Session VIII: Patents and Biotechnology

International Aspects of Patent Protection for Biotechnology

By

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International Aspects of Patent Protection for Biotechnology†

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INTRODUCTION

The British press during the past week or so has been carrying articles about a speech by Dr. Andrew Lindsey of Mansfield College, Oxford. What he said is that in granting a patent for the "Harvard mouse"[1]—the mouse that is predisposed to cancer and which is used for testing drugs used in the treatment of human cancer—the European Patent Office has "achieved the lowest status granted to animals in the history of European ethics. It shows," he says, "that we have reached a humanistic dead-end street in which limits imposed by God are gone. The world is not ours to master or control; our status should be that of creatures, not of creators."

Now, he's an Oxford man. Much of the basic work in the biotech industry is done at Cambridge. The "Harvard mouse" comes from Cambridge, Massachusetts. I don't know if this colors his approach to the subject, but maybe it does.

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1. *See* Onco-mouse/Harvard, Decision of 3 April 1992, [1992] O.J. Eur. Patent Off. [O.J.E.P.O.] 568 (Examining Div.), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 106, E-35, *acq.*, Case T 19/90, [1990] O.J.E.P.O. 12/476 (Tech. Bd. App. 1990), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 19/90-1, *rev'g and remanding*, Decision of 14 July 1989, [1989] O.J.E.P.O. 11/451 (Examining Div.), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 106, E-17.

I. BACKGROUND

A. *The New Situation*

Biotechnology is one of the world's oldest technologies. As an example of this fact, people have been brewing beer for thousands of years; that's a straight biotech process. So why do we now have a situation where people are getting excited about the patents in this area?

I think there are two reasons: The first is the fact that in certain aspects of this technology one is dealing with living materials. This raises questions that the patent systems in most countries have not had to deal with before.[2] The other is that this is perhaps the first time that the patent system has been of vital importance in the early stages of development of a new science, and this in itself raises a number of problems as to the appropriate scope of protection given.[3]

B. *Development of the Industry*

In order to understand the problems presented to the patent world in the field of biotech it is worthwhile to look briefly at the history of the industry as it has developed. The 1970s saw the introduction of the two major new techniques on which most modern biotechnology was founded, namely recombinant DNA technology (genetic engineering) and the introduction of techniques for producing monoclonal antibodies.

To understand the issues involved, however, we have to start a little further back. The knowledge that long chain molecules pres-

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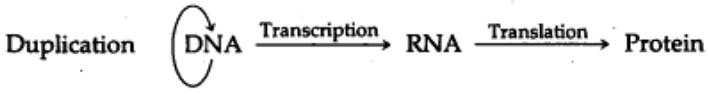
2. The U.S. Plant Patent Act of 1930, 35 U.S.C. §§ 161-164 (1988), which might be regarded as an exception to the statement, is in many respects more of a copyright-type statute than a patent one. Rights are confined to excluding asexual reproduction of the plant or its sale or use and the plant is effectively defined in terms of its picture. These restrictions make the protection close to the copyright principle of protecting against copying of an expression rather than the patent principle of granting a right to exclude others from using the new ideas defined in a patent's claims.

3. One might have thought that the computer industry would have given us some guidance in this area, but, unfortunately, in the early days of computer development the focus was much more on copyright and trade secret protection then on securing patent rights. Thus, in the computer industry, patent issues really only emerged at a comparatively late stage in the development of the industry.

ent in cells as part of chromosomes known as deoxyribonucleic acid contain genetic information goes back to the 1920s. But, it was not until 1953 that Francis Crick and James Watson—while working in Cambridge—showed that DNA exists in cells in the form of a double helix, that is to say, there are two strings of polymer which are complementary to each other. Each strand comprises a backbone of phosphate and sugar molecules—deoxyribose being the sugar—with a base attached to each sugar unit. The combination of the sugar unit and the base is known as a nucleotide. Only four bases are involved, namely, adenine (A), cytosine (C), guanine (G), and thymine (T). It was already known that the total number of adenine molecules present equal the total number of thymines and the total number of guanines equals the total number of cytosines.

Crick and Watson in their theory pointed out that in the two strands of nucleotides forming the double helix, adenine was always paired with thymine on the opposite strand and guanine with cytosine. Thus, this meant that each strand could act as a template for construction of the opposite strand. While this insight provided the key to understanding how DNA might be replicated during cell division—the strands become unwound for a while and a new "opposite" strand is constructed on the template of a single strand of the unwound double helix—it did not explain how the DNA forming a gene performed any other function in the body. The answer to this question was provided in 1956 by Francis Crick in the so-called central dogma of molecular biology. It is as follows:



RNA referred to in the central dogma is another polynucleotide chain. This time, however, the backbone sugar is ribose as opposed to deoxyribose as in the case of DNA. Another major difference between DNA and RNA is that RNA normally exists as a single strand. In the production of proteins according to the central

dogma, strands of messenger RNA are formed from the template of the temporarily decoupled DNA double helix by a process known as "transcription." This messenger RNA is then acted upon by a ribosome (a structure contained in the cells which itself contains substantial amounts of RNA) to assemble amino acids present in the cell to form a polypeptide or protein. This operation is known as "translation." However, it was not until 1966 that the code by which particular sequences of nucleotide in DNA led to a polypeptide containing a particular sequence of amino acids was worked out. According to this code, groups of three bases on the DNA determine the location of a single amino acid in the resulting polypeptide. Since there are sixty-four possible combinations of three bases (4^3) and only twenty amino acids used in the production of polypeptides, it gives rise to interesting possibilities and, in fact, several different combination of bases may result in the same amino acid in the final polypeptide. In all, sixty-one of the possible sixty-four combinations define a particular amino acid. The remaining three combinations code for stop signals to indicate where the gene ends.

From 1970 onwards, numerous enzymes called "restriction enzymes" have been found that cut DNA at points where a specific combination of bases occurs. The discovery of these enzymes constituted the gateway to recombinant DNA technology or genetic engineering. An enzyme was already known that joins pieces of DNA together. Once restriction enzymes became available for "precision cutting" of DNA, this permitted one to take a piece of DNA from one DNA chain and insert it into a different DNA chain. The first successful attempts at doing this were in San Francisco and Stanford in 1972. These techniques enabled one to take a gene from one organism and insert it into the DNA of a different organism. Thus, for example, DNA's that code for production of proteins such as insulin, human growth hormone, and tissue plasminogen activator have been inserted into bacteria to cause such bacteria to produce these proteins. Similarly genes leading to a predisposition to develop cancerous tumors have been introduced into the embryos of mice so as to produce mice that are susceptible to tumors for use in cancer research.

Research during much of the 1970s and early 1980s was focused on development of techniques for this purpose. Two key elements exist in doing this: first, identifying a gene having particular properties, and second, introducing it into a cell where it can function to produce significant quantities of the desired protein.

Techniques such as "Southern blotting" (named after its inventor E.M. Southern), a description of which was published in 1975,[4] provided powerful tools to enable researchers to start to identify which portions of a length of DNA contained a particular series of bases. This was instrumental in meeting the first requirement.

Work on the second element focused on the means for introducing "foreign" DNA into a suitable cell. Normally this is done by incorporating the desired DNA into a vector that can be introduced into the cell. A particularly convenient form of a vector is a plasmid. Plasmids are relatively small, often circular, pieces of DNA that are common in many bacteria and some other forms of cell. Alternative vectors include viruses, bacterial phages, and other DNA fragments. In particular, much work was done on the means for controlling when an organism would or would not produce a desired product. Cells are at all times producing a large number of proteins. Many of these are enzymes for internal use within the cell. Others are materials to be secreted into the body or the environment. Production of particular materials at particular times is governed within the cell by regulatory regions and signal sequences on the DNA. These are regions that determine whether there will be transcription of a particular piece of DNA at any given time. These sequences may be responsive to the environment so that, in ways that are still not fully understood, a cell will only produce a particular product under certain circumstances responding to an external stimulus. Similarly, since some proteins are for internal use within a cell only and some are for excretion, the DNA has to provide coding to indicate to the cell wall that the protein produced may pass through it and be released into the environment. Furthermore, certain proteins are only released into the

4. E.M. Southern, *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophonesis*, 98 J. MOLECULAR BIOLOGY 503 (1975).

environment after they have been "coated" with sugar molecules. Early work in this field concentrated on the use of bacteria for production of such proteins because the lack of a nuclear wall in procaryote cells such as bacteria was expected to make genetic engineering easier. However, it soon became clear that for certain purposes—for example, the coating of the protein with appropriate sugars—to minimize the differences from human equivalent, cells of higher organisms (eucaryotes such as yeasts, plants, and animals) were needed.

In 1985, two major events occurred: (1) the introduction of gene machines; and (2) the introduction of polymerase chain reaction technology. The first of these are computer-controlled apparatus that enable chemical synthesis of long chains of DNA. The second is a technique for enzymatic reproduction of pieces of DNA to produce a large number of copies of it. The introduction of these two techniques has gone a long way towards demythologizing biotechnology in the eyes of patent examiners and has resulted in an increasing tendency toward tougher examination worldwide.

The second major strand of biotech practice, relates to antibodies. Here the great step forward was in 1975 when Kohler and Milstein—also like Watson and Crick, working in Cambridge —discovered that by fusing certain types of cells together to produce something known as a hybridoma, they could cause the resulting fused cell to produce a monoclonal antibody, that is, an antibody specific to particular function. By 1980, human monoclonal antibodies were being produced; by 1985, recombinant antibody-enzyme molecules were being produced; and, in 1989, production of antibodies in plants was achieved for the first time.

II. INTERNATIONAL AGREEMENTS

A. UPOV Treaty and the Strasbourg Convention

The first attempt at international harmonization of intellectual property law relating to biotechnology occurred in the field of plants. In 1961, after several years of discussion as to whether protection for plants could fit comfortably into the patent system, a separate treaty for the protection of plants was adopted: the

International Convention for the Protection of New Varieties of Plants ("UPOV Treaty" or "UPOV Convention" or "Treaty").[5] Major features of the UPOV Treaty were that it would provide protection for plants and seeds as long as the plant constituted a new, stable, and homogeneous variety. Although this protection could be through the patent system, under the UPOV Treaty, dual protection by patent and plant variety rights for the same botanical genus or species was prohibited. In a 1991 revision of the Treaty, the prohibition on dual protection was abolished. The special nature of "living" material was recognized in the Treaty by requiring that the rightsholder must remain in a position to produce propagating material throughout the entire period of protection.

In 1963, the Council of Europe[6] created the Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions ("Strasbourg Convention").[7] The Strasbourg Convention never has had any real independent existence of its own—it was only ratified by sufficient number of countries to come into effect in 1980, after the European Patent Convention[8] had come into effect. Its definition of "patentable subject matter" was adopted by the drafters of the European Patent Convention and thus provides the European definition and has proved to be a model in many other countries throughout the world.

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5. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, *as revised*, Geneva, Oct. 23, 1978, 33 U.S.T. 2703 [hereinafter UPOV Treaty]. The treaty is commonly known as the UPOV Treaty from its initials in French—Convention Internationale pour la Protection des Obtentions Vegetales. The UPOV Treaty was recently amended and opened for signature in Geneva on March 19, 1991, ("Amended UPOV Treaty") and is awaiting ratification by five states, of which at least three must have been a party to a prior version of the treaty. Amended UPOV Treaty, Mar. 19, 1991, Geneva, *reprinted in* 3 Eur. Pat. Handbook (MB), ch. 90.

6. The Council of Europe was established in 1949 to promote co-operation between European countries in several areas including social and scientific ones. It is a body best known for its work on the European Convention on Human Rights. Its membership is different from and it has no formal relationship with the European Community.

7. Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions, Strasbourg, Nov. 27, 1963, Eur. T.S. No. 47, *reprinted in* 3 Eur. Pat. Handbook (MB) ch. 92 [hereinafter Strasbourg Convention].

8. Convention on the Grant of European Patents, *opened for signature* Oct. 5, 1973, 13 I.L.M. 270 [hereinafter European Patent Convention].

The Strasbourg Convention definition required that an invention must be new, susceptible of industrial application, and involve an inventive step.[9] It specifically excluded from patent protection plant and animal varieties and essentially biological processes for the production of plants and animals.[10] During the 1950s, Germany had, in fact, granted at least one patent relating to a plant variety. Thus, it was not a foregone conclusion that the Strasbourg Convention would exclude protection for plant and animal varieties. However, since the member states of the Council of Europe were essentially those who had been the leading participants in the work leading up to the adoption of the UPOV Convention and since agricultural interests in Europe were at the time—and in a significant sense still are—opposed to patent protection for plant varieties, it is not surprising that the prohibition was adopted. It is of interest to note, however, that the prohibition did not extend to all living things; there was a specific exception for microorganisms—the "industrial" nature of which had long been recognized in the brewing industry.

Before progressing further in considering the development of the patent law in this field, it is worthwhile to briefly consider the essential differences between patent rights and plant variety rights. Seed registries had started as a private German scheme in 1905, and after the Second World War they were created as national bodies by a number of European countries. Typically, these were under the auspices of the Ministry of Agriculture. Thus, to a significant extent, that were dealt with by a different set of bureaucrats from those who were involved with intellectual property.

Such vesting of interests was a significant factor in the development of rights in this area. Traditional plant variety rights arose as a result of cross-breeding of varieties—a normal biological means to produce a new variety having particular characteristics. These factors led to the adoption of a definition of what was protectable by a plant variety right in terms rather different from traditional patent protection. Thus, according to the UPOV Treaty, a plant

9. Strasbourg Convention, *supra* note 7, art. 1.
10. *Id.* art. 2.

variety right extends to a new variety of plant which is "clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common general knowledge" at the time of seeking protection.[11] Such characteristics must, however, be susceptible to precise description and recognition. Furthermore, the variety must be sufficiently homogeneous and stable in its essential characteristics after repeated sexual reproduction or vegetative propagation.[12] On the other hand, no requirement exists for describing how the variety is obtained, merely the giving of a "variety denomination" to act as the generic name for the variety.[13] However, the holder of the right had to maintain itself in a position to supply propagating material of the variety at least throughout the lifetime of the protected right, which is fifteen years for plants and eighteen years for certain "slow-growing" plants such as vines and trees.[14] Moreover, as long as repeated use of the variety is not required to produce it, the original rightsholder has no rights in respect of any new variety that someone else may create using the protected variety as an initial source.[15] Thus, a plant variety right essentially protects the originator of a variety from competition by others who have obtained a plant from him who then go on to grow further "copies" of the plant in question by normal reproductive techniques, and only accidentally protects the originator of the variety from competition by others who reproduce the hybrid in question themselves, totally, independently from the work of the plant variety rightsholder. To this extent, the protection afforded by a plant variety right is perhaps more akin to that of copyright than to traditional patent protection.

The UPOV Treaty was amended most recently in 1991.[16] The amendments will come into effect when ratified by five countries, at least three of which must already be members of the Strasbourg Convention. There are five principle changes:

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11. *See* UPOV Treaty, *supra* note 5, art. 6(1)(a), 33 U.S.T at 2711.
12. *See id.* art. 6(1)(c)-(d), 33 U.S.T at 2712.
13. *See id.* art. 13, 33 U.S.T at 2715.
14. *See id.* art. 8, 33 U.S.T at 2712.
15. *See id.* art. 5(1), 33 U.S.T at 2710.
16. *See* Amended UPOV Treaty, *supra* note 5.

One, after a transitional period, member states will have to provide protection for all genera and species of plants.[17] Under previous versions of the UPOV Convention, countries could opt to protect only a limited number of species.

Two, the definition of what is meant by a "variety" has been revised and narrowed so that it now reads:

> '[V]ariety' means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be
>
> —defined by the expression of the characteristics resulting from a given genotype or combination of genotypes;
>
> —distinguished from any other plant grouping by the expression of at least one of the said characteristics and
>
> —considered as a unit with regard to its suitability for being propagated unchanged.[18]

The rightsholder will, however, now be entitled to a royalty or the products of the harvest obtained from the growth of plants deriving from propagating material to which he has rights unless the rightsholder did in fact have "a reasonable opportunity to exercise his right in relation to . . . the propagating material" itself.[19]

Three, it will now be possible for countries to provide for dual patent and plant variety protection.[20]

Four, the duration of protection for most plants is extended to twenty years, and in the case of vines and trees to twenty-five years.[21]

Finally, the definition of infringement of the proprietor's rights has been amended with respect to propagating material taken from the protected variety so as to cover not only production, offering for sale and marketing, but also the act of reproduction.[22] This

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17. *Id.* art. 5.
18. *Id.* art. 1(vi).
19. *Id.* art. 14(2).
20. *Id.* art. 32.
21. *Id.* art. 19(2).
22. *Id.* art. 14(1).

then raises questions as to the position of farmers who grow crops largely for production of their seeds, such as those who grow grain. The revised version of the Treaty gives member states the right to address the problem by restricting breeder's rights "in order to permit farmers to use for propagating purposes, on their own holding, the product of the harvest which they have obtained by planting on their own holdings."[23]

B. *The European Patent Convention*

Returning now to European development of the law in this area, as noted above, the definition of patentable inventions set out in the Strasbourg Convention was in large measure adopted by the European Patent Convention[24] which was signed in 1973 and came into effect in 1978 with the opening of the European Patent Office ("EPO") in Munich.

Article 53(b) of the European Patent Convention provides that patents shall not be granted for "plant or animal varieties or essentially biological process for the production of plants or animals." The Article goes on to state that "[t]his provision does not apply to microbiological processes or the products thereof."[25]

The European Patent Convention has two other patentability bars that relate to biotech. First, Article 53(a) bars the grant of patents for inventions whose publication or exploitation would be contrary to *ordre public* (public policy) or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.[26] Second, Article 52 effectively bars the grant of patents for methods of treatments of humans or animals by surgery or therapy and also of diagnostic methods practiced on a human or animal body.[27]

Article 53(b) provides an interesting sidelight on the significance of the interpretation given to the European Patent Convention

23. *Id.* art. 15(2).
24. European Patent Convention, *supra* note 8.
25. *Id.* art. 53(b), 13 I.L.M. at 286.
26. *Id.* art. 53(a), 13 I.L.M. at 286.
27. *Id.* art. 52, 13 I.L.M. at 285.

by the EPO. The Austrian Patent Office Board of Appeals, in a case that was based on Austrian national law, opined that the wording in the European Patent Convention barring grants of patents for "plant or animal varieties" extended to microorganisms, notwithstanding the fact that the Convention specifically states that "microbiological process or the products thereof" are not covered by the bar. It took the view that it was impossible to draw a dividing line between plants and animals on the one hand and microorganisms on the other.[28]

This view was different from that taken by the European Patent Office in its original guidelines ("EPO Guidelines"), which stated that "microorganisms themselves . . . when produced by a microbiological process" were patentable.[29] In 1981, the EPO Guidelines were expanded to make it clear that propagation of a microorganism was a microbiological process and so the product of such a propagation (i.e., the microorganism itself) was in principle capable of protection. The only exclusion on protection for microorganisms was when what was sought to be claimed was a discovery rather than an invention, i.e., the microorganism is itself found in nature and is being claimed in such a way that the natural material falls within the scope of the claim.[30]

Following a modest international outcry at the decision of the Austrian Patent Office, the Austrian Parliament promptly passed legislation bringing Austrian practice into line with that of the EPO.[31]

1. Patent Protection of Higher Life Forms

On the question of protection for higher life forms, the Examining Division of the EPO ("Examining Division") at first rejected claims to the so-called "Harvard mouse." This was a mouse particularly susceptible to cancer and thus a valuable research tool, and

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28. Judgment of Mar. 7, 1985, Austrian Patent Board of Appeals, Case B52/84, *translated in* [1986] O.J.E.P.O. 4/109.

29. EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, ch. IV, pt. C, para. 3.5-3.6 (1992) [hereinafter EPO GUIDELINES].

30. *Id.* ch. IV, pt. C, para. 3.5.

31. Law of June 17, 1986, Bundesgesetzblatt für die Republick Österreich (Aus.), *translated in* [1987] O.J.E.P.O. 133.

the subject matter of the first animal patent granted in the United States.[32] The ground was that claim was to a new animal variety.[33] In view of the way the case was decided and the loose way in which the case has been discussed, it is important to note that the main claim was not in fact directed to a mouse but covered all non-human trans-genetic mammals whose germ cells and somatic cells contained a specified gene.[34] The Examining Division concluded that the Strasbourg Convention—from which the EPO's prohibition on patenting of animal variety derived—had no contemplation of granting patents on any type of animal, and consequently the relevant provisions could not be interpreted to provide for such protection now. However, it determined that no issues of public policy or morality arose from the application.[35]

On appeal the EPO Board of Technical Appeals ("Appeals Board") decided that the Examining Division had not properly considered the meaning of the term "animal variety" in the prohibition.[36] This could not simply be equated with "animals" since the linguistics of the various equally authentic tests in three languages did not permit such an interpretation. In particular, the word used in the German text of the European Patent Convention—*tierarten*—clearly indicated that a specialized meaning had to be given to the term. Thus, on remand further consideration of what was meant was necessary. In addition, the Examining Division was directed to reconsider the evidence on the question of whether the grant of patents for animals might be contrary to *ordre public* or morality.[37]

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32. *See* U.S. Patent No. 4,736,866, 1089 OFFICIAL GAZ. PAT. OFF. 703 (Apr. 12, 1988).

33. Onco-mouse/Harvard, Decision of 14 July 1989, [1989] O.J.E.P.O. 11/451 (Examining Div.), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 106, E-17, E-19.

34. *Id.* at E-18.

35. *Id.* at E-30 to -33.

36. Onco-mouse/Harvard, Case T 19/90, [1990] O.J.E.P.O. 12/476 (Tech. Bd. App. 1990), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 19/90-1.

37. *Id.* at T 19/90-12. An interesting jurisprudential issue on the question of interpretation of the European Patent Convention was touched upon in the Appeals Board's decision when it expressed the view that "the purpose of a law (*i.e., the ratio legis*) is not merely a matter of the actual intention of the draftsmen [legislators] at the time when the law was adopted, but also of their presumed intention in light of changes in circumstances which have taken place subsequently." *Id.* at T 19/90-9.

After such reconsideration, the Examining Division issued a decision to grant a patent for the invention.[38] The Examiners noted that the claims were not directed to any particular sub-species of animal (in fact the claims covered all genetically modified non-human animals into which the appropriate genes had been introduced) and so concluded that what was claimed could not be considered to be an animal "variety."[39]

On the question of the *ordre public* or morality, the Examining Division believed that a balancing test was appropriate in every case depending on the invention in question, with three factors needing to be considered in the present case: (1) the interest of mankind in providing remedies for dangerous diseases; (2) protection against uncontrolled dissemination of unwanted genes; and (3) prevention of cruelty to animals.[40] Since, in the instant case, the invention opened the way to needing fewer animals for experimentation and the invention could be practiced in a way such as to avoid widespread dissemination of genes, the Examining Division concluded that the advantage of providing a tool for use in the fight against cancer outweighed the possible negative factors and thus the invention was patentable.[41]

The "Harvard mouse" decision has been much criticized in Europe and the patent is subject to multiple oppositions on the ground that the grant was, in fact, contrary to the EPO's decision and in breach of the European Patent Convention's prohibition of the grant of patents on subjects that were contrary to *ordre public* or morality. The grant of the patent also attracted the passage of a critical non-binding resolution by the European Parliament ("Parliament").

Since the grant of the "Harvard mouse" patent, the EPO has reported that it has rejected a patent application[42] on morality

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38. Onco-mouse/Harvard, Decision of 3 April 1992, [1992] O.J.E.P.O. 568 (Examining Div.), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 106, E-35, E-36 (grant of European Patent No. 0 169 672).

39. *Id.* at E-37.

40. *Id.* at E-38.

41. *Id.* at E-28.

42. Parliament Calls for EPO's Withdrawal of Onco Mouse Patent, 7 World Intell.

grounds, although no decision yet seems to have been published. In this application, the modified mouse was particularly adapted to use in the testing of cosmetics. It seems that the benefit to society was not perceived as being sufficient to overcome possible cruelty to the animal.

For the time being, the EPO seems to be slowing down action on further animal cases until a decision is reached on the oppositions in the "Harvard mouse" case. The issue remains a hot one and is at the core of the delays that have occurred in adopting the European Community's Proposed Directive on biotechnology inventions ("Proposed Directive").[43]

In *Hybrid Plants/Lubrizol*, a prior case before the Appeals Board, no such issue of morality seemed to arise on the question of the patentability of claims to a process for rapidly developing hybrids and commercially producing hybrid seeds, to hybrid seeds themselves, and to phenotypically uniform plants obtained from such seeds.[44] The relevant questions were simply whether these were claims to "plant varieties" or "an essentially biological process for the production of plants."[45] Although the steps recited in the process claim were only crossing and cloning steps, it was held that due to the special sequence in which these steps were to be taken, the process ceased to be "essentially biological" and so was patentable.

In *Hybrid Plants/Lubrizol*, the Appeals Board observed:

> [I]nstead of the traditional approach of creating a single new crossing first and trying to propagate the individual result afterwards, the specific arrangement of the steps as presented . . . provide a process with a reversed sequence: it multiples the parent plants by cloning and then crosses the cloned, and thus derived, parent lines on a large scale

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Prop. Rep. (BNA) 91 (1993).

43. Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, O.J. C 10/3 (1989) [hereinafter Proposed Directive].

44. *See* Hybrid Plants/Lubrizol, Case T-320/87, [1990] O.J.E.P.O. 3/71 (Tech. Bd. App. 1988), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 320/87-1.

45. *Id.* at T 320/87-6.

> repeatedly to provide the desired resulting hybrid population. This arrangement of steps is decisive for the invention and permits the desired control of the special result in spite of the fact that at least one of the parents is heterozygous. The facts of the present case under appeal clearly indicate that the claimed processes for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product in the present case show important technological character."[46]

As far as the plant per se claims were concerned, the Appeals Board first had to determine what was meant by the term "variety." It found that is had no generally accepted meaning but noted that the restriction in the definition of patentable subject matter had "been adopted in part to prevent overlap between the protection provided by patents and the provided by plant breeder's rights laws."[47] The Appeals Board went on to observe that hybrids such as those claimed were not protectable by plant variety rights so that no possibility of double protection arose.[48] It decided that a "variety" meant a "multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation on every propagation cycle."[49] The Appeals Board concluded that because plants obtained by the present invention were derived from a heterozygous patent they lacked sufficient stability to be a variety and thus did not fall within the prohibition on protection of "plant varieties."[50]

Although the question of morality had not been considered during the prosecution of the *Hybrid Plants/Lubrizol* application, a number of groups have filed oppositions to the patent alleging that the grant was contrary to the morality provision of the European Patent Convention. The oppositions are still pending.

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46. *Id.*
47. *Id.*
48. *Id.* at T 320/87-7.
49. *Id.*
50. *Id.*

2. Patent Protection for Lower Life Forms

So far as protection for lower forms of life is concerned, the EPO Guidelines for examination make a number of points on the question of patentability of microbiological inventions. Since these guidelines are for the most part the result of hard-crafted compromises between various national positions, they should perhaps be accorded more weight than might otherwise be the case.

The EPO Guidelines state that a "microorganism can be protected per se if it is a product obtained by a microbiological process. The term microorganism covers plasmids and viruses also."[51] Therefore, it is clear that per se protection can be obtained for products of genetic engineering. Mutation techniques probably also count as "microbiological processes" for the purpose of the provision, although in this case there may be problems in connection with reproductibility of the invention. In dealing with the question of sufficiency, the EPO Guidelines make an oblique reference to this problem indicating that there may be a "fundamental insufficiency" in a specification if "the successful performance of the invention is dependent on chance."[52] They cite microbiological processes involving mutations as an example of such a category.

Difficulty also arises in the case of microorganisms which occur naturally and are isolated from their natural environment. "Discoveries" are unpatentable under Article 52(2)(a) of the European Patent Convention. A similar provision is found in the law of those countries that adopted the "European" definition of what is patentable. Unfortunately, the EPO Guidelines avoid the specific issue of whether isolation of a naturally occurring microorganism is merely a discovery rather than an invention. The EPO Guidelines do, however, say with respect to substances in general that "if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is 'new' in the absolute sense of having no previously recognized existence then the substance per se may be patentable. An example of such a case is that of a new substance which is discovered as

51. EPO GUIDELINES, *supra* note 29, ch. IV, pt. C, para. 3.5.
52. *Id.* ch. IV, pt. C, para. 3.5.

being produced by a microorganism."[53]

In practice, the Examining Division seems to be allowing claims to isolates of naturally occurring microorganisms if there is anything inventive in the isolation process or if the phenotype, as obtained by isolation, differs in some way from that as found in nature. The same principles apply for example to new plasmids obtained from naturally occurring microorganisms. So far, however, there has been no Appeals Board decision on these issues.

The position taken on the question of the need for reproductibility adopted by the European Patent Office is that the EPO accepts that the deposit of an organism in a culture collection from which it can be obtained meets the requirements for reproductibility of the invention.[54] The EPO's view seems to be followed in most countries that have harmonized their law with the European Patent Convention.

A somewhat related issue is the question of how to define certain biotech products. This is perhaps most acute in the field of long-chain DNA or RNA fragments where it may be extremely tedious to determine the exact sequence of nucleotides present. The EPO will often permit restriction maps to be used for this purpose. Such maps are maps of a piece of DNA indicating the locations at which certain enzymes will cut the chain. Frequently these are coupled with statements that other specified enzymes have no effect on the chain at all. Thus, such maps provide a type of "fingerprint" for the fragment in some ways analogous to the fingerprint provided by an infra-red spectrum in traditional organic chemistry.

An interesting issue on the degree of specificity required for such maps arose in the case of *Ajinomoto/Composite Plasmid*.[55] In this case, the Opposition Division of the EPO ("Opposition Division") had rejected an opposition wherein it had been alleged that a claimed plasmid was anticipated on the basis of a prior disclosure on the ground that the opponents had not shown the DNA sequence

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53. *Id.* ch. IV, pt. C, para. 2.1.
54. *Id.* ch. IV, pt. C, para. 3.6.
55. Case T-109/92, [1992] EUR. PAT. OFF. REP. 163.

of the claimed plasmid to be identical with that of the prior reference. The Appeals Board reversed this decision and remanded the case to the Opposition Division for further consideration. The Board felt that a conclusion of identity between the two plasmids could be drawn on the basis of the facts that the restriction maps were very similar as was the list of enzymes that did not cut the DNA at all. However, it felt that, in view of the incorrect approach taken by the Opposition Division, the patentees should have a further opportunity to show that there was in fact a difference between the plasmids.

Similar problems exist in connection with definitions of monoclonal antibodies. They are illustrated by two decisions relating to different patents of Ortho Pharmaceutical Corporation, both of which were revoked by the Appeals Board after oppositions had been filed.[56] Both patents claimed mouse monoclonal antibodies defined in functional terms as reacting with one type of cell but not reacting with other types of cells and claimed a hybridoma said to produce such antibodies. This hybridoma was defined solely by a culture collection deposit number. The Board noted that, while functional definitions were often appropriate to define inventions that could not readily be defined in any other way, this should not mean that an undue burden could be put on one seeking to know the ambit of the claims. The Board's view was that "[i]f the description of the invention leaves the skilled person in doubt, so that he cannot carry out the invention by applying his skill and a reasonable amount of experiment, then the disclosure is not sufficient."[57]

In these cases it was found that to determine which attributes would meet the criteria of the claims "means a huge amount of effort and, above all, it is not certain that (a suitable) hybridoma can be selected at all."[58] The patentees had argued that their deposit and description of a particular hybridoma meant that they had

56. Monoclonal Antibody/Ortho, Case T-418/89, [1993] O.J.E.P.O. 20 and Case T-495/89, [1992] EUR. PAT. OFF. REP. 48.

57. Monoclonal Antibody/Ortho, Case T-418/89, [1993] O.J.E.P.O. 20.

58. *Id.* at 27.

given a description of how to produce one embodiment of the invention and this was all that was required. Unfortunately for the patentee, it was shown by the opponents that the hybridoma in question in fact produced antibodies that at least to some extent reacted with cells with which the claims required that they did not act. Thus, the argument failed on factual grounds. The Board was not required to decide how broad a claim was appropriate based on a single culture collection deposit.

The fact that the deposited hybridoma did not produce antibodies as described in the specifications further meant that the deposited hybridomes could not be regarded as being examples of "the invention." As such, claims to the hybridomas themselves also had to be revoked.[59]

C. *National Laws*

1. Higher Life Forms

Probably the first country to try to come to grips legislatively with the problems of patentability of plants or animals was, somewhat surprisingly, Hungary. The Hungarian Patent Law of 1969[60] contained a number of specific provisions on these topics. Thus, Article 6(2) provided that: "Plant varieties and animal breeds and the process for obtaining them shall be patentable if the variety or breed is new, homogenous, and relatively stable."

The Hungarian law also dealt with the vexing question of exactly what type of monopoly should be granted for such plants or animals given their self-replicating abilities that do not exist for other types of inventions. The law provided that the patentee's exclusive rights were confined to "the sexual or asexual propagating material" of the plant variety or animal breed. However, the law did also provide specifically that export of the propagating material to other countries where similar protection did not exist was subject to the grant of permission by the patentee.[61]

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59. *Id.* at 32.

60. Patent Law of 1969, art. 6(2) (Hung.).

61. *Id.* arts. 68, 71. The Hungarian law was amended in 1984 to comply with the UPOV Treaty. *See* Patents Laws of 1969-1983 (Hung.). As amended, all provisions relating to patents for plants and animals are grouped in Part III of the law. The new

Only a little later—and no less bold—was Mongolia, whose patent law specifically states that "new and improved breeds of farm animals and poultry and new varieties of agricultural plants and other flora" are patentable, even if they were created "by selection."[62]

Other countries have been slower to deal with the issues, possibly because of the morality issue that has come to the fore in the EPO. Many countries have specific provisions barring the grant of patents for inventions whose publication or exploitation would be contrary to morality. These include: Austria,[63] Bahamas,[64] Belgium,[65] Brazil,[66] Chile,[67] the Czech Republic,[68] Denmark,[69] Finland,[70] France,[71] Germany,[72] Honduras,[73] Hungary,[74] Italy,[75] Japan,[76]

Article 67 reads: "A plant variety is patentable if it is distinguishable, novel, homogeneous and stable and if it has been given a variety denomination apt for registration." As amended, the rights granted by such a patent are also the same as those set out in UPOV Treaty.

62. Patent Law of 1970, art. 21 (Mong.).

63. *See* Patent Law of 1990, § 2(1) (Aus.). Section 2(2) bars the grant of patents on plant and animal varieties.

64. *See* Patent Law of 1965, § 9 (Bah.). Section 9 bars the grant of patents for plants or animal varieties.

65. *See* Patent Law of 1984, § 4(2) (Belg.). Section 4(1) bars the grant of patents for animal varieties and some plant varieties.

66. *See* Patent Law of 1971, § 9(a) (Braz.). Section 9(a) bars the grant of patents on inventions "the purposes of which are contrary to . . . morality . . . to religious cults or to sentiments that are worthy of respect and veneration." There are no specific provisions relating to plants or animals.

67. *See* Patent Law of 1991, § 38 (Chile). Section 37 bars the grant of patents to plant or animal varieties.

68. *See* Patent Law of 1990, § 4(a) (Czech.). Section 4(a) bars the grant of patents for inventions that are contrary to the "principles of humanity or morality." Section 4(c) bars the grant of patents for plant or animal varieties.

69. *See* Patent Laws of 1967-1989, § 1(4) (Den.). Section 1(4) bars the grant of patents for plant or animal varieties.

70. *See* Patent Laws of 1967-1985, § 1(4) (Fin.). Section 1(4) bars the grant of patents for plant or animal varieties.

71. *See* Intellectual Property Code of July 1, 1992 (Fr.). L 611-17b bars the grant of patents for some plant varieties. L 611-17c bars the grant of patents for animal varieties.

72. *See* Patent Law of 1980, § 2(1) (F.R.G.). Section 2(2) bars the grant of patents for animal and some plant varieties.

73. *See* Patent Laws of 1919-1976, art. 6 III (Hond.). There are no specific provi-

Korea,[77] Norway,[78] Romania,[79] Russia,[80] Saudi Arabia,[81] Spain,[82] Sweden,[83] Switzerland,[84] and the United Kingdom.[85] Furthermore, Decision 313 of the Andean Pact, which provides the basis for the patent laws of Colombia, Ecuador, Peru and Venezuela contains a similar provision.[86] In Japan, the definition of a patentable invention is that it involves use "of a law of nature in the highly advanced creation of technical ideas."[87]

In 1975, the Japanese Patent Office published Standards for the

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sions relating to plants or animals.

74. *See* Patent Laws of 1969-1983, § 6(3)(b) (Hung.).

75. *See* Patent Laws of 1939-1987, § 13 (Italy). Section 13 bars the grant of patents for animal varieties.

76. *See* Patent Laws 1959-1987, § 32(3) (Japan). There are no specific provisions relating to plants or animals.

77. *See* Patent Law of 1990, § 32 (Korea). Section 31 specifically provides for patent protection for a "new and distinct variety of a plant" which reproduces itself asexually. There are no specific provisions on other types of plants or for animals.

78. *See* Patent Laws of 1967-1980, § 1(4) (Nor.). Section 1(4) bars the grant of patents for plant or animal varieties.

79. *See* Patent Law of 1991, § 12 (Rom.). It should be noted, however, that Section 11 specifically provides protection for stable plants and animal breeds, thereby preempting any argument on the application of moral principles to these two issues.

80. *See* Patent Law of 1992, art. 5(3) (Rus.). Article 5 bars the grant of patents for inventions that are "contrary to the public interest or to the principles of humanity and morality." This section also bars the grant of patents for "agricultural crops and breeds of animals."

81. *See* Patent Law of 1988, § 8 (Saudi Arabia). Section 8 bars the grant of patents on inventions that are contrary to the Shari'a.

82. *See* Patent Law of 1986, § 5(1) (Spain). Section 5(1) bars the grant of patents on animal varieties and some plant varieties.

83. *See* Patent Laws of 1967-1983, § 1(4) (Swed.). Section 1(4) bars the grant of patents on plant and animal varieties.

84. *See* Patent Law of 1976, § 2 (Switz.). Section 1(a) bars the grant of patents on plant varieties and animal breeds.

85. *See* Patent Act of 1977, § 1(3). The British statute is a little different from most of the others in that Section 1(3) bars the grant of patents only if publication or exploitation of the invention "would be generally expected to encourage offensive, immoral, or anti-social behavior." The same section bars the grant of patents for "any variety of animal or plant."

86. Industrial Property Law, Andean Pact Cartagena Agreement, Decision 313, art. 7(a), *reprinted in* OFFICIAL GAZ. EXTRAORDINARY 4451 (Aug. 5, 1992). The position in Bolivia, which is also a pact member, is less clear.

87. Law No. 121 of 1959, art. 2(1) (Japan).

Examination of New Plant Varieties ("Examination Standards").[88] According to the Examination Standards, such inventions include inventions of bred varieties per se and inventions of processes of producing the plants of such bred varieties. Such plants, however, had to be able to maintain a sufficient degree of homogeneity and perpetuity to enable this to be applicable for an industrial purpose. To be patentable, under the Examination Standards the new plants had to be morphologically or physiologically different from the prior plants as a result of differences in their genes.

One or two patents for plants as such seem to have been issued with these guidelines. However, Japan also has an Agricultural Seeds and Seedlings Law[89] dating back to 1947 which was revised in 1982 to become more similar to the U.S. Plant Variety Protection Act of 1970.[90] Under the Japanese law, protection may be granted to those who bred stable new plant varieties. The administration of this is under the auspices of the Japanese Ministry of Agriculture and Fisheries.

Unfortunately, a jurisdictional dispute developed between the Japanese Patent Office and the Japanese Ministry of Agriculture and Fisheries. The resolution of the dispute resulted in a de facto situation in which the Patent Office refrains from granting patents for plants per se and confines itself to the granting of patents on processes for developing new plants. Under Japanese law, the direct product of a process claim is an infringement of that claim. However, uncertainty exists as to whether natural reproduction of a plant that was itself produced by a patented process can be regarded as infringement of that process.

Since the basis of the demarcation lines drawn between the different Japanese agencies seems to have been based on the old UPOV Convention rule against double protection by patent and plant variety rights, and this distinction has been removed in the

88. Law No. 115 of October 2, 1947 (Japan).

89. Law No. 71 of 1982 (Japan).

90. Pub. L. No. 91-577, 84 Stat. 1542 (1970), *amended by* Pub. L. No. 96-574, § 1, 94 Stat. 3350 (1980) (codified as amended at 7 U.S.C. §§ 2321-2583 (1988 & Supp. IV 1992)).

most recent revision to the UPOV Convention, it is to be hoped that the question of "who does what" may be revisited in the near future and patent protection for plants more fully established. So far as animal patents are concerned, the Japanese Patent Office still apparently takes the view that the grant of such patents would be contrary to the "morality" provisions of the Patent Law. It may be hoped that a liberal construction of a similar provision in Europe may lead to reconsideration of this position as a result of talks on harmonization between the "big three" patent offices.

Problems as to the patentability of hybrid plants arose in Canada in the case of *Pioneer Hi-Bred Ltd. v. Commissioner*,[91] which was heard by the Canadian Supreme Court in 1989. Patentability was actually rejected on the grounds that the application had not contained sufficient disclosure as to the nature of the invention. Questions of sufficiency will be considered later in this paper. Of interest to the present point, however, is the Supreme Court's comments as to whether there was in principle any objection to patentability of a new soybean variety. The case had originally been rejected by the Canadian Patent Office on the ground that plant varieties did not fall within the definition of "invention" contained in the Canadian Patent Act.[92] An invention was defined as "any new and useful art, process, machine, manufacture, or composition of matter or any new or useful improvement in any art, process, machine, manufacture, or composition of matter."[93] The statute also contains a provision rejecting patentability for "any mere scientific principle or abstract theorem."[94]

Unfortunately, the Canadian Supreme Court, having set the scene, ducked the issues. It noted that there are two distinct types of genetic engineering: (1) traditional crossing of plants leading to hybrids; and (2) manipulation of genes by "artificial intervention." The court noted that traditional breeding methods had not been regarded as patentable. The Court stated:

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91. 60 D.L.R.4th 223 (1989).
92. *Id.* at 225-26.
93. Patent Act, R.S.C., ch. P-4, § 2 (1985) (Can.).
94. *Id.* § 27(3).

> Hi-Bred is asking this court to reverse a position long defended in the case-law. To do this we would have, inter alia, to consider whether there is a conclusive difference as regards patentability between the first and second types of genetic engineering, or whether distinctions should be made based on the first type of engineering, in view of the nature of the intervention. The court would then have to rule on the patentability of such an invention for the first time. The record contains no scientific testimony dealing with the distinction resulting from use of one engineering method rather than another or the possibility of making distinctions based on one or other method.[95]

The court went on to note that this issue is a complex one and, since the case could be decided on the question of adequacy of disclosure, it did not reach any decision on the basis of the basic issue.[96]

Interestingly, in amending the relevant portions of their statutes, while harmonizing much of the rest of their law to the European Patent Convention and generally following the format used in other countries, Belgium,[97] France,[98] Germany,[99] and Spain[100] specifically provided for patent protection of microbiology inventions. They also provided protection for any plant varieties for which protection was not available under their individual plant protection laws. The Italian law contains no prohibitions on patents for plant varieties at all. However, the laws of most of the other member states of the European Patent Convention follow the Convention wording on this point.

In Mexico, vegetable "varieties" are patentable.[101] On the other hand, vegetable "species," animal "species," or their varieties, and, essentially, biological processes for the obtention or reproduction

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95. *Pioneer Hi-Bred*, 60 D.L.R.4th at 231 (1989).
96. *Id.* at 238.
97. *See* Patent Law of 1984, § 4(1) (Belg.).
98. *See* Patent Law of 1990, § 7(b) (Fr.).
99. *See* Patent Act of 1980, § 2 (F.R.G.).
100. *See* Patent Law of 1986, § 5(1)(b) (Spain).
101. Patent Law of 1991, art. 20 (Mex.).

of plants, animal species or their varieties are not patentable. Since these features were new in the 1991 law, it remains to be seen how the examiners and courts will treat the division between certain plant claims and other plant and animal claims. However, it seems experienced claims and the EPO in this area affected the drafting of the law and may also affect its interpretation.

Patents are granted for novel plants in Korea,[102] and there are theoretical grounds for believing that novel animals should be patentable also but no such patent seems to have been issued yet. In Australia and New Zealand, the law provides that a patent shall be granted for a "manner of new manufacture"[103]—a term that first appeared in the English Statute of Monopolies in 1624.[104] As the term has been interpreted by the court, it seems that in principle both plants and animals may be patented, although as yet there do not seem to be any specific decisions on point.[105] On the other hand, the new Russian law maintains a bar on the patentability of "agricultural crops and breeds of animals."[106] Nor, contrary to expectations, does the latest amendment of the Chinese law permit patents of plants as such.[107]

2. Patentability of Other Biotech Products

Patentability of lower life forms has been less difficult. Most countries, in facing the question of what is to be patentable in this field, have applied the law as it has developed in the chemical arts analogously to biotechnology. The application of these principles has, however, not been entirely straightforward since there has been a tendency not to grant patents for living matter. The first supreme

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102. *See* Patent Act of 1961-1990, art. 31 (Korea).

103. Patent Act of 1990, sched. 1 (Austl.); Patent Act of 1953, § 2 (N.Z.).

104. An Act Concerning Monopolies and Dispensations with Penal Laws and the Forfeitures Thereof, Statute of Monopolies of 1623, 21 Jac. ch. 3, (623-24) (Eng.).

105. By way of caution, however, it should be noted that although the statute makes no reference to questions of morality, it does provide that patents shall not be granted if such grant would be "mischievous to the state" or "generally inconvenient"; in New Zealand the courts have reused to grant patents for medical treatments based in part on these provisions.

106. Patent Law of Russian Federation of Oct. 7, 1992, art. 5(3).

107. Patent Law of 1985, art. 25 (P.R.C.). However, "processes for producing" animal and plant varieties are patentable.

court to be forced to grasp this nettle was that of the Federal Republic of Germany which, in 1975, was confronted with claims relating to baker's yeast.[108] In its official headnote to its decision, the Court stated: "Product protection for a new microorganism is allowable if the invention shows a reproducible way to produce the new microorganism."[109]

The Court noted that "organisms existing in nature should remain available to everybody" and that protection is "also excluded for those microorganisms that are produced by a non-reproducible, induced mutation or a non-reproducible hybridization."[110] However, it has long been established in West German law that patents can be granted for inventions concerning hitherto unknown forms or isolations of natural substances. In 1977, in the *Antanamide* case,[111] the Court went further and upheld a per se claim to a cyclic decapeptide, antanamide, that had been extracted from amanite fungus on the ground that this product was new, since no one had suspected its prior existence so that it had never previously been available to the public. There seems to be no reason why this principle should not apply to an isolate of previously unknown microorganisms, even though it pre-existed in nature. In 1980, in *In re Microlife Technics Inc.*,[112] the Court held that mere deposit of a microorganism with a culture collection without disclosure of a repeatable method for its manufacture does not justify the granting of patent protection for the microorganism per se since disclosure of a means of repeating the invention was an essential consideration for a patent. In the *Antanamide* case, the reproducibility requirement had been met by describing a synthesis of the new compound. This expedient may not be readily available for new microorganisms. However, this decision was overruled by the

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108. Judgment of Mar. 11, 1975, (Baekerhefe/Baker's Yeast), Bundesgerichtshof (BGH) (F.R.G.), *reprinted in* 6 I.I.C. 207 (1975).

109. *Id.*

110. *Id.*

111. Judgment of July 18, 1977, Bundespatentgericht (BPatG) (F.R.G.), *reprinted in* 10 I.I.C. 494 (1979).

112. Judgment of December 11, 1980, 12 Entscheindungen des Bundesgerichtshofes in Zivilsachen [BGHZ] 862 (F.R.G.), *translated in* 12 I.I.C. 862 (1981).

decision in the *Rabies Virus* case in 1987, where it was held that in the interests of European harmonization, the provision of the European Patent Convention relating to the case of deposit of microorganisms to meet the requirements of the law, having regard to sufficiency of disclosure, should apply in Germany also.[113]

The Japanese Patent Office issued specific guidelines on inventions relating to microorganisms in 1979.[114] Revised guidelines for applied microbiology, including appendices on microorganisms and genetic engineering were issued in 1984. The guidelines accept the patentability of microorganisms as such and provide that in the case of a microorganism that has been isolated from nature the claim "must include the phrase isolated in a substantially pure form." Furthermore, they require that the claim specify the nature of the novelty of the claimed organism, although this may be accomplished by reciting a difference in properties of the new microorganism, for example, a claim to "bacillus subtilis having no sporogenic ability." In cases where a naturally occurring microorganism is claimed that has been obtained by routine screening, however, it may be difficult to persuade the Japanese Patent office that an inventive step forward has been made so that the invention is nonobvious.

In Australia, the Patent Office held, in *In re Ranks Hovis McDougall*[115] that mere isolation by an unspecified method of something that occurs in nature is unpatentable. The decision did, however, acknowledge the patentability of a "new microorganism which has improved or altered useful properties" which is obtained "by some man-controlled microbiological process."[116]

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113. Judgment of Feb. 12, 1987, Bundesgerichtshof [BGH] (F.R.G.), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 121, 121/11, 121/16.

114. *See* JAPANESE PATENT OFFICE, GUIDELINES FOR EXAMINATION OF INVENTIONS OF MICROORGANISMS, ch. 1, para. 3 (1979) (Japan). The guidelines define microorganisms as yeasts, molds, mushrooms, bacteria, actinomycetes, algae, viruses, protozoa and the like and for convenience culture tissues of animals and plants.

115. In re Ranks Hovis McDougall Ltd., 46 A.O.J.P. 3915 (1976) (Austl.), *reprinted in* 8 I.I.C. 453 (1977).

116. *Id.*

In Canada, the Commissioner in *In re Abitibi*[117] allowed claims to a novel mixture of fungi—some of which were novel—which had been caused to become acclimatized to spent sulfite liquors. It commented, however, that "the organism claimed should not, of course, have existed previously in nature for in that event the 'inventor' did create it and the 'invention' is old."[118] These dicta are in line with an earlier Canadian Patent Office decision in *In re 086556*[119] to the effect that claims to a novel human liver cell line resulting from an unexpected chance mutation were unpatentable on the ground that the cell line was already in existence through fortuitous circumstances before the applicant did anything that could be considered inventive. Method of use claims based on the unexpected utility of the cell line were patentable. The Appeals Board decision, approved by the Commissioner in *Abitibi*, stated that the rationale of that decision also applied for "all microorganisms, yeasts, molds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa, in fact, all new life forms which are produced en masse as chemical compounds are prepared."[120]

Statutory changes in the laws in Korea,[121] Mexico,[122] and Russia[123] have also now permitted the grant of patents relating to microorganisms. Serious problems as to the patentability of microorganisms or indeed, any living organisms still exist, however, in a number of countries. For example, the Indian Patent Office has recently issued a circular stating that inventions relating to "living material"—defined as including even DNA strands themselves—were not patentable. Such reasoning exists—at least in case of product per se claims—in Taiwan where even claims to

117. 62 C.P.R.2d 81 (Bd. App. 1982).

118. *Id.* at 91.

119. 35 C.P.R. 2d 56 (Bd. App. 1975).

120. *See In re Abitibi*, 62 C.P.R.2d at 81.

121. Patent Law of 1961-1990, art. 4 (Korea).

122. Patent Law of 1991, art. 20 (Mex.). The Mexican statute contains no general provision relating to morality, possibly because of the need to emphasize the secular nature of the State. However, the statute seeks to fill in some of the blanks arising from this omission by specifically barring the grant of patents for genetic material and living matter comprising the human body.

123. Patent Law of 1992, art. 5(2) (R.S.F.S.R.).

recombinant vectors are currently refused.[124] Furthermore, several countries, most notoriously Argentina and Taiwan, require full sequence data for DNA fragments that are to be patented.

D. *Novelty and Inventive Step*

In addition to the questions of whether biotechnological inventions comply with the requirements for statutory subject matter for protection, such inventions must also meet the additional requirements of novelty and non-obviousness. Such issues have only been considered by a few courts outside the United States; most of these are in Europe. It is probably most convenient to start first with the European Patent Office's view.

The first case to come before the EPO Appeals Board was Biogen's patent application for alpha interferons.[125] The patent was opposed by nine different opponents. The main claim read as follows:

> A recombinant DNA molecule for use in cloning a DNA sequence in bacteria, yeasts or animals cells, said recombinant DNA molecule comprising a DNA sequence selected from:
>
> (a) the DNA inserts of
>
> Z-pBR322(Pst)/HclF-4c
>
> Z-pBR322(Pst)/HclF-2h
>
> Z-pBR322(Pst)/HclF-SN35
>
> Z-pBR322(Pst)/HclF-SN42 and
>
> Z-pKT287 (Pst)/HclF-2H-AH6
>
> said DNA inserts being exemplified, but not limited to, the DNA inserts of the recombinant DNA molecules carried by the microorganisms identified by accession numbers DSM 1699-1703, respectively,
>
> (b) DNA sequences which hybridize to any of the fore-

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124. Patent Law of 1944, § 4 (Taiwan). The law specifically bars the grant of patents for microorganisms.

125. Biogen/Recombinant DNA, Decision T-301/87, [1989] O.J.E.P.O. 11 (Tech. Bd. App. 1989), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 301/87-1.

> going DNA inserts and which code for a polypeptide of the IFN-α type, and
>
> (c) DNA sequences which are degenerate as result of the genetic code to the DNA sequences and inserts defined in (a) and (b) and which code for a polypeptide of the IFN-α type.[126]

Certain features of this claim are worth noting before proceeding further. First, the list of "clearly defined" DNA inserts, group (a), are defined in terms of plasmids from which they are available. Second, the group (b) DNA fragments are defined in a functional manner, specifying that they hybridize with—i.e., have a sequence of bases that is complementary to—the fragments mentioned in group (a) and which have a particular function, namely that will code for alpha interferon (polypeptides). Third, the group (c) is defined as being the functional equivalents of (a) and (b) but limited to those wherein certain specific nucleotides have been replaced by other nucleotides which are known, as a result of the degeneracy of the genetic code, to result in the same amino acid in the final protein. It has been previously noted that there are only twenty amino acids that are used in polypeptide production, but there are sixty-four possible combinations of three bases, so that certain different three base combinations code for the same amino acid. This is what is know as the "degeneracy of the genetic code."

The claims were attacked on three main grounds: (1) they were unclear in such references to "hybridization" and "degeneracy"; (2) they gave insufficient specification information to allow the invention to be repeated; and (3) they lacked novelty over the contents of certain "gene banks" that existed previously.

It was also argued that in any case the claim was defined too broadly having regard for the limited disclosure given as to how it should be carried out. This objection was dealt with very succinctly by the Board which pointed out that prior case law held that the sufficiency requirement was satisfied if at least one way was clear-

126. *Id.* at T 301/87-2.

ly indicated enabling a skilled person to carry out the invention.[127]

On the second issue noted above regarding insufficient information, the Board disposed of the issue very succinctly:

> There is no necessity to provide instructions in advance how each and every member of [a] class would have to be prepared . . . . [V]ariations in the construction within a class of genetic precursors, such as recombinant DNA molecules claimed by a combination of structural limitations and functional tests, are immaterial to the sufficiency of the disclosure, provided that the skilled person could reliably obtain some members of the class without necessarily knowing in advance which member would thereby be made available.[128]

In the techniques employed there was no guarantee that the same product could be obtained, even by carrying out identical steps. Nevertheless, if the steps taken would necessarily result in one member of the class being obtained, even if it was not the same as the member that was obtained on the previous operation, this would suffice. As the Board noted, it is the nature of processes starting from natural sources and aiming at genes coding for polypeptides that individual variations might inevitably occur. In the present case, by defining the products in terms of their hybridization ability and the type of polypeptide that was to be produced, sufficient definition had been imparted to insure that they knew what fell within the scope of the claim.

The final major ground of objection was that the claims lacked novelty. Of course, there previously existed a cloned library of large, random, embryonic human DNA fragments, the so-called Lawn Gene Bank which was available to the public. The DNA contained in this bank would apparently hybridize with the DNA inserts mentioned in the main claim, and code for an alpha interferon-type polypeptide. The patentees' arguments that their claims were novel notwithstanding the existence of this bank were basical-

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127. *Id.* at T 301/87-11.
128. *Id.* at T 301/87-1.

ly that the bank contained no index as to which DNA fragments had which properties. Thus, the Board concluded that the DNA sequences claimed the first claim had not therefore "been made available" to the public in any meaningful way.[129]

Furthermore, it appeared that the nature of the basis for the preparation of the Lawn's Gene Bank (human liver) would not have been a source for one looking for DNA likely to be useful in production of interferon. Additionally, appropriate probes for testing whether the DNA in the Lawn's Gene Bank would hybridize were not readily available. Thus it was held that the existence of the gene bank did not destroy the novelty of the claim. The Board responded:

> As a matter of general interest, it can be stated that even if some fragments of the collection were to have all the required properties, the availability of such material without undue burden had not been established. The fact that such phages are hidden in a random collection of 240,000 unidentified individual samples is not irrelevant to the issue.[130]

The Board did not agree with the opponent's submissions that the situation was the same as that where there was incidental reference to a prior disclosure in an unindexed book in a library. The Board commented:

> The interrogation of a library material, is at least for some members of the public, a direct mental procedure. The collection in the present case must be interrogated by physical inter-actions, and a consequent biochemical process in each case. Although any vial containing the relevant phage is a separate entity, it is impossible to get to the vial without working through tens of thousands of samples. The circumstances are such as if the material were under lock and where the key has to be first manufactured and applied.[131]

If anything, according to the Board:

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129. *Id.* at T 301/87-12.
130. *Id.* at T 301/87-13.
131. *Id.*

> the situation resembles that prevailing with natural substances . . . and is rather like the isolation of a component or bacterium from soil where the same exists in admixture with other useless materials. Thus, the idea that the gene bank itself would once for all anticipate an invention relating to a nucleotide sequence which may be contained therein somewhere, cannot be sustained.[132]

The question of clarity of claims also came up in the case of *Hoechst/Plasmid pSG2*.[133] In this case, the Appeals Board stated that in order for a claim to a plasmid to be properly characterized, it required details not only of its source microorganism and contour length, but also of its restriction map. In this case, the examining division had rejected claims directed to a plasmid found in a particular strain of streptomyces as being obvious since in its view one would expect to find plasmids in streptomyces. In addition, the applicants had not shown their plasmid to have any advantages—such as a shuttle vector—over another plasmid obtained from a different streptomyces strain. On appeal, the claim was allowed since the Appeal Board found that the presence of plasmids in streptomyces strains was rare and that to find one in a strain of a technically useful species of streptomyces provided a useful and inventive step forward in the art.

In the case of *Polypeptide Expression/Genentech*,[134] the Appeals Board considered the obviousness issues that arise in connection with recombinant DNA technology and also the question of how broadly it was appropriate to claim inventions in the field. In this case, the claim was directed to a recombinant plasmid suitable for transformation of a bacterial host wherein the plasmid comprised a homologous regulon, (i.e., DNA normally present in the cell in question that controls the transcription of a gene) a heterologous DNA (i.e., DNA alien to the bacterium in question) that encodes for a functional polypeptide, and one or more termination codons.

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132. *Id.*

133. Decision T 162/86, [1988] O.J.E.P.O. 12/452 (Tech. Bd. App. 1987), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 162/86-1.

134. Decision T 292/85, [1989] O.J.E.P.O. 7/275 (Tech. Bd. App. 1988), *reprinted in* 4 Eur. Pat. Handbook (MB), ch. 103, T 292/85-1.

The claim was extremely broad, essentially covering any plasmid that claims a homologous regulatory region together with alien DNA coding for a protein. The Examination Division had argued that the claim should be limited at least to known bacteria, plasmids, and polypeptides.[135] It also indicated that it objected to the idea that components could be defined in functional terms in this area of technology since this could result in claims of extreme breadth.[136]

In *Polypeptide*, the relevant prior art involved work which showed that insertion of heterologous regulons and heterologous polypeptide-coding DNA into a bacteria had not succeeded in producing useful polypeptides. It also included an article that had suggested that extensive translation of functional heterologous polypeptides might occur if one could simply ensure that in transcribing the DNA the right groups of three nucleotides were read together. Thus, in the view of the Examining Division, what the applicants had done was really nothing more than define an obvious problem more precisely rather than provide the solution to it.[137]

The EPO Appeals Board first dealt with the issue of the suitability of functional language in the claims, noting that in other areas of technology such language had been approved "if such features cannot otherwise be defined more precisely without restricting the scope of the invention."[138] It went on to state that "there was no valid reason why this should not be equally true for the field of biotechnology as in other fields of technology."[139] The Board could see no particular reason why the terms "plasmids" or "bacteria" should be restricted to known plasmids or bacteria anymore than in other areas of technology the term "resilient means" or "amplifying means" should be restricted to known expedients.[140] Insofar as the question of obviousness is concerned, the Board noted that although the prior art clearly showed that the objective

135. *Id.* at T 292/85-2.
136. *Id.*
137. *Id.*
138. *Id.* at T 292/85-7.
139. *Id.*
140. *Id.*

obtained by the present invention was a desirable one, prior art had never suggested that a way to do this was to couple a heterologous coding region with a homologous regulon. This, coupled with the fact that, once the invention was disclosed it was immediately used made it clear that an inventive step existed. The Board recognized that it was granted a very broad claim and concluded its opinion as follows:

> The Board of Appeal recognizes the inventive step and broad applicability of the plasmids claimed in the present application. This necessitated the careful assessment of the scope of the subject matter claimed in order to give a fair protection to the proprietor. Unless the features of the claim are construed as proper in embracing present and future uses of the invention, and in fact all conceivable uses of the inventive idea, the patent system would fail to serve its purpose.[141]

Here, therefore, the Appeals Board sees no problem in granting broad protection to a new technique with extremely wide applicability in the recombinant genetic field.

The EPO Appeals Board's liberal approach contrasts starkly with the results achieved on another Genentech patent in the English Court of Appeal in the famous *Wellcome-Genentech* tissue plasminogen activator (t-PA) case.[142] There, the main claim read, "recombinant tissue plasminogen activator essentially free from other proteins of human origin."[143] This case has caused an enormous fuss. There are three extremely long decisions by the English Court of Appeals, all of which concluded that the claims were unpatentable, and all of which gave totally different reasons as to why they were unpatentable.

I think the case really has to be viewed on its facts as much as

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141. *Id.* at T 292/85-16.

142. *In re* Genentech Inc.'s Patent, 1989 REP. PAT. DESIGN AND TRADEMARK CASES [R.P.C.] 147 (Eng. C.A.). In this case, Wellcome Foundation Ltd. had petitioned for revocation of Genentech's patent on tissue plasminogen activator immediately after its grant.

143. *Id.*

anything else. Before the application was filed it was known to be desirable to produce tissue plasminogen activator, which is a chemical which breaks down blood clots. It was known that recombinant DNA technology had been used to produce other useful chemicals which were somewhat similar but not quite as complicated. It was also known that a particular human melanoma cell line would secrete natural tissue plasminogen activator. An article had discussed this and made the suggestion that one possibility for achieving large-scale production at relatively low cost was the insertion of an extrinsic plasminogen activator gene into an expression plasmid of *E. coli*. The article stated: "As a first step in this direction, we had isolated the RNA for extrinsic plasminogen activator in an active form on those melanoma cells."

I think that this case really goes to show that we've got to be careful about not drafting claims too broadly. The English Court of Appeal basically said, yes, Genentech had done something useful in establishing that sequence of the DNA required, but that claim should not just attempt to cover all of what was *a desideratum* that obviously one wanted to achieve and which there is no reason why those skilled in the art would doubt that they could achieve. So be careful about the wording of your claims.

This case has been cited by some as being the basis for saying that all sorts of different things might not be patentable, including cures for cancer. I don't think that analysis stands up at all. As I say, I think it really is, at the end of the day, a fairly fact-specific case. It's very difficult to extract any common rationale out of the three judgments.

Where you've got a cure for cancer, some have said that this would not be patentable because you have just evolved routine technology. That's not really the case. If you discover that a particular gene will do something which will cure cancer, then, as long as the fact that that gene will cure cancer has not been published somewhere before, incorporating that into a plasmid and then producing something from that is, in my view, quite clearly patentable.

This conclusion is supported by the fact that the European Patent Office issued a different patent to Genentech, on different

claims from those which were under opposition in the United Kingdom. This involved a tissue plasminogen activator, as encoded by the DNA product obtained from RNA, extracted from a melanoma cell line and having a specific restriction. So that in this case you've got protection for something which is really quite similar to what was rejected by the United Kingdom, but, because it was not couched in such broad, all-encompassing terms, the thing went through and I have no doubt that it will stand up.

I was asked to say something briefly on the question of the European position on infringement of process claims, whether importation into a European country of a product produced by a patented process elsewhere would be an infringement.

Article 64(2) of the European Patent Convention gives protection to the direct product of a patented process.[144] However, this Article does not address the issue which has become a very live one here recently: what happens if you have a patented organism in the United States that is used overseas to produce something and then the product of that production is brought into Europe.

There is no direct product in this case if all you have is a claim to the organism. Therefore, you should make sure that your European applications claims go not only to the organism itself but also to their use in producing whatever it is that is of interest to you.

E. *The European Community's Proposed Directive on Legal Protection of Biotechnological Inventions*

Clearly the question of patentability of animals has brought the questions of patent protection more fully into the area of public debate than is normally the case. This is exemplified by the problems that the European Community has faced in attempting to adopt a Directive on patentability in this area.

The Directive was first proposed in 1988 as a response by the Commission of the European Communities ("Commission") to a perception that research in the biotech area in Europe was lagging behind that of the United States and Japan. The Proposed Direc-

144. European Patent Convention, *supra* note 8, art. 64(2).

tive was published by the Commission in 1988.[145]

The Proposed Directive was subject to intensive discussion by Parliament when it was first submitted. This discussion delayed progress interminably and the draft was finally given the necessary initial consideration by Parliament in October 1992.[146] In doing so Parliament suggested many amendments.[147] These were duly considered by the Commission which then produced a revised draft last December.[148] This draft was to be considered by the Council on April 15 and 16.[149]

As originally proposed, the Proposed Directive, in order to avoid barriers on trade between Member States resulting from dif-

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145. Proposed Directive, *supra* note 43. This Directive was proposed by the Commission under its powers under Article 100a of the Treaty of Rome, which is one of the provisions added by the Single European Act. Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 (1958), *amended by* Single European Act, O.J. L 169/1 (1987), [1987] 2 C.M.L.R. 741. The Commission has proceeded under the so-called "cooperation" procedure with the European Parliament.

Under the European Community's legislative procedures, adoption of legislation of this type under the cooperation procedure, which was introduced as part of the 1992 program for completion of the internal market, requires that legislation is first proposed by the Commission. It is then submitted to Parliament for a first reading and then reconsidered by the Commission to see whether amendments are required in the light of Parliament's proposal. The draft is then referred to the Council of Ministers for it to adopt a "common position." It is then returned to Parliament for a second reading. Only after this is the legislation actually adopted by the Council of Ministers. The vote required for adoption depends upon whether Parliament and the Commission agree with what is before the Council. If they do, then a qualified majority in the Council will suffice. If they do not then the Council can adopt the legislation only by acting unanimously. [Eds. note: On November 1, 1993, the Maastricht Treaty came into force. Treaty on European Union, Feb. 7, 1992, O.J. C 224/1 (1992), [1992] 1 C.M.L.R. 719. Its "co-decision" procedure will replace the cooperation procedure and be used after the "common position" is adopted by the Council.]

146. On October 29, 1992 the European Parliament voted to approve the Proposed Directive, subject to its various amendments and, therefore, completed the first reading of the Parliament under the cooperation procedure. Legislative Resolution No. A3-0286/92, O.J. C 305/173 (1992).

147. Proposal for a Council Directive on the Legal Protection for Biotechnological Inventions, O.J. C 305/160 (1992) [hereinafter Parliament Amendments].

148. Amended Proposal for Council Directive on the Legal Protection of Biotechnological Inventions, O.J. C 44/36 (1993) [hereinafter Amended Proposal].

149. [Eds. note: The date the proposal is going to be considered has since been changed to December 16, 1993, and a common position is expected.]

ferences in legal protection for biological inventions in the various Member States, would have required that Member States amend their patent law to provide that the subject matter of an invention shall not be considered unpatentable only because the subject matter relates to "living" matter. The initial draft set out the requirement that a process which requires human intervention consisting in more than merely selecting an available biological material and letting it perform in its inherent biological function under natural conditions should potentially be considered patentable subject matter. It also made clear that simply because something existed in a mixed form in nature, does not mean it is inherently unpatentable. The Proposed Directive did, however, exclude from protection the types of plant varieties that are protectable under plant variety act legislation. It will be recalled that the UPOV Treaty requires Member States to preclude double protection by patenting and plant variety rights.[150]

The Proposed Directive, in addition to stating that subject matter of this type must be patentable also, however, set out certain limitations on the scope of protection that should be granted. Perhaps, the most important of these is in respect of the rights that are to be granted in cases where a patented process relates to the production of living matter or matter containing genetic information such as, for example, a strand of DNA. In this case, one must consider whether the progeny of the living organism produced by the process or, for example, bacteria that result from replication of a cell into which the DNA material produced by the patented process has been inserted are to be considered infringements of the patent claim. It will be recalled that in general, European law provides that the direct product of a patented process is an infringement of that patented process. The question here is whether naturally resulting replicas of that direct product are also infringements. The original draft Directive prescribed that such replicas will be regarded as being direct products.

As noted above, the Proposed Directive was severely mauled by Parliament. Among Parliament's proposed amendments were

150. UPOV Treaty, *supra* note 5, art. 2, 33 U.S.T. at 2704.

the following: (1) that a prohibition on patents for the human body or "parts" thereof (it was not clear whether an isolated gene would be regarded as a "part" under the prohibition);[151] and (2) that an elaboration on the question of what was contrary to *ordre public* or morality so as to prohibit patents for "unnatural processes for the production and modification of animals or [which] cause unnecessary suffering or unnecessary physical harm to the animals concerned."[152]

Industry was aghast at these amendments and made representations to the Commission. The latest version, produced by the Commission in December 1992 and currently under consideration by the Council, attempts to meet some of the problems.[153]

In rewording the draft, the Commission seems much more aware than it was initially that as a practical matter it has to have a reasonably good fit with both the European Patent Convention and the, as yet inoperative, Community Patent Convention. As now proposed by the Commission, the draft follows Parliament's proposal, the main features of the Directive would be as follows: First, a provision that something should not be unpatentable simply because it uses or is applied to "self-replicating living matter" or "any matter capable of being replicated through a biological system or by any indirect means."[154] The first half of the latter provision clearly covers genetic material. However, what the second half means is open to question and does not seem to be explained in the Commission's explanatory memorandum or the recitation of the draft. More significantly, however, the redraft picks up the European Patent Convention's prohibition on the grant of patents on inventions whose publication or exploitation would be contrary to public policy or morality. Furthermore, it sets out certain specific examples of what is to be regarded as being unpatentable as follows:

(a) the human body or parts of the human body per se;

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151. Parliament Amendments, *supra* note 147, amend. 15.

152. *Id.* amend. 18.

153. Amended Proposal, *supra* note 148.

154. *Id.* art. 2(1)-(3).

(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;

(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.[155]

The explanatory memorandum comments that so far as (a) is concerned, the "per se" wording shows that it is not intended to exclude from patentability "parts" that have been severed from the body, such as human cell line or a process of producing a human antibody. In a shot at the U.S. National Institute of Health's proposal to patent gene fragments, however, the explanatory commentary states:

> It goes without saying that, if the applicant simply wishes to patent a mere part of the "human body" per se, e.g., a human gene, neither the function of which nor the protein for which it codes is known, exclusion from patentability would apply.[156]

So far as the second element in the list of unpatentable subject matter is concerned, the Commission states that its purpose is "to leave open the possibility of granting legal protection to inventions capable of improving considerably the lot of certain human being suffering from deep-seated illness."[157] However, this provision must be read in conjunction with a later provision in the draft that restates the European Patent Convention's prohibition on the grant of patents for methods of treatment of the human body "by surgery or therapy" but which provides that products "for use" in such methods are patentable.

This provision has caused problems in the pharmaceutical area in the past, but by various acts of sophistry the EPO has found itself able to allow claims along the lines "compound X for thera-

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155. *Id.* art. 2(3)(a)-(c).

156. Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, COM(92)589 final—SYN 159 [hereinafter Explanatory Memorandum].

157. *Id.*

peutic use" or "for treatment of disease Y" in the case of a first medical use and "use of compound X for preparing a medicament for treatment of disease Z." in respect of subsequent medical uses, even though the only novelty involved was the fact that X could be used to treat Y or Z. Apparently the Commission envisage such claims in the biotech area and possibly for useful human genes as long as the treatment involved is not one for a "non-therapeutic purpose which is contrary to the dignity of man," although possibly this will need to be reworded in non-sexist language before being adopted.

The third group of inventions that the draft would not specify as being unpatentable is concerned—a topic that was subject to heated debate in Parliament—and the Commission has not adopted all of Parliament's proposals in this area. The Commission points out that ethical issues relating to research in this area are dealt with in other legislation such as the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.[158] Thus, attempting to regulate such activities by the patent law would be out of place. On the other hand, some consideration to animal rights must be made. Hence, the compromise wording is broadly in agreement with the Examining Division views in the "Harvard mouse" case discussed previously.[159]

In other provisions of the draft that acts to provide a gloss on the wording of the European Patent Convention, the draft seeks to clarify what is meant by the term "essentially biological process." It will be recalled that the EPO itself bars patents for such processes. The proposed wording reads as follows: "In determining whether this exclusion applies, human intervention and its impact on the result achieved shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a mere production process shall be patentable."[160] Again this seems

158. Mar. 18, 1986, Strasbourg; *see also* Council Directive of 24 November 1986 on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Regarding the Protection of Animals Used for Experimental and Other Scientific Purposes, 86/609/EEC, O.J. L 358/1 (1986).

159. *See supra* notes 1, 32-41 and accompanying text.

160. Amended Proposal, *supra* note 148, art. 6.

broadly in line with the EPO's decision in the *Hybrid Plants/ Lubrizol* case.[161] Finally, in the area of defining patentable subject matter, the draft seeks to remove the possibility of rejection of an application for lack of novelty simply because what is claimed formed part of an existing material. This again seems to be codification of the EPO's decision in the *Biogen* case.[162]

Chapter II of the draft defines the rights arising from patents in this area and addresses the difficult question of whether a patent should cover progeny of something produced by a patentable process. The basic scheme is that protection extends "to biological material directly obtained using that process and to any other biological material derived from such biological material through multiplication or propagation and possessing the same characteristics."[163]

However, this general right is subject to a number of limitations as follows:

(1) an exhaustion of rights if the products in question derived from biological material marketed by the patent holder or with his consent for the purpose of multiplication or propagation,[164]

(2) rights of farmers to use seeds resulting from cultivation of crops "on their own farms" for sowing at a later time[165] or for farmers who rear livestock using livestock protected by a patent "for multiplication purposes on their own farms to renew their stock;"[166] and

(3) provision for the grant of a compulsory royalty-bearing, non-exclusive license under patent for those who hold a plant variety right that is dominated by

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161. Hybrid Plants/Lubrizol, Case T-320/87, [1990] O.J.E.P.O. 3/71 (Tech. Bd. App. 1988), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 320/87-1.

162. Biogen/Recombinant DNA, Decision T-301/87, [1989] O.J.E.P.O. 11 (Tech. Bd. App. 1989), *reprinted in* 5 Eur. Pat. Handbook (MB), ch. 103, T 301/87-1.

163. Amended Proposal, *supra* note 148, art. 10(2).

164. *Id.* art. 11.

165. *Id.* art. 13(1).

166. *Id.* art. 13(2).

> a patent and vice versa if this is in the public interest.[167]

The Commission comments that it is skeptical about the need for farmer's rights, but in view of the extremely strong views expressed by Parliament on the subject, it "has finally accepted it to allow the Council to discuss it as part of a continuing cooperation procedure." The Commission notes that:

> the fact that the vast majority of Parliament's members are in favour of introducing farmer's privilege into patent law is a political sign which the Commission cannot ignore in the context of a cooperation procedure. This is all the more true as the lack of a solution to the problem would prevent work from continuing on the proposal for a Directive as a whole despite its having been before the Council and Parliament since the beginning of 1989. By accepting farmer's privilege, the Commission is seeking first and foremost to unblock the cooperation procedure so as to enable the Council to state its position on the proposal as amended in the light of Parliament's amendment and to examine Parliament's reasons.[168]

It remains to be seen what view the Council will take.

One further point to note on this topic is the fact that the Community Patent Convention also contains some provisions relating to limitations on a patent right. The most significant of these is in respect of "acts done for experimental purposes relating to the subject matter of the patented invention."[169] Of course the Community Patent Convention may never come into effect[170] and if it does, it may be of interest to only a few inventors if the costs are too high. However, similar provisions exist in several national laws.[171]

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167. *Id.* art. 14(1).

168. *See* Explanatory Memorandum, *supra* note 156.

169. Convention for the European Patent for the Common Market, Dec. 15, 1975, Luxembourg, art. 27(b), O.J. L 17/1 (1976).

170. The Community Patent Convention will only come into effect on ratification of all the Member States of the European Community. *See id.* arts. 94, 98.

171. *See, e.g.*, Intellectual Property Code (Law 92-597 of July 1, 1992) L613-5(b) (Fr.); *see* Patent Act of 1968, *as revised* Dec. 16, 1980, art. 11(2) (F.R.G.); *see* Patent Act

On the question of deposit requirements, the draft would make mandatory deposit in a Budapest-Treaty-recognized International Depository[172] before filing of the patent application if the biological material used or to which the patent relates is "not available to the public" and "cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art."[173] The draft requires that such deposit material must be available at least to independent experts from the stage of earliest publication of the patent application and to everybody after the grant of the patent. However, any such person who obtains a sample must give an undertaking: "(a) not to make it or any matter derived therefrom available to third parties, and (b) not to use it or any matter derived therefrom in any country except for experimental purposes."[174] Furthermore, if the patent application is refused or withdrawn or the patent revoked or cancelled, the depositor of the sample may request that access to the deposited material be restricted to independent experts for a period of twenty years from filing the application and that such experts be required to give undertakings as discussed above.

The final substantive provisions of the draft go to question of burden of proof. In this case, the current version of the draft has been changed from the original proposal so as to bring it more closely into conformity with the Community Patent Convention. The revised wording is as follows: "If the subject-matter of a patent is a process for obtaining a new product, any identical product produced by any person other than the patent holder shall, in the absence of proof to the contrary, be deemed to have been obtained by means of the patented process."[175] The original wording on this point was to reverse the burden of proof in such cases in obtaining both "new" and "known" products.

Act of 1977, § 60(i)(b) (U.K.).

172. *See* Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, Apr. 28, 1977, art. 3, 32 U.S.T. 1242.

173. Amended Proposal, *supra* note 148, art. 15(1).

174. *Id.* art. 15(3).

175. *Id.* art. 17(1).

As noted above, once the Council has adopted a common position on the draft, it then goes back to Parliament for a second reading. If the Council appears to be unanimous in its position, there is little more that the Parliament can do at this point since a unanimous vote of the Council can overcome any opposition by Parliament. If, however, there is less than unanimity in the Council, adoption of the Directive by a qualified majority will require that the text adopted is one with which Parliament agrees.[176] Thus, it may still be a while before this Directive actually comes into force.

CONCLUSION

As can be seen from the history of the Proposed Directive, the "morality" debate has probably not yet been concluded in Europe and even when it is, there is no certainty that the same conclusions will be reached in other countries having totally different cultural backgrounds. However, as noted previously, prohibitions on the grant of patents on inventions whose publication or exploitation would be immoral, exist in many countries' patent laws in addition to the European Patent Convention. The introduction of moral issues into what has traditionally been a particularly rational part of the law is itself fraught with problems. Insofar as such issues are incorporated into the law, it seems generally desirable that this should be effected by clear actions by the appropriate legislatures. However, such bodies are notoriously slow at addressing such issues for fear of offending part of the electorate. This seems to be the reason why the European Community's draft gives examples only of what is to be unpatentable and none of what may definitely be patented. And this is from what is said to be the Western world's legislature that is least beholden to voter pressure!

As we have seen many, but by no means all, advanced countries see nothing immoral per se in granting exclusive rights for new life forms, although statutory prohibitions exist in many as to particular forms and these are unlikely to be amended until the

176. [Eds. note: The common position is now considered under the new co-decision procedure provided by the Maastricht Treaty. This procedure gives Parliament more leverage through the new conciliation procedure.]

morality issue is resolved, since the burden of proof always lies on the proponents of change. So far as the patentability of animals is concerned, while one can take the view that patent law as such is neutral on the question of whether animals should be specifically created for research or foodstuff purposes, the "antis" argue that the patent system, by providing an enhanced economic incentive for the production of such animals, promotes the production of more animals of this type and so the denial of patent protection would be useful in the overall fight against such animal experiments. However, the issue seems to be resolving itself in the same way as previous disputes relating to the use of animals in research, that is to say, by means of a balancing test between the benefit to be brought to mankind or other animals and the suffering inflicted on the animal. Stating the test, however, is easier than applying it. Will the benefit given by a more succulent pork chop be sufficient to justify a patent on a pig that has been genetically modified to enable it to grow more rapidly under factory farming conditions? What is even more worrying is that it is likely that patent offices will have to carry out this test and it is not clear how they are or will be equipped to perform it.

The second major morality issue, that of the patentability of inventions relating to the human genome, is even more difficult. The Thirteenth Amendment to the Constitution of the United States[177] and Article 4 of the Universal Declaration of Human Rights[178] both prohibit slavery. Thus it seems that no one could assert rights over another simply because he or she contains or was produced with the aid of a patented human gene. What rights, therefore, are potentially available as patentable subject matter on parts of the human genome? Those relating to genetic material itself and use of the gene in question in therapy? This issue is of course simply a new version of one that has confronted the pharmaceutical industry for many years. After a prolonged battle, patent protection for new pharmaceuticals per se is now available in most major countries of the world. Protection for new methods of treating disease using an old pharmaceutical is much more prob-

177. U.S. CONST. amend. XIII.

178. G.A. Res. 217(III), U.N. GAOR, 3d Sess., at 71, U.N. Doc. A/810 (1948).

lematic. A further moral issue intrudes here, however. There are two basic ways in which gene therapy may be carried out. The first is with respect to the somatic cells of a person so as to try to replace a defective gene in those cells. Except for the techniques employed and the hoped for permanence of a cure obtained in this way, the patentability of such techniques raises essentially the same issues as the patentability of conventional therapies. Namely, the question of whether a physician or surgeon should be subject to a patentees rights when carrying out a treatment on a patient. Some argue that this is no different from the requirement not to prescribe drugs that infringe a patent; others see it differently. The second possible type of genetic therapy involves modification of the germ cells in an embryo, for example, to remove a gene that may predispose the individual to a particular disease. It may also have other effects on the individual's integrity as a human being. Clearly, here there is a more significant moral issue. However, again it seems a little cavalier to leave such issues to the average patent office examiner.

Coupled with the morality issue are some purely economic ones such as: Exactly how broadly should protection be granted in the incipient days of a new industry? More specifically, to what extent should those who by purely natural means propagate or breed living organisms be required to be subject to the patent rights of the originator of one of the ultimate ancestors of the progeny in question, albeit possibly several generations earlier? If such rights are to exist what form should they take? Is an injunction appropriate to prevent a bull from doing "what comes naturally" or can we say that in the state of today's agricultural industry this rarely happens and so traditional means of relief are appropriate?

A second economic/competition law issue is how is an infant industry best helped by the patent system? As we saw in the British t-PA case, the English Court of Appeal was skeptical about granting rights that were too broad in case these rights stifled rather than promoted invention.[179] As was seen in the *Magill* cases,[180] the

179. *See* In re Genentech Inc.'s Patent, 1989 R.P.C. 147 (Eng. C.A.).

180. Radio Telefís Éireann v. Commission, Case T-69/89, [1991] 4 C.M.L.R. 586

European courts have on occasion stepped in to order the grant of licenses where an intellectual property right owner has been using his rights in such a way as to prevent others from obtaining access to the basic raw material required to permit competition. Would the same happen in the biotech area if patentees refuse to grant licenses to patents covering basic techniques? Probably.

Finally, outside the strictly patent arena, there is a geopolitical question spawned by the Nairobi Convention on Biological Diversity signed at last year's so called "Earth Summit" in Rio de Janeiro.[181] Should commercial enterprises that make a profit for use of genetic material found in a third-world country pay royalties to that country for the privilege of using the material?

Clearly this is going to be a stimulating and demanding area in which to practice for many years to come.

(Ct. First Instance) (Magill TV Guide intervening); British Broadcasting Corp. v. Commission, Case T-70/89, [1991] 4 C.M.L.R. 669 (Ct. First Instance) (Magill TV Guide intervening); Independent Television Publications Ltd. v. Commission, Case T-76/89, [1991] 4 C.M.L.R. 745 (Ct. First Instance).

181. United Nations Conference on Environment and Development, Convention on Biological Diversity, *opened for signature* June 5, 1992, Nairobi, *reprinted in* 31 I.L.M. 818 (1992).