beoogt ten aanzien van alle praktisch toepasbare uitvindingen aan de uitvinder het exclusieve recht te geven gedurende een zekere periode zijn vinding te exploiteren. Een exclusief recht wil zeggen het recht om anderen te verbieden de vinding zonder zijn toestemming commercieel toe te passen. Onderzoek en ontwikkeling met de geoctrooieerde werkwijze of het geoctrooieerde produkt zijn wel toegestaan.

De uitvinder verricht zijn onderzoek omdat hij verwacht dat er vraag is naar zijn vinding en besluit pas tot dat kostbaar onderzoek over te gaan indien hij verwacht dat er een redelijke kans is dat hij zijn onderzoeksinspanning kan terugverdienen.

Dat terugverdienen kan hij doen door zelf de produktie ter hand te nemen danwel door een ander door middel van een licentie het recht te geven te produceren. Via een licentievergoeding, die per definitie redelijk moet zijn omdat hij anders geen geïnteresseerde wederpartij zal aantreffen, kan hij het rendement op zijn onderzoekswerk halen.

c. Het kwekersrecht

In de sfeer van de plantenveredeling bestond eveneens de behoefte aan de bescherming van de ontwikkelaar van een ras. Op dit specifieke

terrein heeft echter van oudsher de gedachte vooropgestaan, dat de veredelaar weliswaar bescherming verdiende, doch dat anderzijds de belangen van de voedselvoorziening en daarmede van de land- en tuinbouw vereisten, dat op basis van beschermde rassen nieuwe variëteiten zouden kunnen worden ontwikkeld, die op hun beurt bescherming verdienden.

Anders immers dan in het octrooirecht, waar van tijd tot tijd op basis van een anders uitvinding wordt voortgeborduurd, is dat bij de plantenveredeling regel. Eveneens speelde een rol dat hier vaak van stapsgewijze verbeteringen sprake is, zodat vereisten van inventiviteit en nieuwheid een veel geringere rol kunnen spelen dan in het octrooirecht. In beginsel komt elk voordien niet bestaand ras voor kwekersrecht in aanmerking. In beginsel, want voor lang niet alle gewassen staat kwekersrecht open. Nederland en een aantal andere UPOV-landen werken met beperkte lijsten.

De bescherming die het kwekersrecht biedt is derhalve beperkter dan die van het octrooirecht: de kwekersrechthouder heeft slechts het uitsluitend recht op het voor handelsdoeleinden voortbrengen en verhandelen van teeltmateriaal van het ras waarop hij het kwekersrecht heeft (artikel 40 Zaaizaad- en plantgoedwet). Voor het overige zijn er grote overeenkomsten met het octrooirecht.

d. Samenhang tussen geldend octrooirecht en kwekersrecht

De ontwikkelingen op het gebied van de biotechnologie maken thans, dat een deel van de veredelingsarbeid grotere overeenkomsten gaat vertonen met het bijvoorbeeld technisch en chemisch ontwikkelen van «uitvindingen». Dit komt ondermeer tot uitdrukking in de Rijksoctrooiwet en het Europees octrooiverdrag, die beide weliswaar bepalen dat octrooi op planten- en dierenrassen en op werkzaamheden van wezenlijk biologische aard niet kan worden verleend doch dat dit niet geldt voor microbiologische werkwijzen en de daardoor verkregen voortbrengselen (artikel 3 Rijksoctrooiwet, artikel 53, Europees Octrooiverdrag). Overigens blijft daarbij de vraag actueel of, gelet op de eisen die aan octrooieerbaarheid overigens worden gesteld, voor deze werkwijzen, en hun voortbrengselen ook steeds octrooi zal kunnen worden verleend.

Ontwikkelingen in internationaal verband

e. UPOV- en EEG-voorstellen

De werking van de hierbovengenoemde artikelen van Europees Octrooiverdrag en Rijksoctrooiwet heeft echter slechts betrekking op een deel van de problematiek. Ook in de sfeer van het kwekersrecht zelf, dus op het niveau van plantenrassen gaan steeds meer stemmen op die betogen dat de positie van de kwekersrechthouder ten opzichte van volgende veredelaars te zwak is. Zowel in EG-verband als in het kader van het Verdrag inzake de bescherming van kweekprodukten (UPOV) wordt daarom thans aan een versterking van de positie van de kwekersrechthouder gewerkt, langs de volgende lijnen:

- kwekersrecht zou voor alle gewassen moeten worden opengesteld;
- het zogenaamde «farmers exemption» moet worden beperkt tot datgene wat het oorspronkelijk was: het recht om voor eigen gebruik een deel van de oogst achter te houden als teeltmateriaal;
- de omvang van het kwekersrecht moet worden vergroot, waardoor het zich niet alleen uitstrekt tot teeltmateriaal, maar eveneens tot bijvoorbeeld plantecellen, andere plantedelen en planten tot en met het eindprodukt;
- er moet nadere invulling worden gegeven aan de zogenaamde «minimum distance», de mate waarin een ras van zijn voorganger moet verschillen om voor kwekersrecht in aanmerking te komen;
- er dient een «afhankelijk kwekersrecht» te komen.

Deze laatste onderdelen behoeven, mede gezien hun samenhang, enige toelichting. Zoals gezegd kan bij de huidige stand van zaken een ieder voortborduren op eens anders beschermd ras, zonder dat daar een recht op vergoeding voor de kwekersrechthouder tegenover staat. Reeds door een minimale variatie aan te brengen kan een nieuw ras ontstaan waarvoor kwekersrecht kan worden verleend en dat zodoende in rechtstreekse concurrentie treedt met het eerste ras, dat wellicht ten koste van grote financiële inspanning en langdurige research is ontwikkeld. Teneinde hieraan het hoofd te bieden werkt men in UPOV-verband aan een zogenaamd «afhankelijk kwekersrecht», waarbij de volgende kwekersrechthouder een redelijke vergoeding aan zijn voortganger moet betalen.

Daarnaast wordt de eis van een zekere «minimum distance» gesteld, een eis welke in zekere mate overeenkomt met die van «nieuwheid» zoals het octrooirecht die kent. In onderling verband leiden de eis van de «minimum distance» en het afhankelijke kwekersrecht er toe, dat niet elk ras dat slechts een zeer gering verschil ten opzichte van zijn voorganger vertoont, door kwekersrecht wordt beschermd en dat, wanneer bescherming door kwekersrecht plaatsvindt, de ontwikkelaar van het voorgaand ras een redelijke vergoeding kan krijgen. Op deze wijze wordt getracht een evenwicht te vinden tussen de belangen van de ontwikkelaar van het eerste ras en de belangen van volgende veredelaars, telers, consumenten en de samenleving in het algemeen. Immers, bij een te grote bescherming stopt de ontwikkeling van nieuwe rassen evenzeer als bij een te geringe bescherming.

De Commissie van de Europese Gemeenschappen heeft eind 1988 een ontwerpverordening voor een gemeenschappelijk kwekersrecht opgesteld, die van nagenoeg dezelfde uitgangspunten uitgaat als die welke in UPOV-verband thans actueel zijn.

Voorts heeft de Commissie eind 1988 een ontwerp-richtlijn opgesteld betreffende de bescherming van biotechnologische uitvindingen.

De Commissie beoogt daarmede:

a. een eenduidige interpretatie te bewerkstelligen binnen de Lid-Staten van de betrokken bepaling van het Europees Octrooiverdrag (EOV), en

b. gemeenschappelijke regels vast te stellen die in nationale regelgeving zouden moeten worden vastgelegd, ten aanzien van onderwerpen die nog niet, of niet op adequate wijze, in het EOV en nationale wetgeving zijn vastgelegd.

Een communautair standpunt is wenselijk. Thans zijn uiteindelijk de rechterlijke instanties van de betrokken Lid-Staten vrij om de bestaande regelgeving te interpreteren. Een overeenkomstig het EOV door het Europees Octrooibureau verleend octrooi kan in de verschillende Lid-Staten alsnog worden beoordeeld op zijn geldigheid en reikwijdte. Het zou strijdig zijn met de rechtszekerheid indien de principiële vraag tot hoe ver het octrooi op plantaardig materiaal reikt per land verschillend zou worden beoordeeld. Dat staat ook haaks op de gedachte van de gemeenschappelijke markt. A fortiori is het in het zicht van 1992 ongewenst dat de Lid-Staten nu nog afzonderlijk via wetgeving een eigen invulling zouden gaan geven aan het vraagstuk van intellectuele eigendomsbescherming van (genetisch materiaal van) planten.

Reikwijdte en afstemming van octrooi- en kwekersrecht

f. Toekomstig kwekersrecht en octrooi

Op het gebied van levende materie wordt zoals eerder vermeld veel onderzoek verricht naar de dragers van erfelijke eigenschappen. Dit

onderzoek kan leiden tot het isoleren, beschrijven en toepasbaar maken van bestaande, maar niet eerder gekende, genen. Daarnaast wordt gewerkt aan het ontwikkelen van nieuwe genen. Het resultaat van dit onderzoek, een gen, kan, mits nieuw en inventief, in aanmerking komen voor octrooibescherming. In zo'n geval kan de exploitatie van het gen door derden slechts met toestemming van de octrooihouder plaatsvinden.

Onderzoek op het gebied van planten strekt doorgaans tot het inbrengen van nieuwe eigenschappen in bestaande rassen. De kweker/octrooihouder zal zijn onderzoekskosten moeten terugverdienen door middel van de exploitatie van deze nieuwe rassen. Hij brengt het nieuwe ras daartoe in het verkeer, waartoe hij onder het kwekersrecht een exclusief recht heeft. De vraag die thans met name in internationaal kader aan de orde komt is hoe nu de reikwijdte van het octrooi op het gen en de rassenbescherming onder het kwekersrecht zich met elkaar verhouden. In het beschermde ras zit immers een octrooirechtelijk beschermd gen.

Bij de beantwoording van deze vraag geldt als randvoorwaarde, dat de voorziening van de markt met teeltmateriaal tegen redelijke voorwaarden verzekerd is (vgl. art. 42 Zaaizaad- en Plantgoedwet).

Aan deze randvoorwaarde kan slechts worden voldaan, indien aan twee secundaire voorwaarden wordt voldaan.

1. De biotechnoloog en de plantenveredelaar moeten voldoende terugverdienmogelijkheden hebben. Immers, indien de vaak hoge ontwikkelingskosten van nieuwe variëteiten niet kunnen worden terugverdiend stopt de ontwikkeling. Er zal dus moeten worden voorkomen, dat anderen van de uitvinding kunnen profiteren zonder dat daar een redelijke vergoeding voor de «uitvinder» tegenover staat.
2. Anderzijds moet worden voorkomen, dat de uitvinder vanuit zijn bevoorrechte, beschermde positie door het stellen van onredelijke eisen de voorziening van de markt met teeltmateriaal in gevaar brengt.

In het kader van het bestaande kwekersrecht is ieder vrij bestaande plantenrassen als uitgangspunt te nemen voor het ontwikkelen van nieuwe rassen. Hierdoor wordt een concurrent/veredelaar in staat gesteld een recht te verkrijgen op een «nieuw» ras, dat wat erfelijke eigenschappen betreft, voor 99% gelijk is aan dat van zijn voorganger. Het hoeft slechts op één enkel punt van zijn voorganger te verschillen om kwekersrecht te verkrijgen. De 99% overige eigenschappen, waarin vaak de voor de land- en tuinbouw wezenlijke eigenschappen liggen besloten, kunnen zonder enige vergoeding door de «nieuwe» rassenontwikkelaar worden overgenomen. Ook afgezien van de ontwikkelingen op het gebied van de biotechnologie, heeft dit in kwekerskringen tot toenemende kritiek geleid. Het doet immers geen recht aan al het werk dat door de oorspronkelijke kweker is verricht om de bijzondere overige eigenschap(pen) in te bouwen. In het navolgende zal daarom worden uitgegaan van een, zoals hiervoor onder e. aangegeven, verstrekt kwekersrecht.

In die situatie zal de relatie tussen de octrooihouder op het gen en de opvolgende kwekersrechthouder(s) er als volgt uit zien:

– In de eerste plaats staat het zowel onder het octrooirecht als onder het kwekersrecht een ieder vrij met planten, waarin een geoctrooieerd gen/werkwijze of die als zodanig zijn gepatenteerd te experimenteren teneinde te trachten een nieuw commercialiseerbaar ras te ontwikkelen.

– Voor dat ras kan kwekersrecht worden gevraagd. Noch het Europees Octrooiverdrag, noch de UPOV-conventie (of de Zaaizaad- en Plantgoedwet) verzetten zich daartegen.

– Voor de commercialisatie van dit nieuwe ras is toestemming van de octrooihouder nodig indien de geoctrooieerde vinding, of dit nu een gen is of zich uitstrekt tot planten, daarin voorkomt.
– Voor volgende veredelaars die dit ras als uitgangspunt kiezen voor verdere veredeling is het voorgaande opnieuw van toepassing: zij mogen vrijelijk experimenteren en kwekersrecht vragen, maar voor eventuele commercialisatie moeten zij bij de octrooihouder te biecht indien het geoctrooieerde gen in de planten van dat ras voorkomt.
– De niet-geoctrooieerde genen in de plant vallen niet onder het octrooi en blijven dus volledig vrij beschikbaar, ook voor commercialisatie.

Globaal bezien lijkt op grond van het voorgaande een werkbare afstemming te zijn bereikt: de ontwikkeling van nieuwe rassen is vrij, de octrooihouder kan een redelijke vergoeding voor zijn uitvinding bedingen. Nadere beschouwing levert echter een aantal mogelijke knelpunten op:
De octrooihouder is niet verplicht mee te werken aan het verlenen van licenties. Dit heeft tot gevolg dat:
– hij de prijs van de licenties zo hoog kan stellen, dat deze prohibitief is;
– hij bij het al dan niet verlenen van licenties zijn eigen «policy» kan volgen;
– hij in het geheel geen licenties kan verlenen om uitsluitend zelf te exploiteren, mogelijk tegen en exorbitante prijs;
– de veredelaar er niet bij voorbaat zeker van kan zijn, dat hij de door hem uit de geoctrooieerde plant ontwikkelde rassen ook zal kunnen exploiteren.

De Nederlandse octrooiwetgeving kent daarom een aantal mogelijkheden teneinde zeker te stellen dat octrooien ook inderdaad worden toegepast en dat geoctrooieerde werkwijze en produkten voor verdere ontwikkeling beschikbaar blijven. Daar is in de eerste plaats de individuele dwanglicentie in het algemeen belang (artikel 34, eerste lid, Rijksoctrooiwet). Voorts de individuele dwanglicentie wegens «niet gebruik» (artikel 34, tweede lid). Tenslotte de licentie ten behoeve van «afhankelijke octrooien» van artikel 34, vierde lid, van de Rijksoctrooiwet. Dit laatste correctief komt erop neer, dat de houder van een octrooi verplicht is licenties te verlenen aan de houder van een volgend octrooi, indien die licentie voor de toepassing van dat octrooi nodig is. Houder van laatstgenoemd octrooi is verplicht wederkerig licentie van zijn octrooi te verlenen.

Synthese

Naar onze mening dient de verhouding tussen octrooi- en kwekersrecht langs de weg van artikel 34, vierde lid, te worden geregeld. Dit zal kunnen geschieden door het verlenen van licentie eveneens verplicht te stellen indien zulks nodig is voor de toepassing van een verleend kwekersrecht, zij het dat daarbij niet, of niet alleen aan wederkerige verlening van kwekersrecht moet worden gedacht, doch (tevens) aan een redelijke vergoeding jegens de octrooihouder. Deze lijn komt overeen met de lijn die de ontwerp EEG-richtlijn inzake de bescherming van biotechnologische uitvindingen op dat punt volgt.

Hierbij vallen een aantal kanttekeningen te plaatsen.

– Een dergelijke constructie kan slechts functioneren bij een als hierboven, in onderdeel e, aangegeven, versterkt kwekersrecht, dat

bovendien voor alle cultuurgewassen open staat. Ik streef er dan ook naar, zowel in EG- als in UPOV-verband de besluitvorming in die richting te bespoedigen. Voorts wordt overwogen op korte termijn het Kwekersrechtbesluit 1975 zodanig te wijzigen dat kwekersrecht voor alle cultuurgewassen open staat.

– Hoewel de ontwerp EEG-richtlijn inzake de bescherming van biotechnologische uitvindingen, zoals gezegd, de verhouding tussen octrooi- en kwekersrecht langs dezelfde lijn regelt, komen daarin toch enige bepalingen voor die tijdens het overleg nog opheldering behoeven. Zo kent de ontwerprichtlijn op dit punt een wachttermijn van drie jaar. Een dergelijke termijn kende ook de vroegere Rijksoctrooiwet en het oorspronkelijke ontwerp van de Zaaizaad- en Plantgoedwet, doch deze termijnen zijn geschrapt omdat zij geen functie hadden. De ontwerprichtlijn dient op dit punt te worden aangepast.

– Voorts geldt de verplichting tot licentieverlening volgens de ontwerprichtlijn alleen, indien het ras «een wezenlijke technische vooruitgang» betekent. Aangenomen moet worden, dat bedoeld is hiermee een aspect aan te duiden dat enige overeenkomst vertoont met de «minimum distance» in het huidige UPOV-verdrag en de ontwerp EEG-verordening inzake communautair kwekersrecht. Ik ben dan ook van oordeel, dat een dergelijk aspect in de sfeer van het kwekersrecht tot gelding dient te komen.

– In elk geval brengt het voorgaande met zich mee, dat formeel wijziging van Rijksoctrooiwet en van de Zaaizaad- en Plantgoedwet noodzakelijk is en dat materieel mogelijk nieuwe kaders moeten worden geschapen om deze nieuwe belangenafweging gestalte te geven.

Samenvatting

Samenvattend komt de door mij voorgestane lijn op het volgende neer:

– Het kwekersrecht moet worden versterkt, met name door het voor alle gewassen open te stellen en een afhankelijk kwekersrecht te creëren

– Rassen of groepen, hoger dan rassen, kunnen als zodanig niet geoctrooieerd worden.

– Octrooi op biotechnologische werkwijzen is mogelijk (zie artikel 3, tweede lid, Rijksoctrooiwet).

– Een dergelijk octrooi werkt door op de voortbrengselen van die werkwijze, dat wil zeggen op het gen en op planten die dat gen bevatten. Voor het ras dat door deze planten eventueel wordt gevormd kan kwekersrecht worden verleend.

– Een dergelijk octrooi werkt vanzelfsprekend niet door op planten die dat geoctrooieerde gen niet bevatten en op het overige erfelijk materiaal in planten die het gen wel bevatten: het overige erfelijke materiaal is dus volledig vrij.

– Het geoctrooieerde materiaal is vrij beschikbaar voor onderzoek en ontwikkeling en voor het aldus ontwikkelde ras kan eveneens kwekersrecht worden verleend.

– Voor de exploitatie van dat kwekersrecht is toestemming van de octrooihouder in de vorm van een licentie nodig.

– De ervaringen in het octrooirecht tot op heden geven aanleiding om te veronderstellen dat licentieverlening zonder tussenkomst van de overheid of een rechterlijke instantie regel zal zijn.

– Voor de gevallen waarin dat niet of niet voldoende blijkt te geschieden wordt artikel 34, vierde lid, van de Rijksoctrooiwet zodanig gewijzigd, dat ook ten behoeve van opvolgende kwekersrechten tot het verlenen van licenties kan worden verplicht onder wederkerige verlening van kwekersrecht, tegen redelijke vergoeding of een combinatie van beide.

– Dit laatste vergt voorzieningen in de sfeer van de uitvoering (beoordelende instantie(s), beroepsmogelijkheden), welke nog nader dienen te worden bestudeerd.

– Dit standpunt zal in internationaal verband worden uitgedragen.

OCTROOIRAAD (Netherlands Patent Office)

2 Patentlaan • P.O. Box 5820 • 2280 HV Rijswijk • The Netherlands • Postbank account 17300
Telephone 070-986655 • Telex 33265-OCTRD-NL • Telefax 070-900190

ANNEX 2 T

Non-official translation of the "Samenvatting" (Summary) on page 8 of the letter from the Netherlands "Minister van Landbouw en Visserij" (Minister for agriculture and fishery) and "Staats-secretaris voor Economische Zaken" (Undersecretary for Economic Affairs) to the Parliament of the Netherlands dated June 23, 1989 (Number 19744, Nr. 4) (Annex 2 O).

1. The plant breeders right must be strengthened by opening it for all plant species and by creating a dependant plant breeders right.

2. Varieties or groups, higher than varieties, can not be patented as such.

3. A patent for a biotechnological process is possible (viz. Netherlands Patent Act, art. 3(2)).

4. By elaboration such a patent protects also the products of such a process, i.e. the gene and plants, containing that gene.

5. It is evident that such a patent neither protects plants not containing the patented gene, nor the further genetic material of plants containing that gene; so that further material is fully free.

6. The patented material is freely available for research and development and for a variety developed by using such material, a plant breeders right can be granted.

7. For exploitation of such a plant breeders right a licence from the patent owner is necessary.

8. From experiences in the patent field it is expected that as a rule such a licence will be granted without intervention by Government or a Court.

9. For those cases where such a licence is not granted voluntarily, art. 34(4) of the Netherlands Patent Act shall be amended in such away that for the sake of exploiting a plant breeders right a compulsary licence can be granted with a reciprocal licence under the plant breeders right and eventually reasonable compensation.

10. Details for such a procedure still have to be studied.

11. This point of view will be disseminated internationally.

Ministerie van Landbouw en Visserij

FACSIMILE

TO
the International Union for
the Protection of New Varieties
of Plants and World Intellectual
Property Organization,
34, Chemin des Colombettes,
CH 1211 GENEVE 20,
Switzerland.

landbouw en visserij

Directie Juridische en
Bedrijfsorganisatorische Zaken

uw brief van	uw kenmerk	ons kenmerk	datum
		J. 898637	October 17th, 1989
onderwerp		doorkiesnummer	bijlagen
Reaction of the interface between patent protection and plantbreeders' rights (CAJ/XX/IV/4).		792206	1

On behalf also of the Minister of Economic Affairs I hereby inform you of the following.

I have taken note with interest of the draft memorandum prepared by the Office of UPOV in cooperation with the International Bureau of WIPO concerning the interface between patent protection and plant breeders' rights (CAJ/XX/IV/4). The draft memorandum provides a clear insight into both protection systems. The examples mentioned in Annex II can be regarded as a valuable basis for further discussion.
The discussion concerning this subject matter has resulted in the Netherlands in a memorandum of the Minister of Agriculture and Fisheries and the Minister of Economic Affairs to be presented to Parliament. An English translation of the memorandum concerned is enclosed.
In short, the memorandum sets out the following course. The Dutch government feels that two conditions play an important role in the relationship between the scope of the patent on the gene and the protection of plant varieties under plant breeders' rights.

- The inventor and the plant breeder must be able to recover the costs incurred for their new products. If the often substantial development costs of new varieties cannot be recovered, development will be stopped. It is therefore to be avoided that other parties benefit from the invention without there being equitable remuneration for the "inventor".
- It is to be avoided that the inventor has such a privileged and protected position as to jeopardize the market supply of propagating material by making excessive demands.

Ministerie van Landbouw
en Visserij
Bezuidenhoutseweg 73
Postadres:
Postbus 20401
2500 EK 's-Gravenhage
Telefoon: 070-7939 11
Fax: 070-793600
Telegramadres: Landvis
Telex: 32040 Lavinl

- To -

To this purpose it is necessary to strengthen plant breeders' right and modify patent law.
As far as patent law is concerned it should be noted that in the existing legal system a plant breeder can make free use of patented material for research and development of a new variety. For the variety thus developed he can apply for breeders' rights. The plant breeder is faced with patent law only when he decides to exploit the new variety. He needs the consent of the patent owner in the form of a licence for exploitation of the new variety. However, it is to be avoided that the plant breeder cannot be certain of the possibility to exploit the varieties which he developed on the basis of the patented plant. In those cases in which the grant of licence is withheld or effected inadequately, it is necessary to incorporate in patent law that for the benefit of subsequent breeders' rights the grant of licenses can be made compulsory under reciprocal grant of plant breeders' right, against equitable remuneration or a combination of both. Patent law will have to be altered to this effect.

The strengthening of breeders' rights involves the following:
- Breeders' rights is extended to all botanical species.
- The (so-called) "farmers' exemption" should only extend to the right to retain for private use part of the crop as propagating material.
- The scope of the plant breeders' rights should be enlarged, so that it extends not only to propagating material, but also to for instance plant cells, other parts of plant and plants up to and including the end product.
- A further definition of the "minimum distance", the degree to which a variety differs from its predecessor, is desirable.
- A "dependent breeders' right" is necessary. This implies that for the exploitation of a plant variety, which differs only slightly from the parent plant variety and which is protected under plant breeders' right, the owner of plant breeders' rights of the parent plant variety is entitled to receive equitable remuneration.

As has been stated, the examples included in Annex II provide room for discussion on this subject matter. We propose to add another example. This example is based on the Dutch point of view as elaborated above. Although example 4 of Annex II provides an adequate basis for reaching a realistic solution, we propose to include a fifth example. This example provides for a statutory obligation to grant a licence, if this is necessary for the exploitation of a granted breeders' right. Subject to the contents of the claim, the patent owner can have a plant breeders' right as described in example 4.

- The -

The advantages described in the possible consequences in example 4 also apply to the proposed fifth example below. The changes in plant breeders' right as mentioned in the examples are of an essential nature. They are at present being prepared in the context of UPOV.

In short example 5 for Annex II is as follows:

I. Changes in plant breeders' rights

- Availability of plant breeders' right for all botanical species.
- Extension of the scope of plant breeders' right so that plant cells, other plant parts and plants up to and including the (end) product come under the scope of plant breeders' right.
- Creation of a "dependent breeders' right". This involves that for the exploitation of a plant variety, which differs only slightly from the parent plant variety and which is protected under plant breeders' right, the owner of breeders' right of the parent plant variety should receive equitable remuneration.

II. To maintain the exception that plant varieties and methods of an essentially biological nature for the production of plant varieties are not eligible for patent.

III. To maintain that plant varieties as such can only be protected via plant breeders' right. There is no objection against patent claims resulting in protection of plants as such.

IV. Changes in patent law

- To introduce the possibility of a statutory obligation to grant a licence if such is required for the exploitation of a granted breeders' right.

As has been stated, this example has virtually the same consequences as example 4, but example 5 has the added advantage that in patent law only the grant of licence needs to be modified.

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J. 898637	October 17th, 1989	3

I hope to have been able to make an effective contribution towards complementing the memorandum (CAJ/XXIV/4) and the discussion concerning the coordination between patent law and plant breeders' right and anticipate the inclusion of this contribution in the debates.

FOR THE MINISTER OF AGRICULTURE AND FISHERIES,
THE SECRETARY-GENERAL,

Memorandum of the Ministry of Agriculture and Fisheries and the Ministry of Economic Affairs of the Netherlands

On the coordination of patent law and plant breeders' rights

Present state of affairs

a. Biotechnological research

Biotechnological research has evolved rapidly in recent years. Until a few years ago this particular field of research was mainly concerned with an examination of the practical uses of microorganisms. The results of this research, new and inventive processes and products, are patentable. However, the research into practical uses of other living matter - including plants, parts of plants and particularly those parts possessing distinctive characteristics, i.e. the genetic material - is now increasingly expanding. The Netherlands is in the forefront of this development. The promotion of research and development activities in the field of biotechnology is one of the focal points of the technological policy. The principle of this policy is that the Netherlands should be able to maintain its leading position in those areas where she has managed to lead the field. An important consideration is that the results of the research are able to make a fundamental contribution to public health (e.g. medicines), the environment (reduction of the waste problem, both by means of introducing biodegradable ways of waste disposal, as well as by means of the reduction of animal waste), and the agricultural sector (new, high-yielding plant varieties, higher disease resistance - which may incidentally also help to force back the use of pesticides - and more generally a faster development of new plant varieties which meet the requirements of both grower and consumer). It is of great importance that the Netherlands do not become dependent on foreign companies for the advantages provided by biotechnological research. The international competitive position, not only of the industry carrying out biotechnological research, but also of the agricultural sector which relies on this research, has to be maintained and enhanced where possible.

The protection of research findings by means of intellectual property protection is an essential component of this policy.

b. Patent law

With regard to all inventions susceptible to application, patent law aims to grant the inventor the exclusive right to exploit his invention during a particular period. An exclusive right means the right to prohibit other parties from commercially exploiting an invention without the consent of the patent holder. Research on and development of the patented process or the patented product are, however, permitted.

The inventor carries out his research because he expects a demand for his invention, and the decision to proceed with high-cost research is made only when he is reasonably confident he will be able to recover the costs of his research effort.

He can recover his investment either by taking charge of production himself or by granting another party a licence to manufacture. By means of a royalty payment, which by definition must be equitable because he would not be able to find an interested party otherwise, he can expect a return on his research activities.

c. Plant breeders' rights

In the field of plant breeding, too, there existed the need for the protection of the breeder of a variety. However, in this specific area it was traditionally felt that although the breeder deserved protection, it was likewise in the interest of the food supply and consequently of agriculture and horticulture that on the basis of protected varieties new varieties, which in turn merited protection, could be developed. Unlike in patent law, where a patented invention is occasionally used as the basis for another invention, this is the rule in plant breeding. Another factor was that there are usually step-by-step improvements in plant breeding, so that requirements of inventive step and novelty are far less relevant than in patent law. In principle each previously non-existing variety is eligible for breeders' rights. This is in principle only, as breeders' rights are by no means open to all crops. The Netherlands and a number of other UPOV countries employ restricted lists.

The protection offered by plant breeders' rights is therefore not as extensive as the protection offered by patent law: the holder of plant breeders' rights merely has the exclusive right to commercially produce and market propagating material of the variety for which he has obtained plant breeders' rights (article 40 of the Plant Varieties and Seeds Act). Otherwise there exist great similarities with patent law.

d. Relationship between existing patent law and plant breeders' rights

An effect of the developments in the field of biotechnology is that part of the work carried out for purposeful breeding is beginning to show great similarities with for example the technical and chemical development of "inventions". This finds expression in the Dutch Patents Act and the European Patent Convention, both of which, although they provide that plant and animal varieties and processes of an essentially biological nature are not eligible for patent, nevertheless state that this does not apply to microbiological processes or their products (article 3 Patents Act, aricle 53 European Patent Convention). In view of the requirements otherwise used to determine patentability, the question remains relevant for that matter whether these processes and their products will always be eligible for patent.

Developments at the international level

e. UPOV and Community proposals

The above mentioned articles of the European Patent Convention and the Patents Act, however, only address part of the problem. In the sphere of plant breeders' rights itself, too, on the level of plant varieties, more and more voices argue that the position of the owner of plant breeders' rights with regard to subsequent breeders is too weak. Both at Community level and at the level of the Convention for the Protection of New Varieties of Plants (UPOV) plans are made to strengthen the position of the owner of plant breeders' rights along the following lines:

- all crops should be eligible for plant breeders' rights;
- the so-called "farmers' exemption" should be limited to its original purpose: the right to retain for private use part of the crop as

propagating material;
- the scope of protection of plant breeders' rights should be enlarged, so that it extends not only to propagating material, but also for example to plant cells, other parts of plants and plants up to and including the end product;
- the so-called "minimum distance", the extent to which a variety must be distinguishable from its predecessor in order to be eligible for plant breeders' rights, requires closer definition;
- a "dependent plant breeders' right" needs to be formulated.

Partly in view of their interrelation, the latter points need further explanation. As has been noted, protected varieties may at present be freely used to create a new variety, without there existing any right to compensation for the holder of the breeders' rights. It only takes a minimal variation to create a new variety which may be eligible for plant breeders' rights and which will be in direct competition with the previous variety, possibly developed at considerable financial effort and after protracted research. In order to redress the balance, UPOV is formulating a so-called "dependent breeders' right" whereby the subsequent holder of plant breeders' rights must pay equitable remuneration to his predecessor.

In addition a certain "minimum distance" is required, which more or less corresponds with the requirement of "novelty" in patent law. Together the requirements of "minimum distance" and "dependent breeders' right" ensure that not every variety which differs only minimally from its predecessor is eligible for protection and that, if plant breeders' rights do apply, the breeder of the earlier variety is entitled to equitable remuneration. In this way an attempt is made to strike a balance between the interests of the breeder of the initial variety and the interests of subsequent breeders, growers, consumers and the community in general. Both overprotection and underprotection stop the development of new varieties.

Towards the end of 1988, the Commission of the European Communities formulated a draft regulation to lay down Community plant breeders' rights virtually based on the same principles as those now relevant in UPOV.

The Commission furthermore formulated a proposal for a directive on the protection of biotechnological inventions towards the end of 1988. It is the intention of the Commission:
a. to reach a uniform interpretation within the Member States of the relevant provision of the European Patent Convention (EPC), and
b. to determine Community rules, to be laid down in the national regulation with respect to issues which have not yet, or inadequately, been laid down in the EPC and the national legislation.

It is desirable to reach a Community position in this matter. At present the judicial authorities of the Member States concerned are free to interpret the present regulations at their discretion. A patent granted by the European Patent Office in accordance with the EPC can always be re-examined in the separate Member States on its validity and scope of protection. It would be contrary to legal certainty if the fundamental question as to how far the patent on plant material extends were to be variously determined by each country. This is also contrary to the idea of the Common Market. Therefore, in view of 1992, it is undesirable that the Member States should at this

moment in time give unilateral definition to the issue of intellectual property protection of (genetic material of) plants by means of separate legislation.

Scope of protection and coordination of patent law and breeders' rights

f. Future plant breeders' rights and patent

As has already been stated, considerable research has been carried out in the field of living matter into the carriers of hereditary characteristics. This research may result in the identification, description and application of existing, but previously unknown, genes. In addition work is being carried out to develop new genes. The product of this research, a gene, is, if new and inventive, eligible for protection under patent. In that case the use of the gene by third parties is possible only after the consent of the patent holder. Research in the field of plants usually concerns the insertion of new characteristics in existing varieties. The breeder/patent holder will have to recover his research costs by means of the exploitation of these new varieties. To that end he will market the new variety, for which he has been granted exclusive right under plant breeders' rights. An issue which will now become relevant especially from an international angle is in how far the scope of patent protection on the gene and the variety protection under plant breeders' rights relate to each other. After all, the protected variety contains a gene protected by patent. The limiting condition in settling this question is that there must be an ensured supply of the market with propagating material against reasonable terms (cf. article 42 of the Plant Varieties and Seeds Act).

This limiting condition can only be fulfilled if two secondary conditions are met.

1. The biotechnologist and the plant breeder must have sufficient opportunities to make a return on their investment. For if the often substantial development costs of new varieties cannot be recovered, development will stop. It is therefore to be avoided that other parties can benefit from the invention without there being equitable remuneration for the "inventor".
2. On the other hand it is also to be avoided that the inventor, from the vantage point of his privileged, protected position, jeopardizes the market supply of propagating material by making excessive demands.

The present system of plant breeders' rights allows the free use of existing plant varieties as the initial source for the development of other varieties. This enables a competitor/breeder to acquire a right for a "new" variety, which, as far as genetic characteristics are concerned, is for 99% identical to its predecessor. It needs only to differ from its predecessor in one single aspect to be eligible for breeders' rights. The other 99%, which often contain the characteristics essential for agriculture and horticulture can be used by the "new" creator without any compensatory payment. Even apart from the biotechnological developments, this state of affairs has come under increasing attack from breeders' circles. It does not do justice to all the effort of the original breeder to insert the other, special characteristic(s). The following discussion therefore is presented from the perspective of a strengthened plant breeders' right, as indicated earlier

under e.

In the case of a strengthened plant breeders' right, the relationship between the holder of the patent on the gene and the subsequent holder(s) of plant breeders' rights would be as follows:

- First, both patent law and plant breeders' rights allow free experiments with plants containing a patented gene/process, or plants patented as such, so that a new marketable variety may be developed.
- It is possible to apply for plant breeders' rights for that new variety. Neither the European Patent Convention, nor the UPOV convention are opposed to this.
- The authorization of the patent holder is required for the commercialization of the new variety if it contains the patented invention, whether it is a single gene or whether it extends to plants.
- For subsequent breeders who select this variety as the initial source for further breeding the above applies once more: they can experiment freely and apply for plant breeders' rights, but in the case of commercialization they must involve the patent holder if the patented gene occurs in the plants of that new variety.
- The non-patented genes in the plant are excluded from patent protection and therefore remain freely available, also for purposes of commercialization.

It would seem that a workable coordination has been effected in this way: the development of new varieties is unrestricted, the patent holder can stipulate an equitable remuneration for his invention. Closer inspection however reveals a few areas of potential conflict:

The patent holder is not legally bound to grant licences. The consequence of this is that:

- he can charge a prohibitively high price for the licences;
- he is free to adopt his own "policy" in granting or withholding licences;
- he can withhold licences altogether so that he has the exclusive right to exploitation, possibly at exorbitant prices;
- the breeder cannot as a rule depend on it that he will be able to market the varieties he developed on the basis of the patented plant.

Because of this Dutch patent legislation provides a few opportunities to ensure that patents are actually used and that the patented process and products remain available for further development. First there exists the individual compulsory licence in the public interest (article 34, paragraph 1 of the Patents Act). Next there is the individual compulsory licence for "non usage"(article 34, paragraph 2). Finally there is the licence on behalf of "dependency patents" of article 34, paragraph 4 of the Patents Act. The latter corrective means that the holder of the patent is legally bound to grant licences to the holder of a subsequent patent, if that licence is required for the exploitation of that patent. The holder of the latter patent is reciprocally bound to grant licences on his patent.

Synthesis

The relationship between patent law and plant breeders' rights should be defined in terms of article 34, paragraph 4. This can be realized when the grant of a licence is also made compulsory if it is necessary for the application of a granted plant breeders' right, although this should not, or not exclusively, involve reciprocal grant of plant breeders' rights only, but (also) equitable remuneration for the patent holder. This line of approach

corresponds with the approach followed by the Community draft directive on the protection of biotechnological inventions.

A few remarks can be made in this place.

- Such a construction can only function in the case of a strengthened plant breeders' right as indicated above under c., which should furthermore be open for all cultivated plants. It is therefore recommended to promote the decision-making process along these lines both at Community level and at UPOV level. A modification in the short term of the Plant Breeders' Decree of 1975 to such an extent that plant breeders' rights will extend to all cultivated plants is furthermore being considered.
- Although, as has been stated, the Community draft directive concerning the protection of biotechnological inventions defines the relationship between patent law and plant breeders' rights along the same lines, there are nevertheless a few provisions which will require further explanation during the consultation. The draft directive for instance provides for a period of three years on this subject. A similar period was provided for in the Patents Act and the original draft for the Plant Varieties and Seeds Act, but these periods were cancelled because they were obsolete. The draft directive needs to be modified on this point.
- Furthermore, the draft directive states that the obligation to grant a licence only applies when the new variety concerns a "fundamental technical improvement". It is to be assumed that here an attempt is made to refer to an aspect which has some similarity with the "minimum distance" in the present UPOV convention and the Community draft regulation on Community plant breeders' rights. It is strongly recommended that such an aspect should enter in force in plant breeders' rights.
- The above means that in any case a formal modification of the Patents Act and the Plant Varieties and Seeds Act is required and that viable new contexts ought to be created to further define the new constellation of interests.

<u>Summary</u>

Summing up, the proposed line of approach means in effect:

- Plant breeders' right needs to be strengthened, particularly by means of extending it to all crops and by the creation of a dependent plant breeders' right.
- Varieties or categories, higher than varieties, are not in themselves patentable.
- Biotechnological processes are eligible for patent (see article 3, parapgraph 2, Patents Act).
- Such a patent also extends to the products of that process, i.e. the gene and the plants containing that gene. Plant breeders' right can be granted to the variety potentially formed by these plants.
- The patent obviously does not extend to plants which do <u>not</u> contain the patented gene or to the other genetic material in plants which do contain the gene: there is therefore no restriction on the other genetic material.
- The patented material is freely available for research and development and the variety thus created is also eligible for plant breeder's right.
- Authorization by the patent holder by means of a licence is required for the exploitation of that plant breeders' right.

- Based on the experiences in patent law up to the present the expectation is that the grant of licence will as a rule take place without the mediation of the authorities or the judiciary.
- For the cases in which this is not effected or effected inadequately, article 34, paragraph 4 of the Patents Act will be modified to such an extent that the grant of licences can also be made compulsory for the benefit of subsequent breeders' rights under reciprocal grant of plant breeders' right, against equitable remuneration or a combination of both.
- The latter requires provisions in the executive sphere (examining bodies, appeal opportunities) which need to be studied in greater detail.
- This viewpoint will be promoted on an international level.

17 October 1989

Ministerie van Landbouw en Visserij
Directie Materiele Zaken
Hoofdafdeling Algemene Secretarie
Bezuidenhoutseweg 73
Postadres: Postbus 20401, 2500 EK 's-Gravenhage
Tel. 070 793911 Fax 070 793600 / Telex: 32040 lavinl

landbouw en visserij

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MAF New Zealand

Plant Variety Rights Office
P.O. Box 24,
Lincoln,
New Zealand

PV 10/3

1 September 1989

The Secretary-General
Office of UPOV
34, chemin des Colombettes
1211 Geneva 20
SWITZERLAND

Dear Dr Bogsch

THE INTERFACE BETWEEN PATENT PROTECTION AND PLANT BREEDERS' RIGHTS (CAJ/XXIV/4)

I enclose as requested in your Circular of 16 June 1989 comments from New Zealand on the above document. The comments were prepared following discussion of the document by a working group of representatives of the Patent Office, Plant Variety Rights Office, breeders, farmers, merchants and the Ministry of Commerce (advisors to the Government on intellectual property).

Yours sincerely

F W Whitmore
Commissioner of Plant Variety Rights

FWW:MBS

Enc

Canterbury Agriculture & Science Centre, Ellesmere Junction Road, Lincoln, New Zealand.
Telephone Christchurch (03) 253-011. Fax (03) 252-946.

COMMENTS ON WIPO/UPOV PAPER

CAJ/XXIV/4

THE INTERFACE BETWEEN PATENT PROTECTION AND PLANT BREEDERS RIGHTS

Prepared on behalf of the

New Zealand Plant Variety Rights Office

August 1989

1 INTRODUCTION

1.01 The Plant Variety Rights Office in New Zealand has consulted with interest groups on the overlap between patent protection and plant breeders' rights protection for plants over a number of years. It established a working party in 1988. That working party held two meetings as a result from which the Commissioner of Plant Varieties was able to present a New Zealand position to the October 1988 meeting of the Council of UPOV.

1.02 By 1989 the working party included representatives of plant breeder and farmer groups, the Commissioner of Plant Variety Rights, the Commissioner of Patents, representatives from the Ministry of Commerce (Industrial Property Advisors to the New Zealand Government) and a representative of the New Zealand Institute of Patent Attorneys. This paper was commissioned following the meeting of the working party on 8 August.

1.03 Because of the diverse interests represented in the working party discussions there was no single view on all of the points discussed. This paper indicates where a consensus was agreed to and where divergent views remained at the end of the discussion.

PART I

- PATENT AND PLANT VARIETY RIGHTS LAW AND PRACTICE IN NEW ZEALAND

2 PATENT PROTECTION FOR PLANTS

(a) Patentability

2.01 The New Zealand Patent Office is unlikely to grant patents for inventions involving classical breeding techniques such as selections, discoveries or crossings by reason of the lack of inventive step. However, where the invention involves the transfer of genetic material into plants, patents have been granted claiming as a monopoly: the genetic material itself, the transferring vehicle, the method of transferring the genetic material and plant material into which genetic material has been transferred.

2.02 Whether an invention is proper subject matter for letters patent depends on the definition of the word "invention". This is defined in the Patents Act as being a "manner of manufacture". The legislation makes no express exclusion of plants or biological processes. What is or is not proper matter for a patent depends on the interpretations of the courts. Where there are no directly relevant decisions the New Zealand Patent Office must set a policy which it believes follows the principles of the decisions of the courts. An invention involving transfer of genetic material into plant material is considered to be a manner of manufacture, while classical breeding is not.

2.03 The position of the New Zealand Patent Office is in sharp contrast to that of the Australian Patent Office which has allowed patents to new plants and

for processes for preparing new plants without making any distinction as to how the new plant was achieved. While the legislative definitions of "invention" in the two countries are very similar, the New Zealand definition and the Australian definition in practice include High Court decisions which import binding territorial differences. The last time (1960) that a court in New Zealand considered an invention involving a biological process* (the injection of an enzyme into livestock prior to slaughter to tenderise meat) it indicated in general statements that biological processes and products should not be rejected as a class, each application should be considered on its merits. The patentability of classical breeding techniques and plant resulting from them should be regarded as not finally settled in New Zealand.

(b) Inventive Step

2.04 The existence of an inventive step in relation to inventions involving plant material is a question of fact in each case. The question to be asked is whether the invention would have been obvious to a person skilled in the art. The need for an inventive step acts as a limitation on granting any broad patents for a minor or cosmetic change to a plant. As more and more genetic transfer techniques and vehicles become known and genes identified it becomes increasingly more difficult for inventions to be unobvious. In classical breeding techniques a mere discovery with nothing more will not amount to an inventive step. However, crossings and selections may involve inventive skill and could possibly qualify.

(c) Enabling Disclosure

2.05 A patent is a social contract. In return for a limited monopoly the patentee must enable the public to put the invention into practice once that monopoly has expired. In New Zealand a patentee must, in the patent specification, "particularly describe the invention and the method by which it is to be performed" and "disclose the best method of performing the invention which is known to the applicant". In the case of inventions relating to plants into which genetic material has been transferred the practice of the New Zealand Patent Office is to require both a written description and an indication that the genetical material is available through a recognised depository or otherwise. The validity of this practice has never been tested in the courts. In 1988 an ad hoc government appointed committee report recommended that New Zealand should accede to the Budapest Treaty on the deposit of microorganisms and to amend the legislation to clarify that such a procedure would result in valid patents.

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* Some would question whether this is a biological process.

3 PLANT VARIETY RIGHT PROTECTION

3.01 The New Zealand Plant Variety Rights legislation has, since 1981, provided coverage for all species of plants except fungi, algae and bacteria.

3.02 The New Zealand legislation also provides reasonably strong protection. Acts which constitute an infringement of Plant Variety Rights are as follows:

(a) Selling or producing for sale reproductive material of a protected variety
(b) Propagating any protected variety of an ornamental or fruit producing plant for the purpose of commercial production of produce
(c) Propagating, selling or using imported reproductive material of a protected variety
(d) Importing produce of a protected variety from a country where plant variety protection is not available for that variety
(e) Using the denomination of a protected variety in connection with the sale of another variety.

3.03 The legislation does allow a farmers' privilege. It has been mooted that this privilege might be eliminated in any case where seeds collected by a farmer were then sown for the purpose of producing a commercial crop of grain. This matter is still being debated between breeders' groups and growers' groups.

3.04 The New Zealand legislation also allows a breeders' exemption.

4 OVERLAP OF PLANT VARIETY RIGHTS AND PATENTS FOR PLANTS

4.01 As mentioned above in paragraph 2.01 the New Zealand Patent Office does permit claims in patents to plant material into which genetic material has been transferred by a molecular biological technique. Any plant breeder who without permission produces a new variety which incorporates that genetic material would infringe the patent right by sale of the plant. However, there is a limitation under the Patents Act to the effect that a claim to a new substance shall not be construed as extending to that substance when found in nature. If such a breeder had found the new variety containing the genetic material existing in nature sale of the new variety would not infringe the patent because of this exception to the patent right.

4.02 While New Zealand legislation does not expressly exclude patenting of plant varieties, no varieties have been patented and accordingly New Zealand has in practice complied with Article 2(1) of the UPOV Convention. This position would change should the Patent Office issue such a patent. Under constitutional practice in New Zealand international treaty obligations can only be enforced when enacted in domestic law. The Patents Act 1953 was enacted much earlier than when New Zealand acceded to the UPOV treaty in 1978. The Patents Act has not been amended subsequent to that accession. It is unlikely that an attack on the validity of a patent which includes a claim to a plant variety would succeed on the basis that New Zealand had acceded to the UPOV treaty.

5 DEPENDENCY

5.01 There is no provision in the New Zealand Patents Act for the holder of a Plant Variety Right to be able to obtain a non-voluntary dependency licence from a patent holder whose patent would be infringed by the exploitation of the Plant Variety Right. The compulsory licensing provisions under the New Zealand Patents Act do provide for the grant of a compulsory licence if the patentee has refused a voluntary licence and the working or efficient working in New Zealand of any other patented invention which makes a substantial contribution to the art is prevented or hindered.

5.02 The Plant Variety Rights holder is not necessarily in a subservient position in the circumstance just outlined. The patent holder is not able (by virtue of the patent) to sell the protected variety without infringing the Plant Variety Right. The sensible solution is a cross-licensing arrangement under the two rights. The balance struck between the parties will very much depend on the value of the transferred genetic material as compared to that of the variety into which it has been transferred.

6 NO PATENT PROTECTION FOR A PLANT VARIETY AS SUCH

6.01 Some working party members were in favour of the principle that there ought not to be patent protection for "a plant variety as such"; but at the same time were in favour of the current practice of allowing patent protection for plant material containing transferred genetical material. Others found it difficult to reconcile the two views. An underlying problem appeared to be different understandings of the words "plant variety as such".

7 SUMMARY

7.01 The New Zealand Patent Office refuses patent applications for classical plant breeding processes and products of those processes. This practice is opposite to that of the Australian Patent Office even though the definition of invention is very similar in each country. A relevant New Zealand court decision casts some doubt on the Patent Office practice and it may be that such inventions can be protected by patents in New Zealand.

7.02 Patents have been granted in New Zealand for plants into which genetic material has been transferred by molecular biological techniques. If there were a plant variety right for a new variety incorporating the genetical material (the subject of the patent) then commercialisation of reproductive material of the variety would infringe the patent. On the other hand the patent holder would not be able to sell the new variety without infringing the plant variety right. This mutual dependency would lend itself to a voluntary cross-licensing resolution.

7.03 The New Zealand Patents Act provides for compulsory dependency licences between two patent holders but not between one patent holder and a plant variety right holder.

PART II

- COMMENTARY ON ASSUMED SITUATIONS (ANNEX II: CAJ/XXIV/4)

8 FIRST ASSUMED SITUATION

8.01 Referring to change 1 New Zealand already does provide plant variety protection for all botanical species.

8.02 There was support for suggested change 2 with a proviso from farmers who wished to retain the farmers'privilege. It goes beyond what the New Zealand law presently covers assuming that "material" has the broadest definition in the proposed Article 2 for the UPOV Treaty (IOM/IV/2 of 22 June 1989).

8.03 Change 3 was a change supported by all of the interest groups represented. The only reservations were in respect of a satisfactory definition of the words "essentially derived".

8.04 Change 4. As indicated earlier there is as yet no consensus in New Zealand as to whether Article 2(1) should be retained or removed. The suggested collision norm would be an introduction of what amounts to a breeders exemption under the Patents Act. This should be contrasted with change 3 of this assumed situation by which the breeders exemption has been eliminated from Plant Variety Rights. Such a collision norm would represent a significant weakening of patent protection and an active discouragement to plant breeding using molecular biological techniques.

8.05 Another possible effect of such a provision would be that patent holders would be less likely to make their genetic material available to other breeders. Patentees would be precluded from being able to exploit their patents through reproduction of plant material while breeders who develop new plant varieties and acquire plant breeders' rights would be entitled to preclude the patent holders. This would be a strong disincentive to making the genetic material available to other breeders.

9 SECOND ASSUMED SITUATION

9.01 Some members of the working party understood the proposal to remove "Any exclusion of plant varieties.....from patent protection" as allowing the patenting only of varieties that clearly and without doubt meet the patenting requirement such as reproducibility and inventive step. On the other hand at least one member interpreted the proposal as opening the door to patenting of many or all varieties, including the products of classical breeding techniques which under a conservative as opposed to a liberal interpretation of patent law, would not be patentable. Because of this difference in understanding it is difficult at this time to comment on some aspects of the proposed changes with a single consensus voice. Bearing the above in mind it may be noted that changes 1, 2, 3 and 4 are already the case, wholly or largely, under New Zealand patent law.

9.02 The concern expressed in consequence 2 concerning the wide scope of protection in relation to a species or to complete taxa of a higher order is

perhaps overstated. The policy of the New Zealand Patent Office is to examine very carefully the scope of protection for which "fair basis" can be found in the specification. Where an invention is not of a pioneering nature the scope of protection is limited to processes and products which are specifically exemplified.

9.03 There was no final consensus as to whether dependency licences (change 6) should be voluntary or non-voluntary. There was a general consensus that any non-voluntary dependency licence should provide an adequate return for the licensor.

9.04 The validity of the comment that there is a legal certainty in protecting plant varieties within one system is open to question. In any infringement suit it is open to the defendant to seek revocation of the Plant Variety Rights grant. A Plant Variety Right has a presumption of validity when granted, but it is by no means certain the court will uphold it.

9.05 The establishing of a patent documentation concerning plant varieties does not appear to be an insurmountable obstacle. The international patent documentation is constantly expanding with the issuing of new patents every week. The incorporation into that documentation of a plant variety database would not significantly increase the practical difficulties of that ever expanding database. Some however would stress that any decision on protection of plant varieties must be based on side-by-side comparative growing trials as distinct from a decision based on comparison of written descriptions prepared from different locations and/or seasons.

10 THIRD ASSUMED SITUATION

10.01 The suggestion to make all changes mentioned in the first and second assumed situations does not seem to be possible. Change 4 of the first assumed situation is incompatible with the changes to the patent system of the second assumed situation. It is presumed that the third assumed situation includes only the first three changes of the first and all of the changes of the second assumed situations.

11 FOURTH ASSUMED SITUATION

11.01 Most members of the working party when considering the changes in paragraph 3 and 4 interpreted the word "product" to include plant material to which genetic material has been transferred. One member however interpreted "product" to mean genetic material or transfer vehicle but not plant material. Depending upon which interpretation is taken the implications are very different.

11.02 The suggestion in consequence 6 that the patent system has some sort of legal certainty which can be increased is very doubtful. A patent is granted with a greater or lesser presumption of validity depending on a large number of factors. No patent is granted with a legal certainty that it is valid.

12 CONCLUSIONS

12.01 It is difficult to state that any single presumed situation was favoured by all the interested parties. The difficulty was enhanced by different understandings of the terminology by members of the working party.

12.02 There was some expression of approval for the fourth assumed situation - but that was based on the understanding that "products" included plants into which genetic material had been transferred.

12.03 If on the other hand one understands that "products" excludes plants into which genetic material has been transferred, the third assumed situation comes closest to the current New Zealand law given that New Zealand patents are routinely granted for plant material into which genetic material has been incorporated and that New Zealand offers strong plant variety rights to all botanical species. The third assumed solution also comes closest to compatibility with the agreed observation that a patent in the field of transfer of genetic material can be most fully exploited through reproduction and sale of plants into which the genetic material has been transferred.

12.04 It was generally agreed that there should be appropriate cross-linking dependency licences systems either of a voluntary or non-voluntary nature. It was also agreed that voluntary licences are to be encouraged because they promote the transfer of know-how.

12.05 The value of non-voluntary licensing provisions was seen not so much in that they were an end in themselves but more that they encouraged voluntary licences.

Royal Ministry of Foreign Affairs

The Royal Ministry of Foreign Affairs presents its compliments to the World Intellectual Property Organization and has, with reference to the latter's note No. C. 5033/U. 1456 of June 16.1989 the honor to transmit the Norwegian Government's observations to the memorandum entitled "The Interface Between Patent Protection and Plant Breeders' Rights".

Enclosed to these observations is a summary of the report of 31. January 1989 from the Committee on Biotechnology which was appointed by a Royal Decree of 12. June 1989.

The Royal Ministry of Foreign Affairs avails itself of this opportunity to renew to the Secretary General of the United Nations the assurance of its highest concideration.

Oslo, 3. October 1989

ROYAL NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

WIPO,
34, chemin des Colombettes,
CH 1211 GENEVE 20 Sveits.

CAJXXIV.REG

JN 004669 JUD
1989

Dr Arpad Bogsch
Director General, WIPO
Secretary-General, UPOV
34, chemin des Colombettes,
CH 1211 GENEVE 20 Sveits

Your ref.	Our ref.	Date
C. 5033/ 457	U. 1456	08.4

THE INTERACTION BETWEEN PATENT PROTECTION AND PLANT BREEDERS' RIGHTS, MEMORANDUM CAJ/XXIV/4

The Norwegian Government welcomes the memorandum mentioned above, especially in a situation where Norwegian adherence to the UPOV Convention is under consideration.In our view, the memorandum will serve as a very useful foundation for a revised document to be presented for further discussions on the relationship between patent and plant variety protection at the joint meeting of patent and PVR experts in January/February 1990.We find, however, that the memorandum is somewhat weighted in favour of the UPOV system of protection.The general discussion parts of the present annex I (para 7-28) could be transferred to the main part of the memorandum in order to achieve a somewhat better balance between the descriptions of the patent and the UPOV systems.A final document ought to strike a better balance between the patent and the UPOV system.We suggest that the description of the UPOV system should be followed by a similar description of the patent system in the next version of the memorandum.

Specific comments:

As far as the prohibition against double protection (in art 2 (1) of the UPOV Convention) is concerned it would be appropriate to mention that prohibition as one of the reasons for the doubts concerning the patenting of plant varieties as listed in para 31.Further, this prohibition is not dealt with in the description of the currently proposed revisions of the UPOV Convention.This seems to need a clarification.

In Norway, plant varieties are not concidered patentable subject matter according to legislation corresponding to art 53 (b) of the EPC.In accordance with the view presented by The Committee on Biotechnology, cf. The Special Report on Biotechnology and Patenting, NOU, 1989:8, summary, p.15. pt. 0.4, naturally occurring or genetically modified plants may not be granted product protection.The present administrative practice corresponds to this view and consequently to a broad interpretation of the law provisions corresponding to art 53 (b) of the EPC.

From a Norwegian point of view, it seems desirable to maintain the prohibition against double protection in the UPOV Convention, provided, however, that the new variety concept will not include material which is considered patentable subject matter according to most patent laws (such as chemically treated seeds, undifferentiated tissue and/or plant cell cultures).In our opinion, a new plant variety definition needs further specificity so that the new definition would not unduly restrict the applicability of patent protection.

We believe that there will be a need for both the patent and the UPOV system in the years to come and that it should be possible to achieve a balanced coexistence of the two systems.Such a coexistence will, as indicated in the two examples presented in annex I, have to be based on mutual licence provisions between patent and plant variety right (PVR) holders.It is of essential importance to keep the primary producers, e.g. farmers, outside the effects of the industrial property rights when applied in practice.Furthermore, the need for a provision based on the principle of "farmers privilege", as it appears in the UPOV Convention, irrespective of the system applied, is recognized.

JN-004669 -UD
1989

Summary

0.1 COMPOSITION AND MANDATE OF THE COMMITTEE

The Committee on Biotechnology was appointed by a Royal Decree of 12 June 1987. It consisted of ten members representing various ministries and interest organizations and its mandate was to examine certain issues arising from the development and use of biotechnology, with special emphasis on environmental and security aspects.

The question of patents or other legal protection of biotechnological inventions was not specifically mentioned in the mandate. However, this question became very prominent during the life of the Committee, and a number of international organizations are presently preparing reports or proposals relating to patents for biotechnological inventions. Among these are the United Nations specialized organization the World Intellectual Property Organization (WIPO), and the European Community (EC).

In a letter to the Committee dated 18 November 1988 the Ministry of the Environment requested it to submit a special report on biotechnology and patenting.

0.2 SUBJECT OF THE SEPARATE REPORT

The separate report deals with patents for biotechnological inventions. The Committee has concentrated on inventions concerned with genetic material or the genetic modification of living organisms.

A patent signifies that the holder has the sole right to make use of the invention for a limited time period (20 years from the time of the application). However, the patent-holder may not make use of the invention if this involves contravening other laws. No one other than the patent-holder may make use of the invention without the consent of the holder or unless there is a compulsory license.

In order to be granted a patent, certain conditions have to be fulfilled (novelty, inventive step reproducibility, industrial applicability). Members of the public have the right to become familiar with inventions that have been patented or for which a patent has been applied.

An important question when considering patents for living organisms or genetic material is the scope of such a patent. This again raises specific questions, such as whether a patent for a living organism capable of reproduction should apply to the progeny, and whether a patent for genetically modified organisms should apply to naturally occurring organisms of the same kind.

0.3 SUMMARY OF THE CONTENTS OF THE SUPPLEMENTARY REPORT

Chapter 1 outlines the Committee's appointment, composition, and work on patent issues.

Chapter 2 gives a short survey of biotechnological methods and the main concepts involved.

A common definition of biotechnology is:

All technology that utilizes micro-organisms, plant or animal cells, or parts of these to produce or modify products, to improve or change plants or animals, or to develop micro-organisms for specific purposes.

The definition covers traditional biotechnological methods in industrial production enzyme technology, cell and tissue technology, and gene technology.

Biotechnology is not a new discipline. It has given us well-known products like beer wine, cheese, yoghurt, yeast, and vinegar About 75 years ago biochemical processes for the production of chemicals like butanol acetone, and glycerol, were developed with the aid of microbiology.

During and after the second world war biotechnological processes were developed for the manufacture of penicillin and other antibiotics on an industrial scale. The first breakthrough in modern biotechnology was a result of the development of gene technology (recombinant DNA techniques). A further advance was made with the discovery of methods for the production of unlimited number of identical antibody molecules (monoclonal anticodies).

Micro-organisms are important «tool components» of biotechnology. Broadly speaking, they can be used instead of the syntethic production of a complex molecule. In other words, micro-organisms are tiny factories for the synthesis of chemical products.

Gene technology is a general term for a number of techniques for altering the genetic properties of an organism.

By means of gene technology micro-organisms can be made to produce specific proteins in relatively large amounts. The appropriate gene is introduced into a micro-organism and the latter is then cultured in a fermentation tank. An example of this is the production of human insulin. The human gene for insulin production is spliced into a plasmid (a ring-shaped DNA molecule) which is transferred to a bacterium. This bacterium is then cultured in large numbers in a fermentation system, where the insulin is produced.

Biotechnology occupies an increasingly important position in various branches of industry, like the chemical industry, pharmaceutics, food production, agriculture, and aquaculture. It is an important area of research and development in medicine and biology. It also makes an important contricution to conservation, e.g. in the cleaning and recirculation of waste water.

The development of biotechnology is to a large extent linked with that of gene technology, for example biotechnological inventions may consist of new techniques for the production of drugs or chemicals. In agriculture and aquaculture biotechnology contributes in the form of living organisms like cereal strains, fish, or domestic animals with new artificially added properties. Protein synthesis provides the possibility of manufacturing synthetic genes and completely new proteins.

Chapter 3 summarizes the regulations and procedures that apply to patents.

The Norwegian patent system is governed by the Patents Act of 15 December 1967 No. 9, and the pertinent provisions and regulations.

A distinction is made between a product patent, a processes patent, and a patent for use.

A product patent grants the sole right among other things to manufacture, market, and sell the product. The product may only be exploited with the consent of the patentholder.

A processes patent grants the sole right to manufacture a product by means of a particular process, and also covers the marketing and use of a product manufactured by this process. It does not prevent others from having the right to produce the same product by other means.

A patent for use grants the sole right to a particular use of a product.

Four main criteria have to be fulfilled for a patent to be granted:

1. The invention must be *new* – it must not have been disclosed or made available to the public previously.
2. There must be an *inventive step*, i.e. the invention must differ *in important respects* from anything already known.
3. The invention must be *reproducible*. The description in the patent application must be so clear that after reading it an expert would be able to reproduce the same result.
4. The invention must have an *industrial* application.

The patent does not give the holder an automatic right to make use of the invention for commercial or industrial purposes. The authorities can forbid or regulate the use of the product or process irrespective of whether or not it has been patented. Acts like the Product Control Act, the Pollution Act, the Work Environment Act, and the Drugs Act must not be contravened.

Chapter 4 discusses the main advantages and disadvantages of the patent system and considers other methods of protection. For example, an inventor can try to protect his or her invention through secrecy instead of patenting it.

The improvement and development of new plant strains is covered by a different form of legal protection, the UPOV convention. The convention offers the inventor protection but the rights granted are not as exclusive as those of a patent.

The conditions of application under the UPOV convention differ in several respects from those governing patents. For example, there is no requirement that the new strain must be a new invention. Previous public knowledge of the strain is not a hindrance as long as it has not been marketed, and there is no requirement of reproducibility.

A system on the lines of the UPOV convention would be simpler to administer and control, especially as regards the progeny of plants and animals. In the primary sector, agriculture and aquaculture, this would be a good alternative to the patent system. In industrial biotechnology, however, it would not afford enough protection.

Chapter 5 deals with patenting and biotecnology under Norwegian law.

The Patents Act does not primarily differentiate between different kinds of technology, but is stipulates several important exceptions for which a patent may not be granted, which are important in a biotechnological context.

The Norwegian interpretation of the Patents Act does not allow the granting of a product patent for plants or animals. The question of a product patent for (genetically modified) microorganisms has so far remained open. The Patent Office has established a basic rule that product patents can be granted for synthetically produced genes.

Patents cannot be granted for essentially biological processes for the production of plants or animals or for traditional methods of breeding of animals or plants. Microbiological processes, including those of gene technology, may, however, be patented.

There are also certain restrictions on the patenting of inventions for use in medicine or food production, or for inventions whose exploitation would be «contrary to morality or public order».

The Committee briefly discusses the questions that the ordinary conditions for granting a patent raise in connection with biotechnological inventions.

The Committee further indicates a number of questions concerning the content of the patent-holder's rights that will arise in the event of patents being granted for living organisms or genetic material. It is emphasized that these are hypotetical questions, since any answers based on present patent law would be uncertain. The Committee takes up, for example, the question of whether a patent would cover later progeny, whether a patent for genetically modified organisms or isolated naturally occurring organisms will also apply to naturally occurring organisms, and what rights the patent-holder would have in the event of a product patent for genetic material.

Chapter 6 describes international developments in patent law. The present trend is towards a more comprehensive protection and increasing harmonization of the regulations between the various countries. The trend in the 1980s has been towards an increase in the granting of patents in connection with living organisms.

A number of reports and proposals concerning biotechnological patents are being drafted internationally. The Committee briefly presents the work being done by the OECD, WIPO, and the Nordic Council of Ministers, and mentions FAO's efforts to preserve the world's genetic resources.

In October 1988 the European Commission presented a proposal for a directive on the legal protection of biotechnological inventions, much of which is based on the work of the OECD and WIPO. The Committee describes the background and content of the proposal and the future handling process.

The Committee's general comment on the Commission's proposal is that it opens up a wider field for the granting of patents. It is too early to say what final form it will take. The Committee considers that it is realistic to predict that the practice of the European Patent Convention will gradually conform to the final EC directive.

Chapter 7 briefly describes the work being done on possible changes in Norwegian patent law.

Chapter 8 presents and discusses the arguments for and against the patenting of biotechnological inventions, which vary according to the nature of the invention. In some cases a differantiation between the industrial and primary sectors is useful as regards the appropriate form of legal protection, i.e. patenting or some other method. Here it may also be appropriate to distinguish between different forms of living organisms.

The Committee points out that the patent system will constitute a general indirect means of stimulating the development of biotechnology, and especially of encouraging industry to invest in biotechnological research, production, and product development. An important point here is that biotechnology has been selected as a primary national investment area in Norway. However, more specific measures may be preferable to stimulate particular trends in biotechnology research.

The Committee discusses whether the patent system can hamper biotechnological developments in certain cases, and points out possible consequences of monopolies resulting from patents.

The Committee weighs up patenting against other methods of stimulation for protecting the patent-holder's economic interests. A system based on the UPOV convention would be simpler to carry out, especially as regards the progeny of plants and animals and would be a good alternative to the patent system in agriculture, fishing, and aquaculture. However, patenting is probably the only form of legal protection suitable for industrial biotechnology, among other reasons because industry is in a different position from

the primary sector, owing to its structure and international links.

The Committee discusses how the patent system can influence the publication of research results and how it can contribute to the financing of research.

This is followed by a summary of the possible effects of the patent system on developments in industry and the primary sector (agriculture, fishing, and aquaculture).

The Committee also raises the question of how the patent system can affect access to genetic resources, including the consequences it could have for gene banks.

A further point is made that patenting may affect questions of distribution between industrial and developing countries. The Committee recommends a more detailed consideration of these issues.

The Commettee indicates the ethical problems particularly connected with patenting. The ethical problems raised by biotechnology in general are dealt with in the main report.

The patenting of genetic material, plants, and animals may raise strong ethical objections, especially in relation to product patents. The question arises of whether anyone has the right to the exclusive use and sale of plants or animals. With regard to micro-organisms, there would for many people be a deviding line depending on whether the micro-organism occurs naturally or is a product of genetic modification.

0.4 THE COMMITTEE'S RECOMMENDATIONS (Chapter 9)

The Committee emphasizes strongly that legal protection for biotechnological inventions should not take forms that create unnecessary new impediments to the exploitation of natural resources, or that contribute to a widening of the gap between industrial and developing countries. The present industrial use of biotechnology indicates that most new inventions in this field will not cause problems.

The Committee wishes to emphasize that the granting of product patents for humans, human organs, or human genes has no ethical justification.

Product patents, processes patents, and patents for use are considered separately.

Product patents

The Committee recommends that procuct patents may *not* be granted for:

- naturally occurring or genetically modified animals or plants,
- naturally occurring micro-organisms,
- naturally occurring genes (isolated or compound genetic material),
- single cells or tissue from plants or animals that can develop into new organisms.

The Committee recommends that product patents *may be* granted for:

- biochemical products of biotechnological processes,
- genetically modified micro-organisms and non-differentiating cells and cell lines (a majority of the Committee).
- A minority of two are not in favour of product patents for genetically modified micro-organisms or non-differentiated cells or cell lines.
- A majority of the Committee recommends that product patents may be granted for synthetic genes for introduction into micro-organisms.
- A minority of two are not in favour of any form of product patent for synthetic genes.

Processes patents

The Committee recommends that processes patents *may be* granted for:

- the production of living organisms with new properties,
- non-differentiating cells and cell lines grown in culture for the production of biochemicals,
- technical procedures for the isolation and splicing of genes,
- the production of synthetic genes.

The Committee recommends that processes patents may *not* be granted for:

- the use of cells or tissue for the production of plants and animals or their organs,
- essentially biological processes for the production of plants or animals.
- The Committee considers that the progeny of plants or animals based on patented processes should be freely available for marketing and utilization.
- As regards micro-organisms produced by a patented process, the progeny should be available for own use but not for commercial exploration.

The Committee recommends that questions concerning the infringement of patent rights should be settled by a court of law in each case, and advises against the introduc-

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tion of a statutory rule reversing the burden of proof. This issue can be reconsidered in the future if necessary.

Patents for use

The Committee recommends that patents for use can be granted for:

- the use of living organisms for a specific purpose. This right should be linked with effective measures for compulsory licenses,
- cells and tissues in culture for the production of specific biochemicals,
- synthetic genes in so far as they are used for the production of biochemicals.

The Committee recommends that patents should *not* be granted for:

- the use of naturally occurring genetic material or synthetic gene sequences based on naturally occurring genes,
- the use of cells or tissue for the development of new organisms.

The Committee indicates the points in the present Patents Act that need to be altered to comply with its recommendations, but does not propose any wording of the alterations.

The Committee recommends that its recommendations form the basis of Norwegian policy in international fora. It has not, however, taken any stand on Norway's attitude to the European Commission's proposed directive and the present negotiations in GATT or on the question of membership of the European Patent Convention.

If international practice should become more liberal as regards the granting of patents than the practice suggested by the Committee, Norway's position will have to be clarified. Among the many issues at stake are whether the changes will involve desirable trends in ethical developments or the use of resources, and what the consequences will be for the economic sector and the environment.

The Committee recommends that Norway become a member of the UPOV convention.

The Committee considers that legal protection for animals, including aquaculture, along the lines of the UPOV system should be taken up internationally.

MINISTERIO DE INDUSTRIA Y ENERGIA
El Director del Registro de la Propiedad Industrial
PANAMA, 1
28036 - MADRID

Madrid, 4 de octubre de 1989.

Sr. D. Arpad Bogsch.
Director General de
OMPI.
34, Chemin des Colombettes.
1211 - GINEBRA 20 (Suiza)

Estimado Sr. Director General:

Adjunto se remiten los comentarios del Registro de la Propiedad Industrial al documento preparado por la Oficina Internacional para la protección de obtenciones vegetales (UPOV) en cooperación con la OMPI titulado "Relación entre la protección por patente y la protección por certificado obtención vegetal" ~~(CAJ/XXIV/4)~~.

Atentamente,

Julio Delicado Montero-Ríos.

REGISTRO DE LA PROPIEDAD INDUSTRIAL

Panamá, 1 - 28071 MADRID
Teléfono 458 22 00
Telex 47020 RPI-E

COMENTARIOS DEL REGISTRO DE LA PROPIEDAD INDUSTRIAL EN RELACION CON EL DOCUMENTO CAJ/XXIV/4 PREPARADO POR OMPI Y UPOV

En primer lugar, conviene mencionar que un proceso de reforma de las actuales leyes nacionales en materia de invenciones biotecnológicas, está actualmente en curso en el seno de la CEE en forma de discusión de una nueva directiva. De manera paralela tambien se está debatiento en la CEE otro proyecto de directiva acerca de los derechos del obtentor comunitario. En consecuencia, sería deseable que las soluciones que se adoptaran en el comite conjunto UPOV-OMPI tuvieran en cuenta los trabajos en curso sobre estos temas y, en la medida de lo posible, armonizaran las diferentes soluciones que para los mismos problemas se están suscitando en estos diferentes foros. Conviene asimismo mencionar que en el seno de la propia OMPI se ha reunido un Comité de expertos para la protección de las invenciones biotecnológicas, cuyas soluciones para los temas que afectan al reino vegetal y a las propias variedades y sus titulos de protección, no coinciden en algunos puntos con las aquí propuestas.

Tras la lectura y estudio del documento CAJ/XXIV/4 de la UPOV, el Registro de la Propiedad Industrial, entiende que la solución propuesta en el caso 4 (Anexo II) -que introduce reformas en el derecho de obtención vegetal y en paralelo, también en el derecho de patentes- seria, en principio y con algunas matizaciones, la mas adecuada de las diversas soluciones que se otorgan.

Ademas, se considera que la protección que debe otorgarse a las invenciones biotecnológicas no debe sobrepasar los límites que, en este punto, se imponen en los diversos tratados internacionales de los que España forma parte y que tienen relación con el tema que nos ocupa.

Sobre la base de estos principios a continuación se realizan diversos comentarios a los puntos concretos contenidos en el caso 4 del documento CAJ/XXIV/4 (Anexo II).

PUNTO 1

No entra este Registro de la Propiedad Industrial a realizar comentarios sobre las modificaciones propuestas al Derecho de Obtención vegetal contenidas en el caso 1 del Documento CAJ/XXIV/4 (Anexo II), al ser competencia esta materia

.../...

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Telex 47020 RPI-E

del Ministerio de Agricultura. No obstante, debemos mencionar que este Registro estaría de acuerdo en evitar la doble protección por patentes, cuando éstas pudieran concederse, y certificados de obtencion vegetal para las mismas variedades vegetales.

No obstante, en cuanto a la norma de colisión contemplada en el punto 4 del caso 1, para evitar la posible anticipación por parte de patentes previas a la variedad vegetal que, ahora con motivo de la extensión de los certificados de obtención vegetal a todas las especies botánicas, se pretendería depositar como título de obtención vegetal, no se comparte en el contexto general del caso 4, la solución aportada por el Documento.

La Oficina española sugeriría la adopcion de un sistema de licencias por dependencia entre patentes y certificados de obtención vegetal que salvaguardase una total reciprocidad. No parece lógico ignorar unos derechos anteriores que pueden afectar incluso a uno de los requisitos fundamentales consignados en la Convención UPOV a la hora de proteger una variedad vegetal y que sería su novedad desde el punto de vista de que sea distinta a otras variedades existentes, aunque éstas estén protegidas a través de patentes o incluso de modelos de utilidad. En este punto quizá sería deseable que las autoridades de examen de variedades, tuvieran acceso a la documentación patente sobre la variedad objeto de examen e incluso a muestras de la misma si éstas hubieran sido depositadas en alguna autoridad de depósito de acuerdo con el Tratado de Budapest.

PUNTO 2

El RPI se muestra de acuerdo con esta declaración general de exclusión de protección a través de patentes de las variedades vegetales, tanto en el caso de patentes de producto como en el supuesto de que se intente proteger por la vía de extensión de protección en las patentes de procedimiento al producto (variedad vegetal) directamente obtenido por el procedimiento patentado.

PUNTO 3

También en este punto la Oficina española se muestra de acuerdo con la propuesta. La extensión de la patente de procedimiento al producto directamente obtenido cuando éste es autorreplicable, a las sucesivas generaciones, no debe tener como objeto encubierto la protección de variedades vegetales a partir de reivindicaciones para células, tejidos, o material que pueda regenerar la planta completa. Hay que reseñar en este

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Teléfono 458 22 00
Telex 47020 RPI-E

punto que al mencionarse la replicacion o la diferenciacion, se está hablando de reproducción vegetativa, asexual por tanto. Pero podrian darse reivindicaciones dentro de una misma patente para material reproductor de tipo sexual, por lo que quiza deberia ampliarse el concepto más restrictivo de replicacion o diferenciacion, a multiplicacion en general, para cubrir estos otros supuestos que afecten a variedades de reproduccion sexual.

PUNTO 4

La Oficina española aceptaría la solución propuesta en cuanto que excluye a las variedades vegetales, si bien sabe que tal exclusión va a ser fuente de amplia polémica entre los círculos interesados. Las mayores presiones de modificación del actual sistema de la UPOV vigente desde 1961 vienen por parte de la industria, mas partidaria siempre del sistema de patentes. Las nuevas técnicas de ingeniería genética han permitido a compañías que nunca han estado interesadas en obtener nuevas variedades, conseguirlas casi de forma rutinaria dentro de sus propios procedimientos biotecnológicos. Un nuevo gen aislado sólo tiene valor economico si se encuentra integrado dentro de un todo, un genoma que pueda expresarse. Es decir debe estar introducido de forma estable y transmisible dentro de una célula. Si ésta es vegetal, por las caracteristicas inherentes a la materia vegetal, va a poder regenerar la planta entera. Si ésta puede reproducirse de forma estable y homogenea ya tenemos una nueva variedad vegetal. Proteger por patentes el gen tan sólo, e ir protegiendo por certificados de obtención vegetal las diferentes variedades donde áquel se vaya introduciendo puede ser una solucion, pero plantea problemas cuando dichas variedades sean obtenidas por terceros si no contemplamos en paralelo algún tipo de compensación para el titular de la patente.

Ademas, por lo que se refiere a la protección de la información genética a cualquier producto que la contenga y/o exprese, el RPI entiende que para que tal protección se produzca debería ser expresamente reivindicada en la solicitud de la patente correspondiente.

PUNTO 5

El concepto de agotamiento del derecho con la simple puesta en el mercado del producto carece de sentido si dicho producto puede multiplicarse, por lo que la tendencia actual es hacer una excepción en este sentido para la materia viva replicable ampliándose el derecho de patente a las sucesivas generaciones.

Desde este prisma España defiende esta postura, siempre y cuando no se incluya en la misma a las variedades vegetales.

REGISTRO DE LA PROPIEDAD INDUSTRIAL

Panamá, 1 - 28071 MADRID
Teléfono 458 22 00
Telex 47020 RPI-E

Está claro que la excepción del agotamiento del derecho no puede aplicarse por igual, a microorganismos que a plantas. Por ello se está a favor de preservar el privilegio del agricultor y a no distorsionar el mercado alimentario de origen vegetal, basado mayoritariamente en un sistema de variedades, con excepciones a la norma de agotamiento del derecho, que por otra parte defendemos para otros productos biológicos (genes, células, hibridomas, microorganismos, etc.). Creemos suficiente remuneración para el obtentor el pago por parte del agricultor del importe de las semillas, sobre todo teniendo en cuenta que éste a la larga va a seguir comprando tales semillas periodicamente, ya que es muy difícil mantener por endogamia una población de una variedad por muchos años.

PUNTO 6

Este punto puede ser de gran utilidad a la Oficina española para solucionar los problemas que plantea la reforma propuesta en el punto 4. Sin embargo sería necesario un estudio jurídico previo en profundidad que analizara la problemática que plantearían cruces de licencias entre 2 derechos diferentes, el de obtenciones vegetales por una parte y el de patentes por otra.

Bundesamt für geistiges Eigentum (BAGE)
Office fédéral de la propriété intellectuelle (OFPI)
Ufficio federale della proprietà intellettuale (UFPI)

3003 Bern
Einsteinstrasse 2
✆ 031/614967

Telex 912805 bage ch
Telefax 031-614895
PC 30-4000-1

U. Zeichen
N. réf.
N. rif.

✆ 031/61

I. Zeichen
V. réf.
V. rif.

I. Nachr. vom
V. lettre du
V. lettera del

30 octobre 1989

Monsieur Arpad Bogsch
Directeur général
OMPI
34, ch. des Colombettes

Mp/hof

1211 Genève 20

Note C. 5034/-457 - Projet de mémorandum "Interface entre la protection par brevet et la protection par certificat d'obtention végétale"

Monsieur le Directeur général,

Suite à notre lettre du 6 septembre 1989, nous avons l'honneur de vous transmettre quelques remarques concernant le document susmentionné, nonobstant les développements récents concernant ce document. Nos remarques seront brèves et ne devront pas être considérées comme exhaustives.

Tout d'abord, nous notons que si le projet traite de manière détaillée la protection de la matière vivante sous le régime de la convention UPOV (dans le texte actuel et dans celui qui est envisagé), il ne le fait pas en ce qui concerne la situation sous le régime du droit des brevets. En particulier, nous sommes de l'avis que les enjeux d'un système tel qu'il est proposé par les solutions contenues dans le document BioT/CE/IV/3 mériteraient des réflexions ultérieures. Par exemple, si le projet de mémorandum fait état de doutes en ce qui concerne la protection dérivée d'un brevet de procédé (par. 76 du projet) ou l'épuisement des droits (par. 41 ss., 53 du projet), il nous semblerait

In einem Schreiben soll nur ein Gegenstand behandelt werden / Ne traiter qu'un seul objet par lettre / Pregasi trattare un solo oggetto per lettera

judicieux d'accorder plus d'attention aux solutions précitées (en l'espèce solutions suggérées 8 et 10) ainsi qu'à leurs conséquences.

Nous regrettons aussi que le projet n'examine pas plus à fond la question de la défense de double protection (article 2 alinéa 1 de la convention UPOV), voire de son abolition. A ce sujet, un examen de la situation aux Etats-Unis, où cette défense n'existe pas, serait sans doute intéressant.

Parmi les sujets qui devraient être approfondis en ce qui concerne le domaine des brevets, nous aimerions encore mentionner la notion de "variété végétale" et la dépendance entre les brevets et les certificats d'obtention végétale. En ce qui concerne le premier point, nous remarquons que le projet de mémorandum se base sur une notion très large de "variété végétale", qui n'est pas limitée à ce qui est protégeable sous la convention UPOV (par. 5 ss., en particulier par. 18 du projet). Comme dans les lois de plusieurs pays (dont la Suisse), la notion de "variété végétale" apparaît aussi dans les dispositions d'exclusion de la brevetabilité, nous craignons qu'une telle définition puisse créer un champ intermédiaire entre le domaine UPOV et celui des brevets, où aucune protection ne serait possible pour les résultats en la matière. A notre avis, un tel champ intermédiaire serait inadmissible. En ce qui concerne le deuxième point, c'est surtout l'article 5 alinéa 5 des propositions de révision de la convention UPOV qui risque de porter un grave préjudice au domaine des brevets. Les explications données à ce sujet au paragraphe 98 du projet nous paraissent être insuffisantes; les conséquences d'une telle disposition pour les titulaires de brevets devraient être clairement indiquées.

Comme nous l'avons déjà mentionné au début, au vu du programme des travaux, ces remarques ne constituent pas une prise de position complète. Néanmoins, nous espérons qu'elles pourront vous être utiles.

Veuillez agréer, Monsieur le Directeur général, l'assurance de notre considération distinguée.

Office fédéral
de la propriété intellectuelle
Le Directeur:

R. Grossenbacher

MINISTRY OF JUSTICE
Division for International Affairs
S-103 33 STOCKHOLM, Sweden
Telephone: 763 1000

7 September, 1989 89-1839

UPOV
34, chemin des Colombettes
CH- 1211 GENEVE 20
Schweiz

Re: The memorandum "The Interface Between Patent Protection and Plant Breeders' Rights" (CAJ/XXIV/4, April 3, 1989)

Sweden welcomes the initiative to elaborate this memorandum. The paper will serve as an useful basis for further discussions on the relationship between patent protection and plant variety protection. However, the facts and views in the document bear a distinct UPOV flavour. Patent protection is given comparably little attention in the document. And to the extent it is dealt with, the text contains some misconceptions and ambiguities. Examples of this can be found in para. 35, 38-40, 42, 45, 56 and 86. Furthermore, the discussion on the possibility of the deletion of the prohibition against double protection in the UPOV convention is not referred to. A final common memrandum ought to strike a better balance between the two systems of protection.

Having said this, we would offer some specific comments on the following paragraphs.

Para 36 (note - there are two such paragraphs), no 1

The words "of plant material" should be deleted, to make it more clear that the object of this sui generis protection is the variety itself.

Para 37

The different concepts of "variety" ought to be described in the same paragraph somewhere in the memorandum to give a better understanding of the various available possibilities. Thus, a description of the "biological" concept, the "UPOV" concept, the "EPO" concept etc., could be included in part II A. Also, a description of the EPO decision T 320/87 should be made in this context. These remarks have a bearing also on paras 13 and 14.

Para 46

One of the important reasons for the prohibition against patent protection for plant varieties in the Strasbourg convention was that, at that time, it was not possible to obtain reproducibility in this field.

Para 48

It would be of great value to have a reference to the source of this information.

Para 51

The problems under a) and b) are confusing to the non-expert, mostly due to the very condensed presentation. Thus they require elaboration. Specifically, the problem under b) needs to be clarified.

Regarding c) the problem seems to center on whether the entire genome is involved (as in traditional plant breeding) or the invention is directed only to a single gene capable of expressing a specific characteristic. The important difference here between PVRs and patents is that the latter covers the physical result as well as other aspects of the idea behind it, whereas a PVR would only cover the physical end result.

Parts of plants are often but not always propagating material -which the first line of c) seems to suggest.

Protection will not invariably be sought for the callus or cell-line of a particular plant. Biotechnological inventions are often characterized by the invention working in a living matter, e.g. a plant, in which case the plant only serves as a host organism. Other species may serve as well as hosts. The importance lies often only in the protection of the gene or other plant material which cannot differentiate. In this situation, it does not seem satisfactory that the only protection available would be the PVR, which can only serve to protect the variety as such.

Para 60

We fail to understand what the "original difficulty" could be. Under Swedish law, as under the EPC, the deposit can only partly replace the description and was never meant to do more than that.

Para 69

The description of the impact of the "farmer's privilege" on the profitability of plant breeding ought to be more neutral and not reflect only the interests of the breeders.

Para 73

The question how far the patent of a gene incorporated in a plant will affect the possibility to get a PVR for the variety needs elaboration. The subject matter of dependancy is here brought to the fore.

Para 74

This paragraph does not seem to refer to arguments in the debate but rather to a conclusion already drawn ("The view is taken..."). A rephrasing seems appropriate.

Further, the beginning of the last sentence ought to be amended to read: "Interpretations of the exclusion..." to reflect that these definitions are being applied in a legally binding context, e.g. in Switzerland and by the EPO.

Annex I

It would be valuable to have a more "patent orientated" example instead of that of dwarf wheat in order to show where a patent could be a more adequate form of protection.

Yours sincerely

Fredrik von Arnold

ad. a.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

13 SEP 1989

Dr. Arpad Bogsch
Director General
World Intellectual Property Organization
34, chemin des Colombettes
1211 Geneva 20
Switzerland

Dear Dr. Bogsch:

In response to your request, we are pleased to provide comments on the draft memorandum entitled "The Interface Between Patent Protection and Plant Breeders' Rights", document CAJ/XXIV/4.

In general, the draft provides a wealth of useful information in analyzing the relationship between patent protection for plants and plant breeders' rights. To a large degree, however, the draft appears to be an attempt to defend plant breeders' rights by subtly calling into question the concept of protecting plants through patents. The draft does this through the repeated raising of perceived problems and hypothetical concerns. Interspersed with expressed misconceptions of how and to what extent patents protect plants and their components, the draft memorandum attempts to cast doubt on the ability of the patent system to protect plants and plant varieties, thus leaving the concept of plant breeders' rights as the only practical means of protection. Although utility patents for plants and plant varieties are not as yet an internationally wide-spread means of protection, that is no basis to dismiss this concept as unworkable and therefore undesirable.

This is especially important in the revision efforts of the UPOV Convention. While there admittedly has to be a relationship between two separate systems of protection that cover the same or similar subject matter, care must be taken that one system of protection is not elevated in favor of another. For example, the proposal that patent rights should not be assertable against the owner of a plant breeder's certificate would relegate patents to a second-class system. Also, the two titles of protection should not be dovetailed in a manner that would adversely modify either one. For example, the concept of forced dependency through the introduction in the patent system of compulsory licensing provisions would be fundamentally unacceptable.

At the same time, care must be taken that the exclusive rights granted to a patentee are limited to the specific technological contribution that the inventor has made to a given field of technology. In other words, although an inventor must be entitled to limited exclusivity of his patented invention, protection must not be so broad as to stifle innovation of similar technology, or improvement of the invention. To the extent, however, that use of an improvement involves use of the initially protected invention, it is not unreasonable to require authorization from the owner of that original invention.

Improvement of the current system of plant breeders' rights, especially within the context of the revision of the UPOV Convention, is a welcome and long-needed effort. It may well be, that an improved system of plant breeders' rights will incorporate some concepts from patent law and diminish the need for many to seek patent protection. Also, strict application of the criteria for patentability may make many improvements in the field of plant breeding ineligible for patent protection, although they may well be qualified for obtaining a plant breeder's right. As a consequence, developments under both titles of protection should be allowed to evolve and to seek their own level of relationship, without being curtailed prematurely by international conventions. Regrettably, this was done by the European Patent Convention years ago, largely on historical grounds rather than as a result of an empirical analysis. To some degree, a similar approach appears to be followed in the current revision of the UPOV Convention. The protection of intellectual property is a continuing process, especially when involving technologies that were either previously unknown or thought to be unattainable. In our opinion, this process should not be hampered if we want to keep providing the incentive for innovation.

These, then, are our general comments regarding the draft memorandum. In addition, we have enclosed specific comments regarding individual paragraphs of the draft memorandum.

Sincerely,

Donald J. Quigg
Assistant Secretary and Commissioner
of Patents and Trademarks

Enclosure

COMMENTS ON UPOV DOCUMENT CAJ/XXIV/4

Paragraph 32. The last sentence of this paragraph represents an example of the general direction taken by the draft memorandum. The sentence first unequivocally notes that "the fact that patent rights are exhausted when goods subject to a patent are placed into the market", and then draws the conclusion that this has the effect of nullifying the benefits of the patent, at least "according to one opinion". If this conclusion were correct, patent rights in a particular invention could not be asserted after the first sale of the patented product. In fact, patent rights are not necessarily exhausted when patented goods are placed into the market place. There is no reason why principles applicable to patented inanimate subject matter cannot also apply to self-replicating products. Accordingly, the doctrine of "repair" or "reconstruction" could well be applied. Under this doctrine, an authorized buyer of a patented product obtains, as part of the implied license to use the patented product, also the right to make "repairs" necessary for its continued use as long as they do not amount to a "reconstruction" of the patented product. Also important is what use the patentee had intended to be made of the patented product when he placed it on the market, including possible field-of-use restrictions. Suffice it to say, the question of whether a patent right is simply exhausted when goods are placed on the market and is therefore ineffective as far as plants are concerned is not as simple as the statement in paragraph 32 appears to imply.

Paragraph 35. This paragraph reaches the conclusion that the difficulty of applying the non-obviousness criterion of patentability in the case of plant inventions "means that in practice it is largely ignored." Despite the difficulty of applying this standard to any complex technology, it does not follow that it can be, or is largely, ignored. The Yoder Brothers case (537 F.2d 1347, 5th Cir. 1976) referred to in this paragraph, did indicate that the court had some difficulty in following the approach to analyzing non-obviousness as laid down by the U.S. Supreme Court in Graham v. John Deere Co., 383 US 1 (1966), and particularly in determining the level of skill in the art. This, however, is not unusual in complex technologies. The U.S. Patent and Trademark Office does not take the approach resorted to by the court in Yoder Brothers (reference to the underlying constitutional standard of "invention"), but determines the level of ordinary skill in the art to include: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field. See Environmental Designs, Ltd. v. Union Oil Co. of Calif., 713 F.2d 693 (Fed. Cir. 1983).

Paragraphs 38-40. In these paragraphs, it is implied that the objective examination under the UPOV Convention, which includes a physical testing of varieties (i.e., a growing test) is essential

for a reliable determination of the distinctness of the variety to be protected. Thus, it is implied that a sense of legal certainty does not appear to be attainable to the same extent under a patent examination system, in view of the difficulty in describing living material. In fact, examination under the U.S. patent system is clearly objective and relies on the industriousness and veracity of the applicant to provide a written disclosure, including a description of the claimed variety in applications for plant and utility patents, in order to obtain a record with the same legal certainty. Indeed, the written disclosure necessary to satisfy the requirements of the applicable statute assists in distinguishing the claimed variety over prior art varieties as well as in identifying any infringing material after the patent has issued. Also, the narrowness of varietal protection offered by the plant breeders' rights system may result in inadequate protection for the full scope of the inventive contribution to the technology.

Paragraph 41. This paragraph again raises supposed difficulties arising from the exhaustion of rights doctrine in the patent system. As already stated in the comments pertaining to paragraph 32, this concept is not as inflexible as portrayed here. Further, if for the sake of argument it were, and if thereby the patentee were limited to profits from only a single sale of biologically propagatable material after having incurred huge research and development costs, the patent laws could well be amended to avoid this obviously inequitable result. Yet here, and again in paragraph 53, the problem of the doctrine of exhaustion is portrayed as an incurable defect of the patent system.

Paragraph 42. The last sentence of this paragraph contrasts the scope of protection under the UPOV Convention with the patent system, stating that the latter "allows inventors to specify the scope of protection by the free formulation of claims". This characterization is ambiguous. While inventors are certainly free to formulate claims, a patent will only be granted on claims that are properly supported by the disclosure.

Paragraph 48. Although the reasons cited in this paragraph for excluding plant varieties under the European Patent Convention (EPC) may be valid, it should also be recognized that the EPC was drafted and negotiated long before the advent of the important field of biotechnology. The exclusion from patentability of plant and animal varieties was based largely on historical grounds rather than as a result of an empirical analysis. Also, the then perceived legal and administrative difficulties have in practice either not arisen, or have effectively diminished.

Paragraph 51. It is startling to note that the draft memorandum uses the argument that "patents should be considered in themselves as an exception from the general principle that technology may be freely used, and therefore exceptions from patenting should be construed broadly". That argument is based on the faulty assumption that, unlike real estate or personal property, technology

cannot be owned. The statement also alludes to the erroneous view that patents are monopolies that take away from the public that which it should be freely entitled to use. An inventor's creation, if patented, is an indication that it was not previously in the public domain and that the public would not have had access to it in any form, but for the inventor's creativity. Be that as it may, a broad interpretation of Article 53(b) of the EPC cannot be supported on the grounds stated in paragraph 51. As a matter of fact, the exception to patenting plant and animal varieties contained in Article 53(b) of the EPC will have to be reconsidered in light of the technological developments in the field of bio-technology. Also, the perceived problems cited in paragraph 51 are not persuasive reasons to broaden the interpretation of EPC Article 53(b). To the extent that a plant is totally represented by a single variety, the narrow interpretation of Article 53(b) is fairly clear. Whether the exception of Article 53(b) becomes meaningless, should a patent claim to a characteristic common to a group of varieties or to a whole species be allowed, can hardly be the problem claimed in this paragraph.

Paragraph 56. This paragraph attempts to discourage the patenting of plant varieties by revisiting the question raised in paragraph 35 with respect to whether and how the patentability criterion of non-obviousness is applied. This time it is noted that little experience exists in the application of the requirement of non-obviousness, and that problems may arise with the breadth of claims. It also asserts that no bodies of art exist within the patent system, resulting in a tendency to grant patents with wide claims. Although the statement goes on to note that these problems are likely to diminish as applicants and examiners gain experience, and as patent documentation is built up, a lingering, and largely unnecessary, doubt has been planted regarding the effectiveness of patents for plant varieties. Although these problems are later dismissed as being only "perceived", they are used nevertheless to "highlight the desirability of protecting plant varieties on the basis of uniform criteria". The implication seems to be that only a plant breeders' rights system has the ability to apply uniform criteria.

Contrary to these and other statements in this paragraph, the U.S. Patent and Trademark Office granted plant utility patents under section 101 of title 35, United States Code, several years prior to Ex parte Hibberd, to plants that were not protected under either the Plant Patent Act (PPA) or the Plant Variety Protection Act (PVPA). The apparent overlap of subject matter which can be protected by either of the latter Acts and by the general (utility) Patent Act was recognized in Hibberd, which held that the PVPA and the PPA were not exclusive forms of protection for plant life, as this would conflict with the granting of patents under section 101. Consequently, in view of the activity in the patenting of plants under both the PPA and the general Patent Law, experience has been gained in the application of the requirement of non-obviousness to plant varieties in the 23 years since the report of the Johnson

Commission and the 13 years since the decision in Yoder Brothers (see also the comments pertaining to paragraph 35). The standard of non-obviousness applied to plant varieties in both plant utility applications and plant patent applications is the same standard as that applied to any utility application in any other technology. In the determination of this issue in applications directed to plants, including varieties, all of the pertinent prior art pertaining to plants, including varieties, is considered. The scope of that prior art includes U.S. and foreign patent literature, Plant Variety Protection Certificates, scientific literature and trade literature. Thus, contrary to the assertion in paragraph 56, documentation concerning the state of the art with regard to plant varieties is not limited, nor does it exist primarily within the UPOV plant variety protection system (actually a very small number of all known varieties). Furthermore, it must be noted that the scope of a patent claim is not solely dependent on prior art applicable thereto, but in large measure depends upon the written description of the plant invention in the patent application and whether such description is in fact an enabling disclosure.

Paragraph 69. Contrary to the assertion in this paragraph that UPOV member States have not availed themselves of the possibility of granting more extensive rights than the minima prescribed by the Convention, the United States has availed itself of that possibility through the granting of patent rights. In this respect, the presumption stated in the first sentence is not correct.

Paragraph 73. This paragraph raises doubts concerning the appropriateness of enforcing patents for genes incorporated into plant varieties, in view of the present provisions of the UPOV Convention. First, it should be remembered that the UPOV Convention is presently being considered for revision and that, therefore, the articles cited in support of the expressed doubt may well be amended. Nevertheless, the subject of enforceability of patents for genes is important, especially within the context of breeders' access to germ plasm.

The presence of a patented gene in a plant variety that is not otherwise protected, will normally not restrict a breeder's access to the germ plasm contained in that variety. There are few serious objections to allowing that variety to be used as an initial source of variation. As a consequence, a breeder could derive a new variety and commercialize it, as long as it did not contain the patented gene. Should the new variety contain the patented gene, the breeder would have to obtain a license from the patent holder to commercialize the new variety. Should a breeder be unwilling to follow that path, he could simply conduct the breeding program with an earlier variety that did not contain the patented gene. As a consequence, plant breeders' access to existing genetic material should not be adversely affected by the presence of patented genes in such material. To maintain, however, that a breeder should have the right to unfettered use of a patented gene in his variety, especially when that gene enhances the variety, would be tantamount to condoning misappropriation of another's property.

Paragraph 81. In comparing the plant breeders' right system with the patent system, the draft memorandum notes that rights granted under the former system attach to something which exists physically, while the patent system grants "property rights in relation to inventive ideas which are abstract in nature". This statement is simply incorrect. Abstract ideas are not patentable. To obtain patent protection, an applicant must describe the invention and the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use that invention. Also, the invention protected by a patent grant must be manifested in the features of some product or process that is clearly and distinctly claimed in the patent, in order to establish the metes and bounds of protection. An exception to these strict requirements lies with asexually reproduced plants protected under the Plant Patent Act. However, a plant patent granted under that Act appears to have characteristics similar to a property right under a plant breeders' system insofar as it attaches only to a plant that exists physically.

The remainder of paragraph 81 again criticizes the patent system as "giving rise to uncertainty", because of the "great difficulty of appling the non-obviousness requirement to plant varieties". It attempts to support this allegation by pointing to the history of the special plant patent. At least as far as the Plant Patent Act in the United States is concerned, this statement is not supported by the facts. That Act has now been in effect for almost 60 years, yet has spawned very little litigation. Further, there is no evidence that any difficulty exists for industry, the public, or the granting agency to administer this law. In passing, however, it is noted that the value of protection provided by the plant breeders' rights system appears not to be questioned, despite the growing uncertainty over the value and limits of the farmer's exemption and the lack of any meaningful definition for minimum distance requirements. This lack, apparently, has resulted in the granting of numerous certificates for plant varieties that insignificantly differ from each other, thereby diluting the value of the rights granted under that system.

Paragraph 84. The "general concern" expressed here regarding the possible inability of breeders to use known genes present in existing varieties appears to be unfounded and was already raised in paragraph 73. This time, the point is raised as a straw man and then partially knocked down as "perhaps nonexistent in practice". Any of the continuing doubts of concern to plant breeders raised here appear to be more in the order of lack of information regarding the patent system, rather than problems inherent in the system itself.

Paragraph 86. As previously noted in relation to paragraph 81, it is not sufficient for purposes of obtaining patent protection to conceive an original and non-obvious idea concerning a variety without either having reduced the invention to practice or described it in a manner enabling a person skilled in the art to

make and use such invention. Moreover, if one assumes that conventional breeding methods are completely unpredictable so that there is no certainty until the plant material physically exists, such does not appear to be the case with breeding techniques using genetic engineering technology. Yet, new varieties established by genetic engineering techniques are also varieties in the truest sense of the word, although it is generally possible to predict their important characteristics without necessarily creating the physical plant.

It is also incorrect to assume that breeders would be deterred or perhaps be prevented by injunction from developing a distinct variety which possesses the characteristics of the patented variety. This assumption is as questionable in the field of plant breeding as it is in any other technology. It is generally not in the interest of patentees to refuse licenses to their inventions. Moreover, in the event that the licensee-breeder discovered that the patented variety in fact did not emerge in accordance with the claims of the patent, the patent would be unenforceable and the license could be terminated. There does not appear to be anything unique in the area of plant breeding that is not shared in other areas of technology with respect to the granting of a dominant patent, or the fact that development of new technology often takes place in both small and large steps. A dependency license is compulsory in nature and unnecessarily detracts from the incentives offered by the patent system. Proposing compulsory dependency licenses, therefore, in accordance with "Suggested Solution No. 11 in WIPO document BioT/CE/IV/3", does not appear to be appropriate, especially in view of the large amount of opposition to such an approach as reflected in WIPO document BioT/CE/IV/4, paragraph 92, dated October 28, 1988, well in advance of the present draft memorandum.

Paragraph 87. This paragraph attempts to make a positive feature of patent protection appear as a complication. It is indeed correct that a patent may be granted for an invention that is described and claimed in terms of the characteristics of the subject plants. This claim may encompass varieties not yet physically established, but only so long as the scope of the claims is commensurate with the scope of the enablement provided by the disclosure in the patent specification, and is novel and non-obvious over the prior art. A plant breeder may well, in the course of developing varieties, conceive and reduce to practice an invention that pertains to a large taxonomic grouping of plants and encompasses one or more varieties. Without the availability of the patent system that offers comprehensive protection for such an invention, the breeder would be forced to obtain individual plant breeders' rights certificates for each variety in physical existence then and there, and would be unable to protect his invention from others who quickly used that invention to incorporate into other varieties. Presently, only the patent system can provide a practical safeguard to protect an invention that transcends a single variety.

Nevertheless, even if a patent were granted on a broad invention, a breeder who developed a new variety that falls within the scope of the claims of that patent, could also obtain patent protection on that variety per se, if it can be shown to be novel and non-obvious over the teachings of the basic patent and other relevant prior art. Although the second breeder would have to obtain a license from the first breeder to commercialize the second variety, the first breeder could not use the second variety without permission from the owner of the subservient patent. Again, this type of interrelationship is not unusual in other technologies and there is no reason why it should pose untoward complications in the field of plant breeding. Still, this paragraph again raises the specter that "some plant breeders might claim that the existence of ... patents could have the effect of inhibiting ... their activities." Aside from the subjunctive nature of the argument citing hypothetical concerns, its basis is questionable.

Paragraph 104. Issue again must be taken with the draft memorandum's characterization of the patent system. As previously stated, the characteristics of a plant cannot be claimed in the abstract. An inventor can only claim the plant in terms of its particular novel and non-obvious characteristics as supported by an enabling disclosure.

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Europäisches Patentamt · Erhardtstraße 27 · D-8000 München 2

Monsieur A. Bogsch
Directeur Général
OMPI
34, Chemin des Colombettes

CH-1211 Genève 20

Erhardtstraße 27
D-8000 München 2

Telephon (0 89) 23 99-0
Telex 5 23 656 epmu d

Zeichen / Reference / Référence: 57.5 A53b) 57.7.8 57.12.3

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Objet : Mémoire intitulé "L'interface entre la protection par brevet et la protection par le certificat d'obtention végétale" (document CAJ/XXIV/4)

Monsieur le Directeur Général,

Je me réfère à votre lettre du 21 juin dernier et vous prie de nous excuser du retard avec lequel nous y répondons.

J'ai l'honneur de vous adresser, en annexe, les observations de l'OEB relatives au document CAJ/XXIV/4.

Je vous prie d'agréer, Monsieur le Directeur Général, l'expression de mes sentiments distingués.

R. Remandas

Renate Remandas
Vice-Présidente

FL014489

Office européen
des brevets

Octobre 1989

Observations relatives au Mémoire

"L'interface entre la protection par brevet et la protection par certificat d'obtention végétale"

(Document CAJ/XXIV/4)

I. INTRODUCTION

1. L'OEB apprécie le travail considérable qui a été fourni par le Bureau de l'UPOV en collaboration avec le Bureau international de l'OMPI.

2. L'Office craint, toutefois, que l'étude ne réponde pas entièrement aux attentes du Comité d'experts de l'OMPI sur les inventions biotechnologiques et la propriété industrielle lorsque ce Comité a demandé de lui fournir des éléments d'information supplémentaire de nature à lui permettre de progresser dans ses réflexions relatives aux Solutions Suggérées Nos 6 et 9 à 11 (cf. Document BioT/CE/IV/4, points 60, 77, 88 et 97).

   Il s'agit, dans ces solutions suggérées, domaines où il est nécessaire de trouver un équilibre entre, d'une part, la protection des résultats de la recherche-développement en génie génétique végétal et, d'autre part, l'utilisation de ces résultats aux fins pratiques de développement de nouvelles variétés végétales.

   Les experts de l'OEB regrettent de ne pas trouver dans l'étude CAJ/XIV/4 d'analyse économique des effets sur les obtenteurs que pourraient avoir les modalités de l'interface entre le brevet et le certificat d'obtention végétale envisagées dans les Solutions Suggérées ci-dessus.

3. L'OEB indique ci-après quelques observations relatives au document CAJ/XXIV/4.

   Concernant le chapitre IV, paragraphes C, D du document CAJ/XXIV/4, relatif aux propositions actuelles de révision de la Convention UPOV figurant dans le document UPOV, l'OEB présente ses observations dans l'annexe au prèsent document, en se référant au document de révision IOM/IV/2.

.../...

II. LES QUESTIONS EN CAUSE

A. La nature de la variété végétale, point 13, dernière phrase

Dire qu'une variété végétale peut être représentée par une cellule ou un protoplaste est exact.

Il faut cependant distinguer entre une cellule représentant une variété à laquelle il est judicieux d'étendre la protection d'un certificat d'obtention végétale et une cellule revendiquée dans un brevet, eu égard à la présence, dans la cellule, d'un composant génétique X, sans que la totalité des gènes de la cellule ne soit revendiquée.

C'est pourquoi, comme l'OEB l'expose dans l'annexe à propos du projet d'article 2ii) figurant dans le document IOM/IV/2, le terme "parties de plante" qui couvre la "cellule" ne devrait pas être inclu de la définition de la variété végétale.

III. HISTORIQUE

Points 30a, 42, 81 à 82, 84 à 87, 103 à 106

A de nombreux endroits, le document reflète une approche erronnée des concepts de base du droit des brevets.

Ainsi, contrairement à ce qu'énonce le point 42, la protection par brevet n'est pas accordée à une idée inventive, mais bien à une solution de caractère technique à un problème.

Les revendications ne sont pas librement formulées, du moins pas dans les pays à procédure d'examen préalable.

En outre, les brevets ne protègent pas des caractères de plantes (cf. points 85, 103), par exemple une faculté insecticide, mais bien un composant génétique dans une cellule végétale, ayant pour effet de rendre la cellule ou la plante résistante à des insectes déterminés.

Point 51

Jusqu'à présent, la distinction entre variétés végétales et catégories plus larges de plantes auxquelles pourraient se référer des revendications d'un brevet, semblait être claire. Une variété végétale s'applique à un phénotype complet d'une plante, telle qu'elle est cultivée (ou, également, multipliée directement à partir d'une cellule).

Par contre, les développements pour lesquels une protection par brevet relatif à des produits végétaux est recherché, concerne, de façon générale, une information génétique déterminée (partie du génome) conférant certaines particularités à la plante, l'information génétique pouvant être utilisée pour un nombre indéterminé de variétés végétales. De tels développements ne sont pas le résultat d'une activité de culture et ils ne sont pas accessibles par la protection relative aux obtentions végétales, de sorte qu'en l'absence d'une protection par le brevet, on serait confronté à une lacune de protection.

Ceci démontre que l'on ne recherche pas une protection par brevet pour des plantes individuelles, mais bien pour des ensembles abstraits de plantes qui sont définies par l'information génétique qu'elles contiennent. Des revendications se référant à de tels ensembles recouvrent bien entendu toutes les plantes concrètes dans lesquelles l'information en question est contenue.

IV. LE DEBAT ACTUEL

Point 63

A. Les problèmes perçus par les auteurs d'inventions biotechnologiques et les obtenteurs en ce qui concerne la protection des innovations dans le domaine végétal

Ce point concerne la notion du libre accès des obtenteurs au génoplasme et exprime une crainte de contrainte négative qui découlerait de la protection par brevet, si elle s'étendait aux plantes.

Il y a lieu d'abord d'indiquer que le principe du libre accès est remis en question par le projet de nouvel article 5(3) de la Convention UPOV.

D'autre part, ce concept est étranger au domaine des brevets, notamment dans le domaine chimique et pharmaceutique. Pour les raisons qui sont celles du domaine des brevets, on doit se demander si l'exclusion temporaire de libre accès au génoplasme des plantes auxquelles s'étendraient les droits découlant des brevets portant sur des composants génétiques nouveaux auraient un effet négatif ou plutôt un effet positif, du fait que les concurrents du breveté sont forcés de développer des solutions indépendantes. L'interdiction d'une protection par brevet ne rend pas automatiquement l'invention connue du public ; au contraire, elle contribue à réduire l'incitation à la recherche-développement et à la divulgation des résultats de la recherche.

Eléments particuliers de la protection applicable aux inventions relatives à des végétaux ayant donné lieu à critiques (page 21)

c) Doutes émis en ce qui concerne l'opposabilité des brevets relatifs à des gènes incorporés dans des variétés végétales

Point 73

Les propositions des Solutions Suggérées 10 et 11 de l'OMPI (cf. document BioT/CE/IV/3) tiennent compte de préoccupations énoncées dans le présent document.

Le présent document n'offre cependant pas d'éléments nouveaux de nature à enrichir le débat très controversé au cours de la 4e réunion du Comité d'experts.

Il est plus que contradictoire de vouloir, d'une part, assurer à l'obtenteur des droits sur des variétés dérivées, comme cela est envisagé dans toutes les variantes de l'article 5(3) du projet de révision de la Convention UPOV (cf. document IOM/IV/2) et, d'autre part, de mettre sérieusement en doute dans le présent document, la question de savoir s'il y a lieu d'accorder des droits à un titulaire de brevet vis-à-vis de l'obtenteur qui ferait usage, dans un but précis, d'un gène divulgué pour la première fois dans le brevet. Une telle situation juridique conférerait une position plus solide à l'obtenteur dont la contribution se distingue de ce qui est connu, seulement sur le plan de la nouveauté qu'au breveté qui a fait un apport inventif au développement de la technique.

e) Doutes concernant la signification du terme "microbiologiques" à l'article 53.b) de la CBE et les conséquences de l'exclusion des variétés végétales sur les revendications relatives à des végétaux ou à des variétés végétales obtenus directement à partir d'un procédé microbiologique

Point 75

Lorsque la Convention de Strasbourg a été adoptée, le génie génétique était inexistant.

Il faut donc apprécier l'article 53b) non pas comme ayant pris en compte ou non l'exclusion des inventions concernant des cellules vivantes résultant des techniques génétiques modernes, mais bien tenir compte des intentions du législateur et des circonstances de fait :

a) Les cellules végétales sont-elles englobées par l'exclusion de l'exclusion au profit des micro-organismes ?

b) L'article 64(2) CBE doit-il subir une exception dans le cas d'un brevet de procédé microbiologique de manipulation de cellules végétales, en ce sens que la protection ne s'étendrait pas aux cellules directement obtenues par ce procédé ?

En ce qui concerne a), la nature de la cellule végétale apparente celle-ci entièrement aux micro-organismes en tant que tels. De même que l'on a admis à ce titre les virus, alors qu'ils ne peuvent se maintenir en vie en dehors d'un organisme plus complexe.

A propos des cellules végétales ou animales d'ailleurs, un des critères décisifs eu égard aux raisons qui ont été à la base de la création des législations spécifiques UPOV, à savoir la faculté de divulgation, n'existe pas puisque les

cellules peuvent faire l'objet d'un dépôt selon le Traité de Budapest et que leur description aux fins d'exigences de la divulgation de l'invention dans une demande de brevet ne pose pas de difficultés.

g) Doutes concernant l'application des principes régissant les brevets à la matière vivante autoreproductible

Point 76

Compte tenu de la parenté des droits en matière d'obtention végétale et de brevets, le Comité d'experts a été saisi d'une proposition (Solution Suggérée n° 10) en matière d'épuisement des droits similaire à celle qui s'applique pour le certificat d'obtention végétale, à savoir que le droit de l'obtenteur renait à chaque reproduction.

Les experts étaient divisés sur la justification de la proposition.

Faut-il comprendre le document CAJ/XIX/4 comme un encouragement des experts à s'orienter dans cette voie ?

ANNEXE I

L'annexe examine deux variétés de blé ; seule l'appendice I intéresse l'OEB (Etats excluant les variétés végétales de la protection par brevet).

Aucun des exemples ne reflète la pratique ; ainsi, dans l'exemple A, on considère que le produit direct d'un procédé de génie génétique est une variété végétale ne nécessitant plus d'activité agricole, alors qu'en pratique, une mise au point de la variété par les méthodes classiques est nécessaire.

On ne perçoit pas en quoi les exemples sont de nature à contribuer aux travaux en cours.

ANNEXE II

Premier cas de figure

Les modifications proposées à la législation UPOV (Modification 4) sont de nature à rendre inefficace le système des brevets (cf. les observations en annexe, relative au projet d'article 5(5) du document de révision de la Convention UPOV, IOM/IV/2).

Deuxième cas de figure

La modification 1 reflète une tendance se dessine au sein de l'UPOV en faveur de la suppression de l'exclusion de choix de protection (interdiction de la double protection).

Les Etats contractants de l'OEB n'ont pas terminé leur réflexion relative au besoin d'envisager une modification de l'article 53b) CBE.

Ceci étant, il est préférable de ne pas fixer la situation d'exclusion au cours de la révision UPOV.

La modification 6 n'est pas claire. Si l'"élaboration" signifie l'expérimentation, elle est acceptable ; si elle englobe aussi une activité ultérieure basée sur l'obtention dépendante, elle se heurte à la même critique que la modification 4 du premier cas de figure.

Troisième cas de figure

Pas d'observations supplémentaires.

.../...

Quatrième cas de figure

Ce cas de figure parait être le plus intéressant à soumettre à la discussion conjointe OMPI/UPOV.

Office européen
des brevets

ANNEXE

Observations relatives aux dispositions du projet de révision de la Convention UPOV figurant dans le document IOM/IV/2, relatives à l'interface entre la protection par brevet et la protection par certificat d'obtention végétale

I. Introduction

1. Depuis toujours, le droit des brevets protège les inventions relevant du domaine de la biotechnologie. Les développements dans le domaine du génie génétique, notamment, ont fait surgir de nouvelles questions en matière d'interprétation des prescriptions relatives à l'obtention et à l'exercice du droit conféré par le brevet.

2. La révision de la Convention UPOV a, entre autres, pour objectif de renforcer le droit de l'obtenteur et d'élargir le domaine d'application pratique du système de la protection des obtentions végétales. Cela soulève des questions de principe affectant le système de protection par brevet et donc la CBE ; il s'agit, en particulier, des questions posées par les dispositions du projet de révision relatives à l'interdiction du choix du système de protection [art. 1er.2)], à la définition de la variété [art. 2.ii)] et à la limitation des effets d'autres droits de propriété industrielle [art. 5.5)].

3. Certains problèmes découlent en partie précisément de l'interaction de plusieurs dispositions. Ces questions appellent, dans le détail, les observations suivantes :

.../...

II. Article 1er.2) - Interdiction du choix du système de protection

4. L'interdiction du choix du système de protection trouvait à l'origine son fondement dans l'idée qu'une protection particulière des variétés végétales devait tenir compte des besoins particuliers existant dans le domaine de l'obtention et de l'exploitation de plantes et que l'applicabilité des catégories générales auxquelles se réfère le droit des brevets aux obtentions végétales ne semblait pas devoir aller sans poser de problèmes. Or, l'évolution en cours tant du point de vue économique que technique permet de douter de la pertinence de ces fondements à l'heure actuelle.

5. Du point de vue technique, le génie génétique a fourni des moyens de modifier intentionnellement des plantes en modifiant leur information génétique, et ce avec une régularité qui - contrairement aux obtentions traditionnelles - donne des résultats reproductibles, au sens que revêt ce terme en droit des brevets. Cette évolution est encore loin d'être terminée.

   C'est pourquoi il est hautement souhaitable, dans le domaine du droit des brevets, de supprimer les dispositions excluant les inventions relevant de la biologie, et notamment les variétés végétales (cf., par exemple, art. 53 b) CBE). Le projet de traité d'harmonisation des législations sur les brevets, établi par le Comité d'experts de l'OMPI, prévoit à cet égard, à l'article 204, variante B, que des brevets doivent pouvoir être délivrés dans tous les domaines de la technique (doc. HL/CE/VII/3).

   Ceci tiendrait compte de l'intérêt qu'il y aurait pour le déposant à ne devoir déposer qu'une seule et même demande pour des inventions relevant du génie génétique et pouvant être définies de différentes manières (par exemple comme gène, plante, variété végétale).

.../...

6. Etant donné les besoins spécifiques des milieux concernés, les particularités actuelles du droit de la protection des variétés végétales sont également devenues l'objet de controverses de la part des utilisateurs de ce système de protection.

   C'est ainsi que le droit de l'agriculteur de produire des semences pour couvrir ses besoins propres, la libre exploitation (gratuite) de variétés dérivées et la limitation des formes d'exploitation protégées au matériel de multiplication sont aujourd'hui tout à fait contestés et se prêtent bien à l'actuelle procédure de révision.

7. Dans ces conditions, il semble que le fait de fixer dans un accord international le principe de l'interdiction du choix du système de protection, et, partant, d'entraver au sein des Etats parties à cette Convention l'évolution du droit des brevets dans un avenir proche soulève d'importants problèmes.

8. La suppression de l'interdiction du choix du système de protection de la Convention UPOV n'aurait nullement pour conséquence d'obliger les Etats contractants à délivrer des brevets pour des variétés végétales. Alors que l'interdiction du choix du système de protection restreint la souveraineté des Etats contractants dans le domaine du droit des brevets, la suppression de l'article 1er.2) figurant dans le projet laisserait à chacun de ces Etats la possibilité d'adopter des dispositions du droit des brevets qu'il jugerait appropriées après avoir pesé les intérêts en présence et compte tenu de l'évolution technique. Cela éviterait des réserves de la part de candidats à l'adhésion à l'UPOV désireux de conserver pour l'avenir cette liberté en matière de règlementation.

9. Enfin, la suppression de l'interdiction du choix du système de protection permettrait de mettre un terme aux différences affectant les situations juridiques et résultant du fait que les Etats-Unis ont utilisé la possibilité offerte par l'article 37 de la Convention UPOV et que, outre des brevets d'invention, ils octroient des droits de protection de variétés végétales (et délivrent des brevets de plantes). Les Etats-Unis ne sont manifestement pas disposés à renoncer à l'avenir aux systèmes de protection parallèles. D'autres Etats contractants ne peuvent user de cette possibilité, car ils ne répondent pas aux conditions énoncées à l'article 37.

   Les Etats-Unis prétendent que la coexistence de la protection par brevet et de la protection des variétés végétales n'a pas entraîné de difficultés dans la pratique. Par ailleurs, il n'a pas été fait état concrètement de telles difficultés aux Etats-Unis.

10. Pour conclure, l'OEB est donc partisan de revenir, dans le présent contexte, au principe général selon lequel les droits de propriété industrielle coexistent avec leurs conditions et leurs effets, et de supprimer l'interdiction du choix du système de protection. Cette interdiction pourrait être remplacée par une règlementation aux termes de laquelle il n'est pas possible de demander simultanément - ou de "cumuler" - une protection par brevet et par le système de la protection des obtentions végétales pour le même objet concret. D'autre part, d'un point de vue terminologique, une telle règlementation se rapprocherait plus de ce que l'on entend par interdiction de "cumul de protection" dans d'autres domaines (cf. art. 139 (3) CBE).

III. Article 2.ii) - Définition de la variété

11. Si l'interdiction du choix du système de protection est maintenue, il y a interaction entre la définition de la variété proposée dans la Convention UPOV et le droit des brevets. Dans ce cas, la notion de variété doit fixer non seulement le champ d'application des dispositions relatives à la protection des variétés mais aussi le champ exclu de la brevetablité.

12. A cet égard, le texte de l'article 2.ii) du projet est inadéquat car il ne présente plus aucun lien avec les critères d'obtention de la protection énoncés à l'article 6, de sorte qu'il étend la notion de variété à l'infini.

En incluant les parties de plantes, la définition vise non seulement des parties de plantes telles que les produits de l'agriculture et du jardinage (fruits et fleurs), mais aussi des parties de plantes servant depuis longtemps à des usages industriels comme les cellules ou les protoplastes, voire des parties de plantes ne comprenant plus le génome complet de la plante, ou encore l'ADN. Il n'existe pas de raison apparente d'exclure désormais ces objets de la protection par brevet. Cette exclusion aurait pour effet d'imposer à des activités industrielles qui n'ont absolument rien à voir avec les obtentions végétales un système de protection des variétés inapproprié. A titre d'exemple, citons l'emploi, dans le domaine de la pharmacie, de lignées de cellules pour la fabrication de produits diagnostiques, consistant à utiliser des propriétés de ces lignées de cellules qui sont sans rapport avec le phénotype de la plante. En outre, pour l'exploitation industrielle de ces lignées de cellules, il est sans importance qu'elles soient, après des modifications de génie génétique, propres à la multiplication de plantes entières.

13. Inversement, il importe de ne pas ignorer le besoin de l'obtenteur d'être protégé contre l'utilisation, au stade cellulaire, de propriétés intrinsèques d'une plante protégée, sans que soit régénérée la plante entière. Pour cela, toutefois, il n'est pas nécessaire d'étendre la notion de variété. Il suffit d'inclure le matériel cellulaire d'une variété protégée dans le champ de protection, soit par une définition appropriée du matériel à l'article 2.iv) du projet, soit dans le cadre des droits d'interdiction concédés à l'obtenteur à l'article 5 du projet.

14. Par ailleurs, l'extension de la définition de la variété donnée à l'article 2.ii) à "tout ensemble de plantes" aux fins "de toute autre forme d'utilisation" suscite des réserves. Elle permettrait en effet de donner de cette disposition une interprétation selon laquelle des plantes dont les codes génétiques ne présentent entre eux aucun point commun peuvent être définies comme une variété, étant donné que les formes d'utilisation prévues à l'article 5 englobent toutes les possibilités. C'est ainsi que, par exemple, toutes les plantes vertes pourraient être considérées comme une seule entité aux fins d'obtention de chlorophylle.

Il semble que ce soit également dans ce sens qu'aille l'article 6.1)c) d'après lequel, en liaison avec l'article 6.1)b), les seuls critères d'appréciation de l'homogénéité sont ceux qui sont pris en considération pour distinguer la variété. Là encore, cette proposition peut donner lieu à l'interprétation selon laquelle des plantes génétiquement hétérogènes peuvent constituer une variété. De tels développements n'entrent pas dans le domaine des obtentions habituelles.

Aussi, conviendrait-il de prévoir à l'article 2.ii) qu'un ensemble de plantes ne peut être considéré comme une variété que si celle-ci représente une entité aux fins de <u>multiplication</u>.

15. Il est impératif de trouver une solution satisfaisante pour la définition de la variété, de manière que l'article 2.ii) puisse servir de critère de délimitation entre la protection des variétés et la protection par brevet. A supposer que soit donnée une nouvelle définition de la variété qui s'écarte des conceptions fondamentales existant jusqu'à présent en matière d'interdiction du choix du système de protection, il est peu probable qu'elle soit reconnue par le droit des brevets. En cas de maintien de la version actuelle, il se pourrait que, pour appliquer les dispositions figurant dans le projet, relatives aux exceptions à la brevetabilité de l'article 53 b) CBE, l'OEB continue à s'en tenir à la définition de la variété donnée dans la version de 1961 de la Convention UPOV, qui avait amené les auteurs de la CBE à rédiger l'article 53 b) CBE.

16. A des fins de cohérence entre l'article 2.ii) et l'article 4, c'est la variante 3 de l'article 4.1) qui doit s'appliquer.

IV. <u>Article 5.5) - Limitation des effets d'autres droits de propriété industrielle</u>

17. Cette disposition a pour but de limiter, voire d'exclure les effets d'autres droits de propriété industrielle dans le domaine de la création et de l'exploitation de variétés. Ceci vaut notamment pour le droit des brevets.

Il semble que le présent projet doit être compris de la manière suivante : selon l'article 5.5)ii) en liaison avec les dispositions du paragraphe 2)iv), le titulaire du brevet doit en tout état de cause tolérer la création de nouvelles variétés ; en outre, conformément à l'article 5.5)i) en liaison avec le paragraphe 1), il lui est impossible de s'opposer à la culture ou à toute autre utilisation d'une variété protégée.

18. Il s'ensuit que si d'importantes réalisations, notamment dans le domaine du génie génétique, peuvent en principe être brevetées, toute utilisation susceptible d'entrer en ligne de compte n'en reste pas moins exclue de la protection par le brevet. Par exemple, un procédé inventif visant à introduire un gène dans une plante utile n'a de sens que s'il est utilisé pour la création d'une nouvelle variété. De même, l'invention consistant à créer un gène qui confère une certaine propriété intéressante à une espèce végétale n'est économiquement utilisable qu'en cas de création et d'exploitation de variétés contenant ce gène. Dans ces deux cas, le détenteur du droit conféré par le brevet n'a aucune possibilité de faire valoir des droits. Cet état de fait n'est rien d'autre qu'une expropriation légale du titulaire du brevet.

19. A supposer qu'une telle expropriation soit admissible au regard du droit constitutionnel, elle aurait en tout cas pour conséquence un délaissement du système des brevets dans ces domaines et, par contrecoup, la conservation des inventions pertinentes sous le sceau du secret d'entreprise, de sorte qu'elles seraient totalement inaccessibles aux obtenteurs intéressés.

20. Même en restreignant le champ d'application des dispositions de l'article 5.5) de telle sorte que (par exemple en supprimant l'alinéa ii)) le titulaire du brevet puisse intenter une action contre l'obtenteur seulement, mais non contre l'utilisateur d'une variété, la protection du titulaire du brevet resterait insuffisante.

Une telle disposition aurait pour effet que les actes visant à créer une nouvelle variété seraient accomplis hors des frontières nationales et que seuls les actes d'exploitation seraient accomplis à l'intérieur d'un territoire protégé. Une possibilité aussi évidente de tourner la

réglementation mettrait le titulaire du brevet dans une situation guère plus enviable qu'une entière privation de ses droits.

21. En conséquence, il conviendrait de supprimer l'article 5.5).

Ceci paraît logique, dans la mesure où il est prévu à l'article 5.3) que l'obtenteur d'une variété mère peut, lui aussi, faire valoir des droits envers l'obtenteur d'une variété dérivée. On ne voit pas pourquoi le titulaire du brevet devrait être plus mal loti.

En ce qui concerne les variantes proposées pour l'article 5.3), remarquons au passage que la concession à l'obtenteur de l'intégralité des droits protégés (y compris la possibilité d'une action en cessation) ne tend pas à empêcher que de nouvelles variétés soient disponibles en tant que matériel de départ. En règle générale, le titulaire du droit protégé à intérêt à ce que son droit soit largement exploité, notamment par l'octroi de licences. Admettre la possibilité de l'action en cessation en plus du simple droit à être indemnisé a pour conséquence que le montant de la licence peut être négocié librement, de sorte qu'il est déterminé en fonction de sa valeur sur le marché et non pas par une décision administrative ou par voie de justice. Ceci est valable tant pour le droit relatif à la protection des variétés que pour le droit des brevets.