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UPOV

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Twenty-second Session
Geneva, April 18 to 21, 1988

REVISION OF THE CONVENTION

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COMMENTS FROM THE INTERNATIONAL CHAMBER OF COMMERCE (ICC)

Document prepared by the Office of the Union

1. The annex to this document contains a statement by the International of Commerce (ICC) on the revision of the Convention that was adopted by its Executive Board on December 1, 1987.

2. It is to be noted that document No 450/608 Rev.1 (page 6 et seq. of the annex) has already been submitted to the Administrative and Legal Committee at its nineteenth session (document CAJ/XIX/6).

[Annex follows]

ANNEX

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Policy and Programme Department — Document No. 450/621 Rev.
1987-11-03 — MCP/SVN — Original — gz

COMMISSION ON INTELLECTUAL AND INDUSTRIAL PROPERTY

REVISION OF THE UPOV CONVENTION

ICC Statement

Submitted for Adoption at the 52nd Session of the Executive Board of the ICC (December 1, 1987)

A D O P T E D

The UPOV Convention has been a great success over the last twenty-five years. As a consequence of the experience gained through that success, and of recent developments in biotechnology, there is both an opportunity and a need for further improvement of the Convention. The ICC applauds the initiative of UPOV in reviewing the Convention at this time, and urges it not to shrink from fundamental changes.

The ICC considers that strong intellectual property protection for owners of inventions is essential to foster technological progress and transfers of technology, and to stimulate trade and investment worldwide. The ICC is convinced, moreover, of the importance of biotechnological development, and sees it as vital to use all means for the improvement and rationalization of intellectual property protection in this area. For these reasons, the ICC has recently drawn up a statement setting out its views on the appropriate treatment of biotechnological inventions, including those concerning plant varieties (Doc. No. 450/608 Rev. 1). This statement is attached: particular attention should be drawn to the summary at the back (summary paragraph 5) and to paragraph 1.2.2. (pp.4, 5) and the whole of paragraph 5 (pp. 16-19), which concern plant variety protection and the UPOV Convention, in particular.

Whilst the above-mentioned ICC paper refers particularly to the role of patents, which it considers very important to introduce, this does not imply a secondary or subsidiary position for plant variety rights. Many important advances in plant biotechnology will not be suitable for protection by patents. Rather the ICC sees a need for plant variety rights to be improved and strengthened, so as to be more fully in balance with patent rights. If this is not done, breeders may attempt to use patents to protect matter more properly the subject of plant variety rights, which

could result in the system not being used as effectively as it should be, or at worst withering into disuse. The UPOV Convention has had the major influence on the evolution of plant variety right protection worldwide, and in effect for many countries has served as a model law. There is thus a tremendous opportunity for UPOV to promote higher standards in those countries which already have plant variety protection, and to encourage the introduction of protection in those countries which so far hang back.

With these introductory remarks, the ICC offers below its specific recommendations for modification of the UPOV Convention.

Article 2

It is suggested that the prohibition on double protection of varieties (both by a special title and by a patent) be deleted. This proposal commands wide though not universal support among those whom ICC has consulted. It has been suggested that the term "patent" in Article 2(1) means "plant patent" (eg. of the type provided in the USA) rather than a utility patent. Normally, however, the provision is interpreted as forbidding utility patents for protectable plant varieties, sometimes even as forbidding any patents whatever covering plants. As countries are naturally anxious to be quite sure that their laws conform to this Article, it is a real obstacle to the grant of any patents on plants. For example, it has clearly shaped the law of the European Patent Convention. For all the reasons set out in ICC's position paper, ICC believes it most important that plant patents should be permitted without restriction, and hence strongly recommends the deletion of this clause. Double protection already exists in patents, designs, trademarks, copyright. Some countries protect devices both by patents and utility models (perhaps the closest parallel). None of these cases causes any difficulty. The ICC has not seen any convincing reasons why patent protection should not exist for plant varieties (or, indeed, plant species or genera).

Furthermore ICC recommends inclusion in this Article of a clause providing that the breeder shall have the freedom to choose the way in which he seeks to protect his new variety; whether by a patent, plant variety right, or both. Furthermore, paragraph 2 of Article 2 should be eliminated. There is a clear need for protection of all plant varieties, regardless of their method of production or end-use: in particular, no sufficient reason can be seen for discriminati against plants which reproduce in a particular way.

Article 3

The principle of national treatment, whereby each country treats residents of other member countries of the Convention in just the same way as its own residents, is seen as very important. It is

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also considered sufficient. The reciprocity provisions of paragraph 3, whereby one country is entitled to withhold from the citizens of another protection which the second country does not grant, is retrogressive. Indeed (as discussed in connection with Article 4 below) it is the exact opposite of what is required. Paragraph 3 of Article 3 should be deleted.

Article 4

It is important to strengthen the provisions of this article.

Numerous inconveniences arise from the fact that species for which variety protection is available differ considerably as between member countries of the Convention. Protection should be both wider and more uniform. One way of doing this, which it is suggested is worth further careful study, is to oblige each member country to provide protection for every genus which is protectable in another country. While at first sight this proposal might be seen as imposing considerable burdens on member countries, it is believed that these are supportable. The proposal does not oblige each country to have an examination system for each genus. Rather, it would encourage countries to rely on the examination systems of other countries. Thus by international cooperation wider protection would be obtainable, and unnecessary costs and wasteful duplication of work avoided.

Article 5

Here again the ICC proposes a major recasting of this article. As it stands at present, the Convention prescribes a uniform but low level of protection of breeders' rights. However, the level of protection may be raised in exceptional cases. The ICC feels this order of priorities should be reversed. The Convention should provide for a uniform high level of protection, subject to derogations for special reasons or in particular circumstances.

Experience has shown without doubt that to limit the rights of the breeder to the propagating material of his variety is inadequate. This permits the breeder to be exploited by those who buy a very small quantity of his new variety, multiply it, and harvest and sell the product. This is seen, for example, with fruit. An orchard grower can buy one specimen of a new apple variety: multiply it in his orchard: and in due course sell many tons of the new variety without paying anything further to its originator. With increasing industrial concentration, examples of this kind will increase. Further, the problem will be increased by biotechnology. In due course, plants will be adapted to produce special chemicals (oils, rubbers, drugs). Concerns would then be able to buy a single specimen of the genetically modified plant: multiply it: and thereafter plant it, crop it and process it to extract the chemical in question for sale, all without further payments to the grower. This is clearly unacceptable. Problems have likewise arisen with imports, for example of cut flowers. In some countries local legislation has dealt with some of these problems, but a uniform treatment would be much better.

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Accordingly, the ICC proposes that the Convention should state that the breeder receives the exclusive right to exploit his variety commercially. This general principle may be subject to justified exceptions. The breeder would be in a much better position to recover the value of his efforts through specialised licensing arrangements, which would probably increase commercialisation of his variety.

Article 5.2 should be maintained, but it should be made clear that the breeder is not obliged to authorise exploitation of his new variety. If he wishes, he should be able to retain a monopoly.

It is seen as important to retain Article 5.3. The public interest in the creation of new varieties absolutely requires that research with protected varieties is not inhibited. However, the rights of the owner of the variety should be strengthened by deleting the words " or for the commercialisation of such varieties" at the end of the first sentence. Sometimes (perhaps through error) a second variety receives a grant of rights when it differs only insignificantly from the variety from which it is derived. This amendment could enable the breeder of the earlier variety to assert his rights in such circumstances.

Article 7

The ICC believes that compulsory examination of new varieties for distinctiveness, uniformity and stability is causing problems, and suggests it be reconsidered. The cost of testing is escalating, which is undesirable whether these costs fall on Governments or breeders. They are time-consuming and delay grant. Even so, the results are by no means assured. If it is considered desirable to retain some kind of examination perhaps the Convention should make clearer that the authorities are not necessarily required to carry out growing tests.

Article 8

Two changes are proposed. Firstly, the term of protection should begin with the date of application. Protection is often most important to the breeder at this time. This would however mean that the right would expire earlier, and for this reason (as well as others) the period of minimum protection should be extended, say to 25 years. If an adequate minimum term of protection is fixed in this way, no particular reason is seen to retain the possibility of different terms for different classes of plant.

Article 9

A suggested minor amendment is to delete the words "in order to ensure the widespread distribution of new varieties" in the second paragraph. This is for two reasons. Firstly, it is not necessarily accepted that the widespread distribution of new varieties is sufficient to justify restriction of the breeder's right. Further, in all cases where the right is restricted the breeder should be treated equitably.

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Article 12

As is well known, the development of plant varieties is a long drawn out process. Before filingin an overseas country,trials in that country may be appropriate. The ICC suggests that the period of priority could be extended to up to 18 months or, preferably, two years. This would enable the applicant to better forecast the commercial value of his new variety. Two years is better than 18 months as it could provide time for an extra season's trials.

Article 13

While the need for the very existence of this article in the Convention has been questioned, the ICC believes, on balance, that it should be maintained, but simplified. For example, why should not the variety denomination consist solely of figures? While this is not a matter directly concerned with amendments to the Convention, the ICC also suggests that the guidelines issues by UPOV on this topic are less helpful than they could be, and should be redrawn.

In the ICC's view, among the changes suggested above priority should be given to revision of Articles 2, 4 and 5.

The ICC repeats its strong support for UPOV's initiative in reviewing the Convention, and looks forward to continuing involvement in the debate.

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COMMISSION ON INTELLECTUAL AND INDUSTRIAL PROPERTY

LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

ICC Statement

adopted by the Commission on Intellectual and Industrial Property

Submitted for Adoption at the 47th Session of the Executive Board of the ICC (December 2, 1986)

BIOTECHNOLOGICAL INVENTIONS

Position Paper
of the International Chamber of Commerce

A. OVERALL POSITION

1.1. There is no doubt that the potential fruits of modern biotechnological research are of fundamental and far-reaching significance and that biotechnology today is therefore of great economic and social importance. There is also wide recognition of the need to stimulate research in this field to ensure that progress is accelerated to the fullest extent possible. **It is the view of the ICC that the patent system offers the best prospect of protecting inventions in biotechnology and thereby stimulating research and accelerating progress.** The patent system achieves this objective in two ways - firstly by offering the inventor a limited period of exclusivity in which to recoup an adequate return on his research investment and secondly by ensuring public disclosure of inventions such that researchers may benefit from the knowledge thereof; not only so as to avoid unnecessary and wasteful duplication of research but also so that this knowledge can act as a stimulus for further inventive activity. In the hundreds years or more that the patent system has existed in various countries around the world, no better system has, to the knowledge of the ICC, evolved and it is therefore believed that **there is neither a need to seek, nor a realistic prospect of finding, a satisfactory alternative system for the protection of biotechnological inventions.**

1.2. It is recognised that **public interest** may well be a relevant factor in some areas of biotechnology and that certain types of research that can be envisaged in this field may raise serious ethical or moral difficulties. It is the view of the ICC however that such issues will always depend on particular circumstances and therefore can not be accurately foreseen nor reasonably prejudged. Moreover, it is, in the first line, the research or the exploitation of the results thereof that create the potential problems. The patentability of any inventions that may result is secondary. Such potential problems **should** therefore **not be dealt with by automatically excluding from patentability whole categories of invention ab initio. Instead, if a line of development indicates that public interest is being or may be seriously threatened, separate national legislation regulating or even prohibiting the research in question and/or the exploitation of the results thereof should be introduced by governmental authorities.**

1.3. It is also accepted by the ICC that **the patent system can and should be improved globally in order to achieve the stated objectives in the field of biotechnology. On the other hand,** biotechnology, among many other areas of technology, is rapidly evolving and **it is considered essential that the flexibility of the patent system be retained** and that special or detailed patent laws

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A summmary of conclusions will be found at the end of the position paper, after page 26.

or rules, adapted to meet the current situation only, be avoided since there is a real risk that they could become obsolete or unmanageable within a short period of time. A liberal and realistic interpretation of existing laws, by way of modification of patent office guidelines or in jurisprudence yet to develop, may well in some instances represent a more attractive and practical approach than enactment of special or amendment of existing patent laws and rules. However, there are other aspects which will inevitably require amendment of the law.

1.4. It is finally noted that **there is an international imbalance in the strength of patent protection available in the biotechnological field.** As will be seen from the detailed discussion which follows, some countries, notably the USA and to a somewhat lesser extent Japan, already offer patent systems and protection which are far more geared to stimulating research and progress in the biotechnology field and protecting the interests of the biotechnological inventor, than many other countries, including Europe. It is an obvious corollary that **biotechnological research investment and progress will be concentrated in those countries offering the best incentive package.** Adequate patent protection is a primary element in an incentive package and the current imbalance is presumably not in the national interests of those countries where this element of the package is weaker. **There is therefore a legitimate need, not only on the part of the biotechnological inventor or industry, but also on the side of national interests that this imbalance be corrected by an international harmonisation and strengthening of patent laws in the area of biotechnology.**

B. DETAILED POSITION

The following detailed discussion deals with what are seen by the ICC as the main issues concerning the protection of inventions in the biotechnological field which will need to be resolved if the desired stimulus for research and progress in the biotechnology field is globally to be ensured.

1. Inherent Patentability

1.1. General view

The ICC has already made the following public statement (at the WIPO meeting of the Committee of Experts on biotechnological inventions and industrial property: 2nd session February 3 to 7, 1986):

."this organisation remains in favour of the utilisation of the patent system to protect biotechnological inventions - this term to be understood in its widest sense. We do not consider that there are either valid or weighty reasons in support of the view that the patent system cannot assure adequate protection of all such inventions, even where living organisms are concerned".

Subject to the usual rules of patentability, namely novelty, inventive merit/unobviousness and industrial applicability/utility, as well as sufficiency of disclosure, **no valid reason is seen why any invention whether it be a product, a process or a use, in any field of science or technology, let alone biotechnology, should as a generality be excluded from patentability.** Indeed it is believed that any such generalised exclusions can and do act as a significant deterrant to research and progress.

1.2. Novel Product Inventions

The ICC thus sees no valid reason why any novel product invention, whether or not it concerns a living organism and whatever its intended use, should automatically be excluded from patent protection. It also sees no logical reason why such inventions in any area of application should be discriminated against in terms of the type or strength of patent protection available to them. In particular, the still widespread so-called "compromise" of providing only for process protection for novel products is in reality very often tantamount to providing no protection at all - as experience has shown in many technical fields, process protection for novel products is largely illusory, being generally easily circumventible and difficult, if not impossible, to police and enforce. This has proved particularly to be the case in the areas relating to novel medicinal, agricultural or foodstuff products, precisely areas in which biotechnology is expected to produce pioneer products.

1.2.1. Microorganisms

In the opinion of the ICC, novel microorganisms per se should be patentable provided the other normal requirements of patentability are met. This should be so whether the microorganism is man-made or is isolated from nature.

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In the case of naturally-occurring microorganisms, providing the patent claim is directed to (or is interpreted as being directed to) a form of the microorganism other than that in which it occurs in nature, for example where the claim recites a particular degree of purity or specifies the absence of natural contaminants, the claimed invention is novel. Assuming there is the necessary degree of inventive merit/unobviousness (which may derive from the product itself if, for example, it was previously unrecognised that it occured in nature, or if, in isolated or purified form, it has some unexpected use) and assuming industrial applicability/utility and the possibility of sufficient disclosure, there is no reasonable ground for refusing a product patent. In this connection, it may be mentioned that many highly important antibiotics had previously existed, albeit unrecognised, in nature. Had they been denied patentability on the "existence in nature" ground alone, immeasurable improvements in health standards throughout the world could have been sacrificed. No sound reason is seen for adopting a different attitude with respect to microorganisms simply because they are living. Today, microorganisms are not only key "intermediates" in chemical and biotechnological processes, but they can also be highly important saleable products as such in many areas, for example in agriculture or in the food or oil industry. One example of such a saleable product is "baker's yeast" (as in the well-known West German BGH decision) on which a great deal of research has been and continues to be carried out. It is therefore considered vital that microorganisms be adequately protectable by patents.

To the knowledge of the ICC, this situation corresponds to the existing legal position in for example USA, Japan and under the European Patent Convention (EPC). There are still, however, many countries which deny product, or indeed any, patents for micro-organisms, whether man-made or naturally-occurring.

1.2.2. Plants

Quite generally, **no good reason is seen why plants or their propagating material should be treated any differently to microorganisms or any other living or non-living subject matter. They should be patentable per se providing the normal requirements of patentability are met.** The ICC does not see that the fact that plants or their propagating material may be protectable under the UPOV convention or under other systems of protection is a logical or persuasive reason why they should be excluded from patentability. While plant variety protection under UPOV continues to fulfil a valuable need, as will be discussed in more detail later in this paper, it is, in the opinion of the ICC, inherently less suitable to stimulate the desired research and progress in the field of modern plant biotechnology. In particular, UPOV plant

variety protection provides neither the necessary degree of exclusivity to stimulate the heavy research investment required, nor the necessary element of early public description and disclosure to aid further research, that are both inherent in the patent system. Therefore, it is considered essential that any exclusions of plant **varieties** from patent protection should be removed. An alternative, which is considered far less preferred however since it would still leave serious doubt as to the true legal position, would be that any such exclusions be interpreted narrowly such that plant **inventions** should be patentable. Furthermore, both patent protection and plant variety protection should be available for inventions that meet the criteria for protection under both systems and it should be a matter for the inventor or innovator and not the legislator to decide whether he needs both or only one type of protection. Double protection is neither abhorrent nor unusual - it often occurs that different aspects of a particular product are not only protected by a number of patents, but also by design, utility model, copyright and/or trademark registration and so on. This situation has led to no serious problems in other fields of technology and therefore there is no reason to assume it would lead to serious problems in the area of plant biotechnology.

The ICC notes that plants are already patentable (following the decision in Hibberd) in the USA, and some other countries such as Canada and Hungary. The EPC excludes plant varieties from patentability [Article 53(b)] but it appears that the European Patent Office at least are interpreting this exclusion narrowly such that, whereas inventions which are limited to specific varieties may be excluded, more general inventions are not. This view also appears to be followed by Switzerland (a member of the EPC) in its recently announced amended patent guidelines. The question appears to be open in Japan. In many other countries, the situation concerning the patentability of plants is either unclear or negative.

1.2.3. Animals

By the same token, the ICC feels that in principle there is no valid reason automatically to exclude animals from per se patents, again assuming the normal requirements of patentability are met. The ICC recognises that this topic is controversial and that in some circles any changes in this direction would be considered premature. It has to be remembered however that, in the case of animals, as opposed to plants, there is not even any wide-spread alternative system on the lines of UPOV so that if animals are excluded from patentability there will be no possibility of pro-

tection at all. This cannot be in the interests of progress in this area where, it is noted, great advances are predicted even if not as rapidly as in other areas. The ICC's view on moral or ethical issues that might arise in specific cases in this area has already been mentioned above. Unfortunately, however, discussion on this theme very often tends to focus more on science fiction than fact and it is frequently overlooked that, while there is obviously no question of wishing to patent humans, the genetic manipulation, for example, of certain types of animals can lead to highly desirable results. Even today, for example, polypeptides are being expressed in insects. One other objection that is sometimes raised with regard to patenting in the animal area is that problems of adequate disclosure will arise in view of the obvious difficulties with regard to deposition of animals. That may be true in some cases but it is also not felt to be a valid reason to exclude the entire area. There will certainly be other cases where a reproducible description can be provided without any deposit at all or by reference to a deposit of animal material which can be used as a source of reproduction, cells, eggs, sperm and so on. Also, problems of disclosure have arisen in the past and satisfactory solutions have been found in order to meet the accepted legitimate need for protection. There is no reason to assume that problems that may arise in the future in this area cannot equally be resolved by pragmatic, practical solutions given the need and will to do so.

Again, it would seem that in the USA and Canada there would, as with plants, be no automatic barrier to the protection of novel animals and the situation under the EPC is on the face of it similar to that for plants, the exclusion of Article 53(b) reading on animal **varieties** only and therefore being susceptible to the same narrow interpretation as is apparently being applied in the case of plant varieties. Again, Switzerland has embodied this narrow interpretation also with respect to animals into its recently issued guidelines. The situation in many other countries is however understood to be unclear or negative.

1.2.4. Other biological materials of a chemical nature

Other key materials in biotechnology which do in the opinion of the ICC need to be patentable obviously include **genes, vectors such as plasmids, enzymes and so on (as well as novel chemical products of biotechnological processes).** It is important to stress the fact (which is sometimes overlooked) that although such materials may be self-replicatable in appropriate hosts, or may be produced by or find their principle use in microbiological or biological processes, they **are chemical compounds. They should be subject to the normal patentability requirements for chemical products and as such should be patentable per se irrespective of their**

manner of manufacture or intended use, if they are novel, inventive/unobvious and industrially applicable/useful.

This is already the situation under many important laws (USA, Japan, EPC and so on) but there are still many countries which provide only process protection in the case of novel chemical compounds. The illusory nature of such protection has already been discussed but can also be illustrated in the case of a novel man-made gene. This could consist of literally hundreds or thousands of nucleotides and could in the course of time no doubt be synthesised. There would however be a myriad of alternatives in the order or manner of linking the nucleotides and it would be a practical impossibility to conceive, support and patent every alternative. No matter how many processes were patented there would therefore as a rule be a means of circumventing the protection.

1.3. Processes for the production of known products

As far as is known to the ICC, most countries which have a meaningful patent system already provide for patent protection for new, inventive and useful processes for the production of known products. In the laws of many countries however, an exception is made for "essentially biological processes for the production of plants and animals". The scope of this exception is highly debatable in the context of modern biotechnological research particularly as the same laws of many countries specifically state that this exception does not apply to **micro**biological processes. Whatever the scope of the exclusion is, however, the ICC believes it to be unjustified. **"Essentially biological processes for the production of plants and animals" should be patentable in the same way as any other process.** Moral and ethical issues that may arise in particular circumstances should, as previously mentioned, be dealt with by non-patent legislation to be implemented as and when the particular circumstances dictate and not by automatic exclusion from patentability of all inventions in this category.

As far as is known to the ICC the main group of countries having the exception referred to in their laws are the member countries of the EPC as well as the EPC itself, although certainly a similar situation has developed in other countries by way of jurisprudence. The ICC believes that there is ample room for narrow interpretation of this exclusion from patentability and that, even though ideally it should be removed, its impact in the field of biotechnological research can be minimised by such interpretation if removal of the exclusion is, at least in the short-term, not feasible.

1.4. New Uses of Known Products

In the opinion of the ICC, there is no valid reason why new uses, whatever the field of application, should not be patentable providing

the other normal requirements of patentability are met. Biotechnology, by making available for testing in large quantities hitherto known but scarce materials, is likely to lead to many inventions of the new use type, for example in such areas as medicine, foodstuffs and agriculture. It is precisely in these areas, however, that the laws of many countries (not however the USA, Japan or under recent case law the EPC) make exceptions as to patentability. In the opinion of the ICC such exceptions are not justified and can only represent a disincentive to research of the type discussed. The exceptions should therefore be removed or their impact minimised by narrow interpretation.

2. Sufficiency of Disclosure

2.1. General View

It is fundamental principle of practically all patent laws that the disclosure of invention must be sufficient to enable the skilled man to carry it out or, in other words, repeat or reproduce it. There can be no dispute as to the justifiability of this "enablement" requirement. The **quid pro quo** for a patent would not be met without it. However, it should equally be recognised that the biotechnological inventor may sometimes, particularly when the invention requires the use of hitherto inaccessible living organisms, be faced with formidable difficulties if not total impossibility in meeting this requirement by way of written description alone. These are, however, practical rather that philosophical obstacles and should not be allowed to hinder the progress of biotechnology. Such pragmatic and practical solutions as the deposition system for microorganisms which has evolved must therefore continue to be sought in the case of similar difficulties which may arise in the future with for example higher organisms. **It is,** however, **the opinion of the ICC that that deposition systems for microorganisms or similar systems that may evolve in the future must be internationally harmonised and strengthened from the viewpoint of the inventor.** It is important that in the biotechnology field the same balance between public interest and inventor interest with respect to the granting of patents is found as in the other fields of technology. There is already clear evidence that the deposition system and the release condition attached to it, despite the well-intentioned merits thereof, are acting as a disincentive to patenting in some areas of biotechnology. The only alternative, trade secrecy, is neither reliable nor rewarding for the inventor, and is certainly not in the interests of progress and the public.

2.2. The Deposition Requirement

2.2.1. When is a deposit required and acceptable?

In the opinion of the ICC, deposition should never be required unless it is essential to enable the skilled man to reproduce the invention without the application of inventive ingenuity. However, if an enabling description is otherwise impossible or difficult, deposition should be accepted as completing the sufficiency requirement, including the requirement for repeatability, and as being sufficient to support a claim to the deposited organism as such. It is important to note that the techniques of genetic engineering, for example, are becoming increasingly reproducible based on a written description involving a known, available starting organism and in this situation no deposit should, it seems, be required. Where an enabling description of this type is not feasible, however, deposition of the starting or final organism (whichever is necessary to ensure reproducibility) should, it is believed, be regarded as completing the sufficiency of the disclosure and supporting a claim to the organism as such. It appears that most major laws already accept these propositions. However, there are some countries that still do not accept the position that deposition can remedy an otherwise insufficient disclosure. For example, in West Germany and Switzerland, it appears that a deposited microorganism cannot be claimed per se unless a reproducible description of its production is also provided. This is clearly an inflexible position that can only prejudice biotechnological research and progress. In addition, there is a tendency in some countries to require deposition whenever a microorganism is mentioned in a patent specification, even though it may for example be well-known and available (commercially or by virtue of an earlier deposit) or merely exemplary of known microorganisms that might be used. Such requirements go beyond requirements in other technical fields and are, in the opinion of the ICC, clearly unjustified.

2.2.2. Where must deposits be made?

Despite the national nature of patent rights and the fact that national disclosures should be locally enabling, it places an intolerable burden on the biotechnological inventor if, for example, microorganisms have to be deposited in every country in which patent protection is sought. Given modern methods of communication and access, national deposition requirements are unnecessary and, on a global scale, wasteful. **In the opinion of the ICC, deposition in a foreign but internationally accepted collection should be regarded as meeting local requirements.**

Many countries (including USA, Japan and EPC countries) have already ratified the Budapest Treaty which embodies this principle. It is believed that other countries should certainly be encouraged to do so or modify their national laws correspondingly.

2.2.3. What may be deposited?

To date, the recognised deposition systems apply only to "micro-organisms" and, on the face of it, that term would not embrace such further self-replicatable material as plasmids, cell-lines and possibly viruses which may at least in some cases present the same difficulties in terms of sufficiency of disclosure as microorganisms. **In the view of the ICC it is essential that deposition of other such self-replicatable materials should also be accepted as a means of completing the sufficiency of the disclosure in relation to inventions thereof or requiring their use. The same should be the case for plants and their propagating materials, animal reproductive material and so on if, as the ICC suggests, the patent system is or should be open to all inventions in these categories.** Practical problems may, as already discussed, arise in certain cases but the perception of these should not be allowed to overrule the principle desirability of deposition.

It is debatable to what extent the Budapest Treaty and national laws need amendment to allow these possibilities but it appears that there is already a wide willingness to interpret the term "microorganism" not in a limited scientific sense but in a liberal sense based on the philosophy and intention behind the deposition system, in order to accomodate such possibilities. Thus International Depository Institutions under the Budapest Treaty have decided that they will accept for example viruses, cell-lines, hybridomas, plasmids, plant-tissue cultures and seeds. This attitude is very much to be welcomed, but of course the mere acceptance by depositories does not guarantee that there will be no problem under national patent laws. There should therefore at least be clear statements in for example national patent office guidelines that these deposits will be recognised as completing the disclosure requirements.

2.2.4. Re-deposition

Under the deposition system as it exists in many countries, the depositor is required to maintain the deposit for a certain minimum period of time (under Rule 9 of the Budapest Treaty, at least 5 years from the most recent request for a sample and in any event at least 30 years). In such a period of time, it can of course, through no fault of the depositor, occur that the deposited material is no longer viable or no longer available. **In the view of the ICC, it is essential that in these circumstances, the depositor should have the possibility of a re-deposit to rectify the matter with no adverse consequences to his patent.**

The Budapest Treaty already provides for this possibility but it is obviously desirable that countries which have not yet ratified the Budapest Treaty should do so, or should at least provide for this possibility under their national laws, regulations or guidelines.

2.3. Deposit Release Conditions

2.3.1. General view

While it is accepted that deposition (in those instances were it is required) is an essential part of providing an enabling disclosure and therefore should take place by the time of filing a patent application, or by the date of the priority application if priority is to be secured, there is great dispute as to when and under what conditions the deposit must be made available to the public. On the one hand it is argued that biotechnological inventions must be treated in the same way as any other type of invention. On the other hand, it is argued that in reality the deposition system is peculiar to the biotechnology field and that in no other field is it required to supply the actual physical means of carrying out the invention, rather than just supplying written information. Deposited material is tangible property, rather than intellectual property, and may be of absolutely vital importance to the proprietor. In addition, the deposition system is open to considerable and highly damaging abuse by the unscrupulous and there is little the proprietor can do to prevent this at least until he has an enforceable right. These factors, it is argued, override the ideal of equal treatment. **In the opinion of the ICC, the deposition system does impose requirements on the biotechnological applicant which go far beyond those in other fields. There is a legitimate need for regulations concerning release of deposits which protect the reasonable interests of the inventor. There is furthermore, an urgent need to harmonise international laws so that all include such regulations.** If, as is the situation today, any major country in which patent protection needs to be sought does not offer the protection on deposits that is needed, then the fact that other countries do is irrelevant. The law of the weakest country will prevail and this may (and there is already evidence in some fields that it does) act as a disincentive to patenting at all and a reliance on trade secrecy instead. As indicated above this is not in anybody's interests.

2.3.2. Time of Release

In the opinion of the ICC release to the public of samples of

deposited material should be required only after an enforceable right is obtained with the obvious consequence that there will be no release if the application is withdrawn or refused. At the time of early publication of patent application in those countries where this system exists, although the patent applicant does acquire certain rights, he cannot enforce them until examination has been completed (which could be years later) and the application has been accepted or granted. He has therefore no means of preventing abuses (the opportunity for which is great) by the unscrupulous. Furthermore, the point at which the full sufficiency of disclosure is of primary significance is not the date of early publication of the unexamined application, but rather the date at which the examined application is published since it is only at this point that an enforceable right namely the quid pro quo for the disclosure and release of the deposit, is obtained. If it is felt necessary to protect other elements of public interest, for example so as to render disclosures enabling and reproducible before release of the deposit to the public, the ICC is of the view that the "expert solution" adopted under Rule 28 of the EPC, whereby the only permitted release before an enforceable right is obtained would be to an independent expert, placed under appropriate obligations, would be an acceptable (though not ideal) compromise.

In the USA and Japan, the ideal position of no release before an enforceable right is obtained is already the law. In the EPC, the so-called "expert solution" has been adopted. However, it has not yet been embodied in the national laws of many of the EPC member countries and, until it is, it remains highly questionable whether it is safe to rely on it since national courts could subsequently nevertheless hold the disclosure to be insufficient. This is probably one reason why the expert solution has apparently been little used. Another reason no doubt is that there are still other countries which, in any event, require free release at the early publication stage. If the deposit must be released for one country there may be little if any point in imposing conditions in another country.

2.3.3. Conditions on release after obtention of enforceable right

Even after an enforceable right has been obtained, it must, in the opinion of the ICC, be recognised that there is great scope for abuse of samples of deposited materials. The possibility stems in part from the self-replicatable nature of the materials. Furthermore, the patentee in trying to enforce his patent is faced with similar problems to those which led to evolution of

the deposition system in the first place, for example the inadequacy of means of characterising microorganisms and therefore being able to prove that the one microorganism is the same as another. To this must be added the same problems of proof in the case of manufacturing procedures involving microorganisms as arise in other fields, particularly when the final product is being imported from a country where there is no patent protection or no means of enforcing it. **In the opinion of the ICC therefore, it is vital that even after an enforceable right is obtained there must be a series of conditions placed on the release of samples and again laws must be harmonised internationally in this respect. The party requesting the sample must be obliged to agree to these conditions and there should be clear and sufficient sanctions in the case of breach thereof.**

In particular the following conditions are considered to be justified (though the precise scope and effect of some may need further refinement), **a prerequisite being that the identity of any party receiving a sample must be notified to the patentee:**

a) **use of released sample for experimental purposes only.** Commercial use under the patent would in any event infringe the patent so that this requirement then merely adds a certain additional protection which may however be important in cases where policing and enforcement of the patent is difficult.

b) **no transfer of released samples to third-parties.** Again, in terms of trying to police and enforce his patent, it is vital for the patentee to be able to keep track of all parties who have obtained access to his deposited material.

c) **no export of released sample.** If samples can be exported by the recipient to countries where there is for example no patent protection, the very means of carrying out the invention will have been presented on a plate. If for example the invention concerns a manufacturing procedure which uses a deposited microorganism then the manufacture can be carried out in the patent-free country and final product imported back into the original country. The patentee will often have no means of proving that his patent has been infringed. It may be argued that this is no different from the situation in other fields but the difference is again that the biotechnological patentee is required to give away the motor of his machine rather than just information.

d) **no release to countries where no enforceable right exists.** In countries where patent protection has been sought but an

enforceable right has not yet been obtained, it would obviously defeat the purposes of the condition discussed under paragraph 2.3.2. above, if release is allowed to such a country before the enforceable right is obtained. In countries where a patent has not been sought or has been refused, this condition is required for the same reasons as discussed under sub-paragraph c) above.

e) **release conditions to apply not only to the deposited material but also to derived material.** This condition is considered vital to prevent for example the possibility of modification, e.g. mutation (which may even be a spontaneous mutation), to get a different microorganism outside the scope of the patent which fulfils the same purpose. In this case, while there may have been a single act of infringement, this may go undetected or be impossible to prove. The modified micro-organism can then be multiplied indefinitely and the patentee may well have no recourse. Other aspects of this problem are discussed later in this paper.

While conditions a) and b) above already apply to some extent at least in a number of countries, their precise effect varies from country to country. The remaining conditions considered necessary are either rare or do not exist at all in any country as far the ICC knows. It is however not believed that the fact that opinions differ widely on the subject of release conditions is a valid reason for not pressing for the improvement and harmonisation which the ICC believes to be urgently required.

3. Scope of Patent Protection

This is a discernible tendency among various Patent Offices to assert that disclosures in the biotechnological field are sufficient or enabling only to the extent that organisms have been deposited and to require consequential restriction of the claims. Restriction in this respect would very often render the protection totally worthless. For example, in the genetic engineering field, useful genes may be expressed in a variety of host organisms and once the basic information as to the nature of the gene and its manner of expression in one or more deposited microorganisms is disclosed, in many cases it will be a relatively routine matter to express it in a different host microorganism of the same or indeed different type or species. Furthermore, it is well-known that it is relatively easy to produce simple mutants or variants of any given micro-organism which will perform the same function. **In the opinion of the ICC therefore, it is essential that Patent Offices and**

Courts should be prepared to allow a scope representing a reasonable prediction beyond the specifically described embodiments, in particular specifically deposited or described microorganisms, as in any other field. Failure to do so will cause inventors to rely on trade secrecy in preference to obtaining patents of little practical value in return for having to publish their inventions.

4. Enforceability of Patent Protection

4.1. General view

Patent protection, no matter how broad and valuable in theory, can be rendered virtually worthless if as a practical matter the patentee is faced with formidable or even insuperable obstacles in policing the patent, proving infringement or enforcing the patent. The biotechnological patentee faces particular problems in this respect, a number of which have already been referred to. It is the view of the ICC that greater attention needs to be paid to practical difficulties of enforcing patents in national laws and that solutions should be found to protect the interests of the biotechnological patentee. Otherwise, again use of the patent system will suffer in favour of trade secrecy. Experience has shown this to be the case in the past in for example the fermentation industry where great strides have certainly been made but there has been relatively little use of the patent system because of the dual problems of deposition and difficulty of enforcement of patents once obtained.

4.2. Reversal of Burden of Proof

It is a cornerstone of most if not all patent laws that it is up to the patentee to prove that his patent is being infringed. The difficulty of doing so has however already been recognised in some areas and the concept of reversal of the burden of proof has evolved in the laws of many countries. In the situation where reversal applies, notably in the case where the patent concerns a process for the production of a novel product, the onus is on the defendant to prove that he is not infringing the patent. In the opinion of the ICC, in view of the ample scope for abuse of samples of deposited material (even if the conditions discussed above are imposed on their release) and the difficulties of proving infringement otherwise, there should be automatic reversal of the burden of proof, if the defendant can be shown to have obtained a sample of the deposited material.

To the knowledge of the ICC such a law exists in no country currently. That, however, is not felt to be a reason why it should not be considered.

4.3. Exhaustion of Rights

The principle of exhaustion of patent rights upon sale of a patented product creates difficulties where the patented product is self-replicating or self-replicatable. A simple example is the case where the product is a living microorganism (such products are already marketed in the agricultural area for example). It is argued by some that a competitor need only obtain a small supply of the product and is then free to multiply and sell the progeny on the principles of exhaustion of rights. By the same token it is argued that he may be able and free to transfer the genetic information from the marketed product to another microorganism to obtain equivalent properties and multiply and sell that. Similar problems arise with seeds. The ICC considers that such arguments stretch the principle of exhaustion far beyond its intended and justifiable purpose. Sale of a patented material obviously must give the purchaser an implied license to use it for its intended purpose. In the case of self-replicating material, it is, equally obviously, not intended that the purchaser should be free to compete with the seller by commercially exploiting progeny or derivatives.

The ICC considers it essential that exhaustion of rights should be applicable only to the actual material sold and purchased, for its intended use, and not to progeny or derivatives thereof which in fact represent new material that has never been sold or purchased and to which the exhaustion principle should not apply. Otherwise, patents to self-replicating material may turn out to be useless or at least of vastly reduced value. To the extent that public interest needs to be protected, for example to allow farmers to use successive generations of seeds to produce for their private consumption (as opposed to commercial purposes), this could be done by overriding provisions.

Exhaustion of rights is a matter not usually dealt with in patent laws and is therefore usually only considered by national courts in interpreting patent laws. It is therefore not surprising that, as far as the ICC is aware, the question of exhaustion of rights in the case of sale of self-replicable material has not been widely considered. Nevertheless, it is believed to be a potentially crucial problem and it is felt essential that it be fully considered and that suitable solutions be found if the ICC's proposition stated above is likely not to correspond to existing laws.

5. Plant Variety Protection and The UPOV Convention

5.1. General view

Plant variety protection for example under the UPOV convention was introduced to meet a legitimate need for protection of new varieties of plants, such new varieties for one reason or another not being susceptible to patent protection. The system has undoubtedly worked well and will certainly continue to play a valuable role in the future. Plant breeding will continue and many varieties produced even with the aid of biotechnology would in any event not meet the criteria (novelty, inventive merit and so on) required for patent protection. **The ICC is therefore in no doubt that Plant Variety Protection is a valuable system of protection and must continue to be available in the future. As briefly discussed in paragraph B 1.2.2. above, however, the ICC does not believe that plant variety protection alone is capable of providing the desired necessary stimulus for research and progress in the field of plant biotechnology and variety development. Thus, while the system can and should be improved its existence must not be allowed to form a barrier to the patenting of true inventions (which meet all the normal requirements of patentability) in the area of plant biotechnology and variety development.**

5.2. The need for patent protection in addition to plant variety protection

There are fundamental differences between the systems of plant variety protection and patent protection. As discussed under 1.1. above, the patent system achieves its objectives in basically two ways, by granting the inventor a period of true exclusivity in which to recoup a return on his research investment and secondly by ensuring an enabling public disclosure of the invention (even if it is never commercialised) which can act as a springboard for further inventive activity. Plant variety protection provides nothing like the same degree of exclusivity and does not involve an enabling public disclosure.

As regards the scope of plant variety protection, the proprietor has the exclusive right to commercial production and the commercial distribution of the propagating material of the protected variety and, in the case of ornamental plants, the exclusive right to commercially use the plants or parts thereof as propagating material in the production of ornamental plants or flowers. The protection firstly does not prevent use of the propagating material for breeding a new variety (unless the propagating material is repeatedly used for production of the propagating material for the new variety). The significance of this in the context of modern biotechnology is huge. For example a great deal of research is currently being carried out to find a way to get crops to fix their own nitrogen requirements from the air and one approach being followed is

to put the Nif genes from a bacteria into non-leguminous species. The first to succeed in doing this will have made an enormous inventive achievement. If his protection is limited to plant variety protection of the particular variety he has done it in, it will be essentially worthless. Others will be free to use his protected variety for the purpose of breading their own varieties having the same main characteristics and the inventor will get nothing in the way of compensation. Secondly, plant variety protection relates only to propagating material and does not extend to plants or parts thereof at the consumer stage, i.e. their distribution outside the propagation stage. It would not for example prevent the importation of the protected variety produced abroad from unlicensed propagating material, a serious problem in many areas. Finally, plant variety protection is limited to the specific variety developed and there is no possibility of any degree of generic protection as under patent law.

As regards the disclosure requirements for plant variety protection, the applicant is required only to provide brief details of characteristics of his variety, how it differs from existing varieties and how it has been obtained. In the latter connection, there is no requirement that this be an enabling description and in practice it is not and in any event the applicant may and usually does request that this not be published. Therefore the plant variety protection system does not contribute to the stock of scientific knowledge in the same way as the patent system, where at least after grant there is an enabling disclosure and in some countries even before grant and indeed shortly after the initial application there is a disclosure which will be sufficient for the purposes of stimulating further research. Unless a protected plant variety is finally marketed the public will never get access to the variety at all, let alone its manner of production.

For these reasons, the ICC strongly believes that there should be no special restrictions on patent protection in the field of plant biotechnology. Furthermore, as discussed already (paragraph B 1.2.2.) it sees no persuasive reason why both patent protection and plant variety protection should not be available in appropriate cases or why the inventor should not be free to chose whether he wants one or both types of protection. For this reason, the double protection prohibition of Section 2 of the UPOV convention, as well as corresponding provisions of national laws, should either be removed or (though this would still leave serious doubt as to the true legal position and is thus far less preferred) be interpreted literally so as to allow otherwise patentable inventions in the field of plant biotechnology the patent protection that they deserve. It is noted that the USA for example has no

such prohibition on double protection.

5.3. Improvement of the Plant Variety Protection System

5.3.1. Extension of Protection to consumer end products

A major problem with the plant variety protection system as it exists today in many countries is **the fact that the protection extends to the propagating material only and not to the plant variety or parts of the plant variety as such.** As discussed above, imports of plants or parts thereof not intended as propagating material cannot for example be prevented by the proprietor of the plant variety right. **In the opinion of the ICC this is inequitable and national laws should be amended to extend the protection to cover the actual end products distributed to the consumer if these are produced from unlicensed propagating material.** It is noted that the UPOV convention would in terms of Article 5(4) of UPOV specifically allow member countries to do this.

5.3.2. Limitations on Protectable Varieties

There are some limitations in national legislation on the types of plant varieties that may be protected. **In principle, the ICC sees no reason why plant variety protection should not be available for any type of plant variety and therefore believes that existing national legislation should be extended, if necessary, to allow this.**

5.3.3. Extension of UPOV to additional countries

At the present time, relatively few countries (seventeen) are members of the UPOV convention in comparison with the number of countries which provide for patent protection. This obviously limits the value of the UPOV convention, and **in the opinion of the ICC, countries which are not already members of UPOV should be strongly encouraged to become members.**

BIOTECHNOLOGICAL INVENTIONS

Summary of conclusions in the Position Paper of the International Chamber of Commerce (ICC)

A. OVERALL POSITION

1.1. It is the view of the ICC that the patent system offers the best prospect of protecting inventions in biotechnology and thereby stimulating research and accelerating progress. There is neither a need to seek, nor a realistic prospect of finding, a satisfactory alternative system for the protection of biotechnological inventions.

1.2. Potential issues of public interest should not be dealt with by automatically excluding from patentability whole categories of invention ab initio. Instead, if a line of development indicates that public interest is being or may be seriously threatened, separate national legislation regulating or even prohibiting the research in question and/or exploitation of the results thereof should be introduced by governmental authorities.

1.3. The patent system can and should be improved globally in order to achieve the objectives of stimulating research and accelerating progress in the field of biotechnology. However, it is considered essential that the flexibility of the patent system be retained so that it will remain capable of accomodating radical technological developments also in the future.

1.4. The ICC sees an international imbalance in the strength of patent protection available in the biotechnological field. Biotechnological research investment and progress will be concentrated in those countries offering the best incentive package of which patent protection is a primary element. There is therefore a legitimate need, not only on the part of the biotechnological inventor or industry, but also on the side of national interests, that this imbalance be corrected by an international harmonisation and strengthening of patent laws in the area of biotechnology.

B. DETAILED POSITION

1. Inherent patentability

1.1. General view

No valid reason is seen why any invention whether it be a product, a process or a use, in any field of science or technology, let alone biotechnology, should as a generality be excluded from patentability. It is believed that any such generalised exclusions can and do act as a significant deterrant to research and progress.

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1.2. Novel product inventions

The ICC thus sees no valid reason why any novel product invention, whether or not it concerns a living organism and whatever its intended use, should automatically be excluded from patent protection. It also sees no logical reason why such inventions in any area of application should be discriminated against in terms of the type or strength of patent protection available to them.

1.2.1. Microorganisms

In the opinion of the ICC, novel microorganisms per se should be patentable provided the other normal requirements of patentability are met. This should be so whether the microorganism is man-made or is isolated from nature.

1.2.2. Plants

No good reason is seen why plants or their propagating material should be treated any differently to microorganisms or any other living or non-living subject-matter. They should be patentable per se providing the normal requirements of patentability are met.

1.2.3. Animals

By the same token, the ICC feels that in principle there is no valid reason automatically to exclude animals from per se patents, again assuming the normal requirements of patentability are met.

1.2.4. Other biological materials of a chemical nature

Genes, vectors such as plasmids, enzymes and so on (as well as novel chemical products of biotechnological processes) are chemical compounds. They should be subject to the normal patentability requirements for chemical products and as such should be patentable per se irrespective of their manner of manufacture or intended use, if they are novel, inventive/unobvious and industrially applicable/useful.

1.3. Processes for the production of known products

"Essentially biological processes for the production of plants and animals" should, the ICC believes, be patentable in the same

way as any other process.

1.4. New Uses of Known Products

In the opinion of the ICC, there is no valid reason why new uses, whatever the field of application, should not be patentable providing the other normal requirements of patentability are met.

2. Sufficiency of Disclosure

2.1. General View

It is the opinion of the ICC that deposition systems for micro-organisms or similar systems that may evolve in the future must be internationally harmonised and strengthened from the viewpoint of the inventor.

2.2. The Deposition Requirement

2.2.1. When is a deposit required and acceptable?

In the opinion of the ICC, deposition should never be required unless it is essential to enable the skilled man to reproduce the invention without the application of inventive ingenuity. However, if an enabling description is otherwise impossible or difficult, deposition should be accepted as completing the sufficiency requirement, including the requirement for repeatability, and as being sufficient to support a claim to the deposited organism as such.

2.2.2. Where must deposits be made?

In the opinion of the ICC, deposition in a foreign but internationally accepted collection should be regarded as meeting local requirements.

2.2.3. What may be deposited?

In the view of the ICC it is essential that deposition of all self-replicatable materials should be accepted as a means of completing the sufficiency of the disclosure in relation to inventions thereof or requiring their use. This should apply also for plants and their propagating materials, animal reproductive material and so on if, as the ICC suggests, the patent system is or should be open to all inventions in these categories.

2.2.4. Re-deposition

In the view of the ICC, it is essential that, in the case of a deposited material becoming non-viable or no longer available during the required period of maintenance, the depositor should have the possibility of a re-deposit to rectify the matter with no adverse consequences to his patent.

2.3. Deposit Release Conditions

2.3.1. General view

In the opinion of the ICC, the deposition system does impose requirements on the biotechnological applicant which go far beyond those in other fields. There is a legitimate need for regulations concerning release of deposits which protect the reasonable interests of the inventor. There is furthermore, an urgent need to harmonise international laws so that all include such regulations.

2.3.2. Time of release

In the opinion of the ICC release to the public of samples of deposited materials should be required only after an enforceable right is obtained. If it is felt necessary to protect other elements of public interest, for example so as to render disclosures enabling and reproducible before release of the deposit to the public, the ICC is of the view that the "expert solution" adopted under Rule 28 of the EPC, whereby the only permitted release before an enforceable right is obtained would be to an independent expert, placed under appropriate obligations, would be an acceptable (though not ideal) compromise.

2.3.3. Conditions on release after obtention of an enforceable right

In the opinion of the ICC, it is vital that even after an enforceable right is obtained there must be a series of conditions placed on the release of samples and again laws must be harmonised internationally in this respect. The party requesting the sample must be obliged to agree to these conditions and there should be clear and sufficient sanctions in the case of breach thereof.

In particular the following conditions are considered to be justified, a prerequisite being that the identity of any party receiving a sample must be notified to the patentee:

a) use of released sample for experimental purposes only.

b) no transfer of released samples to third-parties.

c) no export of released sample.

d) no release to countries where no enforceable right exists.

e) release conditions to apply not only to the deposited material but also to derived material.

3. Scope of Patent Protection

In ICC's view, it is essential tnat Patent Offices and Courts should be prepared to allow a scope representing a reasonable prediction beyond the specifically described embodiments, in particular specifically deposited or described microorganisms, as in any other field.

4. Enforceability of Patent Protection

4.1. General view

It is the view of the ICC that greater attention needs to be paid to practical difficulties of enforcing patents in national laws and that solutions should be found to protect the interests of the biotechnology patentee.

4.2. Reversal of Burden of Proof

In the opinion of the ICC, in view of the ample scope for abuse of samples of deposited material (even if the conditions discussed above are imposed on their release) and the difficulties of proving infringement otherwise, there should be automatic reversal of the burden of proof, if the defendant can be shown to have obtained a sample of the deposited material.

4.3. Exhaustion of Rights

The ICC considers it essential that exhaustion of rights should be applicable only to the actual material sold and purchased, for its intended use, and not to progeny or derivatives thereof which in fact represent new material that has never been sold or purchased and to which the exhaustion principle should not apply.

5. Plant Variety Protection and the UPOV Convention

5.1. General view

The ICC is in no doubt that Plant Variety Protection is a valuable system of protection and must continue to be available in the future. The ICC does not believe however that plant variety protection alone is capable of providing the desired necessary stimulus for research and progress in the field of plant biotechnology and variety development. Thus, while the system can and should be improved, its existence must not be allowed to form a barrier to the patenting of true inventions (which meet all the normal requirements of patentability) in the area of plant biotechnology and variety development.

5.2. The need for patent protection in addition to plant variety protection

The ICC strongly believes that there should be no special restriction on patent protection in the field of plant biotechnology. Furthermore, it sees no persuasive reason why both patent protection and plant variety protection should not be available in appropriate cases or why the inventor should not be free to chose whether he wants one or both types of protection. For this reason, the double protection prohibition of Section 2 of the UPOV convention, as well as corresponding provisions of national laws, should either be removed or (although this is far less preferred) literally interpreted so as to allow otherwise patentable inventions in the field of plant biotechnology the patent protection that they deserve.

5.3.1. Extension of protection to consumer end-products

In the opinion of ICC, it is inequitable that plant variety protection as it exists today in many countries extends to the propagating material only and not the plant or parts of plants as such. It is believed that national laws should be amended so that protection covers the actual end-products distributed to the consumer if these are produced unlicensed propagating material.

5.3.2. Limitations on Protectable Varieties

In principle, provided patent protection is also allowed, the ICC sees no reason why plant variety protection should not be available for any type of plant variety and therefore believes that existing national legislation should be extended, if necessary, to allow this.

5.3.3. Extension of UPOV to additional countries

In the opinion of the ICC, countries which are not already members of UPOV should be strongly encouraged to become members.

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