

Applying Laws to Biotechnology

Problems of applying current patent law to advanced technology; in some cases solutions are suggested

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On October 29, 1982, the United States Food and Drug Administration approved the medical use of bacterially-cloned human insulin. This product, which has been given the trademark "Humulin," is the first product of recombinant DNA technology ever to be cleared for human use.

This is one of the latest milestones in the current rapid development of biotechnology, a development which has been likened by some to the growth of classical organic chemistry which started last century and which from the second half of that century, has had a profound influence on our technology and our environment and still continues to do so.

Indeed, it would seem that biotechnology at present stands on the threshold of a development whose extent can scarcely be imagined even by the most farsighted of future watchers.

Among those who watch this future with a mixture of elation and trepidation are the makers, interpreters and users of our patent systems and laws.

The purpose of this paper is to outline some of the problems which arise in applying existing patent laws to biotechnology and to suggest some solutions to those problems.

It may be useful here to attempt to define what we mean by the terms "biotechnology" and "genetic engineering." In fact, the latter can be regarded as a subset of the former but the following definitions may be useful:

BIOTECHNOLOGY—*Industrial processes based on biological systems involving naturally occurring microorganisms or isolated cells of plants or animals, or microorganisms or cells which have been modified or created by genetic engineering techniques.*

The genetic manipulation of microorganisms or plant or animal cell whether naturally occurring or modified, to produce new types of such microorganisms or cells.

GENETIC ENGINEERING—*The alteration at the laboratory level of genetic material of living cells so that the cells can produce more or*

different metabolic products or perform entirely new functions.

Biotechnology encompasses the very old and the very new. The very new is mentioned above. The very old is, perhaps, not so obvious. But there would be few of us who could go through a single day without encountering a product of a biotechnology process, some of which are many thousands of years old. Beer, wine, tea, bread (real bread), and soy sauce are but a few of the products of one of the oldest biotechnologies, fermentation.

Genetic engineering, is essentially concerned with the production of microorganisms which have artificially modified and are thereby able to produce valuable products (for example, insulin, interferon, somatostatin, and other hormones) or to perform other useful functions, such as the degradation of undesirable substances (e.g. oil pollution), and the leaching of ore deposits.

GENERAL ASPECTS OF PATENT PROTECTION IN THE FIELD OF BIOTECHNOLOGY

There have always been difficulties in applying existing laws to new concepts and this is particularly evident when applying existing *patent* laws to new technologies.

Not surprising, perhaps, when the basic concepts of patent law were first applied to chemical technology they were given an interpretation appropriate to the circumstances existing at the relevant time. The problem is that in many cases these interpretations have become binding precedents for the application of these concepts to new fields of related, yet independent technologies, such as biochemistry.

Indeed, there is a body of current opinion which considers that most, if not all, patent systems and laws are out of step with the technical, economic and social affects of new fields of technology and have not been sufficiently flexible to provide new and appropriate interpretations of the patent law to new fields of technology.

There are a number of basic problems in applying any patent system to the results of research and development in the field of biotechnology in general and genetic engineering in particular.

One particularly basic question is whether living organisms themselves are patentable inventions. The answer to this question will always depend on the legal definition of the term "invention" in a particular country and the interpretation which the courts of that country put upon the term. But there are common and fundamental considerations which will, or should,

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apply in all countries.

Mark Twain once said, "A country without a patent office and good patent laws is just a crab and can't travel any way but sideways and backways."

One American commentator has suggested that the decision of the United States Supreme Court in the Chakrabarty case, which granted the first U.S. patent for genetically engineered microorganism saved the U.S. patent system from being "just a crab" with respect to a new product of new technologies.

What remains to be seen is whether courts in other countries will similarly save their respective patent systems from the fate of the crab.

BIOTECHNOLOGY, INVENTIONS AND THEIR PATENTABILITY

The different kinds of inventions which may arise in the field of biotechnology are best seen from diagram which shows the basic techniques and steps involved.

We can classify areas where potential inventions will arise in the field of biotechnology under the following headings:

Living organisms.

Processes for making or producing living organisms.

New (and old) products from microorganisms.

New uses for products from microorganisms.

Genes and other DNA sequences.

Vectors.

Fermentation process and procedures.

New methods, reagents and procedures.

Obviously, inventions in some of the above categories are clearly of a patentable nature. Equally obviously, there are other areas where the question of patentability cannot be simply resolved.

New products produced by biotechnological processes, will be patentable, at least in those countries where chemical products can be patented, and new biotechnological processes involving the use of living organisms will also be patentable under the normal laws of the country in question. The real problem comes when we consider the question of patentability of living organisms themselves.

LIVING ORGANISMS

The question of whether living organisms are patentable raises numerous questions, not only in the area of patent law but also in the areas of ethics and morality. I shall not deal with the latter two issues here.

By living organisms, we include microorganisms in the broad sense, e.g. bacteria, viruses, yeasts, protozoa and algae. At the other end of the scale we consider living plants and animals. Somewhere between these extremes are animal and plant cells and cell-line cultures.

Our considerations must also include the prohibitions which exist in the laws of some countries which for reasons of a historic nature or otherwise, prohibit the patenting of living organisms or other things which "exist in nature."

We start with the proposition that, generally, new products will qualify for patent protection if they can be considered as having been made by the work of man, and if they belong to the "technical arts" in the broadest sense, and if they are useful.

On the basis of this definition, living organisms which have been modified to useful ends by genetic engineering techniques should be able to fulfill these conditions and thus genetically engineered microorganisms and plants at least should qualify as patentable subject matter.

Obviously, if these genetically engineered products do not occur in nature they cannot be said to be unpatentable on the ground that they are "naturally occurring."

A different question arises, however, when we come to look at products of some genetic engineering procedures which do occur in or form part of some living organism which is of natural origin. I will deal with this point in more detail later.

Microorganisms

A significant number of countries have either indicated they will allow patents for new microorganisms or have actually done so.

As early as 1976, the Australian Patent Office made some significant observations on the patentability of microorganisms in general.

The case in question (Ranks Hovis McDougall Limited's Application) concerned a patent application for a new strain of a microorganism that had been isolated from a soil sample.

The assistant commissioner refused the application on the basis that "no invention was involved in the mere discovery, or the mere identification, or the mere isolation by an unspecified method, or something that occurred in nature," and on other grounds.

He also held that an inventor would make no useful contribution to the art if he merely discovered a naturally occurring microorganism and by altering its conditions of growth, he changed its morphological characteristics.

Different Situation

On the other hand, the commissioner felt the situation would be quite different if in producing the variant by some man-controlled microbiological process, he had produced a new microorganism which had improved or altered useful properties.

To suggest that such a patent should not be granted for an invention of this kind was in the commissioner's opinion, hardly in accord with the views expressed in the NRDC case. (In that case, the Australian High Court gave a very broad and fundamental interpretation of what constituted an "invention" as defined in the Patents Act).

So *new*, artificially-created microorganisms seem to be clearly patentable in Australia. Other countries have taken a similar view, most notably, of course, the U.S.A., where the Supreme Court allowed the Chakrabarty patent. The German Federal Court took a similar view as early as 1975 in the "Baker's Yeast" case.

One recently published survey indicated that microorganisms should be patentable as products in some 28 countries including the EPC, although many of these countries impose some kinds of restrictions. Only four countries seem to have clearly indicated they regard microorganisms as unpatentable.

It still appears to be an open question whether newly discovered and isolated, but naturally occurring microorganisms are patentable. As indicated above, the Australian Patent Office didn't think so in 1976 (although it might feel differently now).

In the U.S.A. the CCPA (*in re Bergy*) held that a biologically pure culture of a newly isolated microorganism was patentable. A strong body of opinion is building up in Europe that inventions of this kind should be patentable there.

Plants and Animals

The Australian Patent Act makes no restrictions on the patenting of living things.

There does not seem to be any reason, therefore, why new strains of plants or animals produced by genetic engineering techniques, should not be patentable under the provisions of the present act.

There are, of course, specific provisions for the protection of plant varieties in a number of countries, notably the United States of America. Australia's plant variety rights bill has not yet been passed by Parliament and it seems unlikely that it will be in the foreseeable future. It is interesting to note, however, that the bill requires a "new plant variety" to be originated by a person, and provides that that person may be one who originated a plant variety by a "humanly induced genetic mutation." It seems that the Plant Varieties Act, therefore, envisages protection for genetically-engineered plants if they otherwise fulfill the conditions of registration.

On the basis of the Chakrabarty decision, it appears that inventions in the U.S.A. would not be denied patent coverage merely because they have the qualities of life, so long as they are the result of human intervention and are not "products of nature." On this basis, at least, it would seem patents for animals might be allowed in the United States.

The European Patent Convention specifically excludes the patenting of plants or animals but this restriction is now under some criticism.

The German Federal Court has had some interesting observations to make on the patenting of animals and the "Red Pigeon" case is notable in this area. In that case, the Federal German Supreme Court ruled that given methods of breeding plants and fermentation processes are in principle, patentable, then it is only logical that the breeding of animals should not be excluded from patentability solely on the grounds that both the means employed and the results are in the biological field. (The court held that that claim to the pigeon itself was not patentable for other reasons but clearly acknowledged its patentability in principle.)

Processes for Making or Producing Living Organisms

It would appear that the above considerations apply when considering inventions in this area. Naturally occurring processes would seem to be excluded but otherwise such processes should be patentable where there is human intervention.

Genes and Other DNA Sequences

Obviously, new procedures for identifying or isolating genes and other DNA sequences from natural sources should be patentable. The main question is

whether the sequences themselves are patentable.

Genes and gene sequences which do exist somewhere in nature, generally do so as part of a much larger sequence and not in any identifiably pure form isolated for a particular purpose.

If we consider a human hormone, such as interferon, we know that there must be a gene which codes for this protein. We also know that this gene will exist somewhere in the human gene pool and to that extent, is "naturally occurring." What must be appreciated, however, is that human DNA is enormously long (it contains about 1 billion bases) and is about 10 million times the length of the interferon gene. Thus, while the human gene for interferon must exist in nature, it is occult; it is completely hidden from human knowledge. Furthermore, except possibly in the living cell itself, it has no independent natural existence; it only exists as part of the enormously long human DNA sequence.

Courts in the U.S.A. and the German Federal Republic have held that naturally occurring substances are patentable, at least when isolated in the pure state, and the Federal German Patents Court as stated:

The fact of the existence of a substance in nature does not of itself preclude the novelty of the invention, provided that those skilled in the art were not aware of such existence.

It seems, therefore, that an individual and newly isolated gene or gene sequence or in fact any other DNA sub-unit, should be patentable subject matter at least when it is first isolated in the pure state.

Vectors

The vectors usually used in genetic engineering (being bacterial plasmid or viral DNA) may be naturally occurring. They may also be genetically engineered. The latter would seem to be clearly patentable but the questions regarding the patentability of naturally occurring DNA sequences would seem to apply to the former. A recombinant DNA vector consisting of the new combination of a plasmid with an inserted section of a foreign gene would clearly be patentable.

Products From Microorganisms

Clearly, any new product, whatever its source, as long as it is unobvious and useful, will be patentable in any country which grants patents for products per se, Australia included.

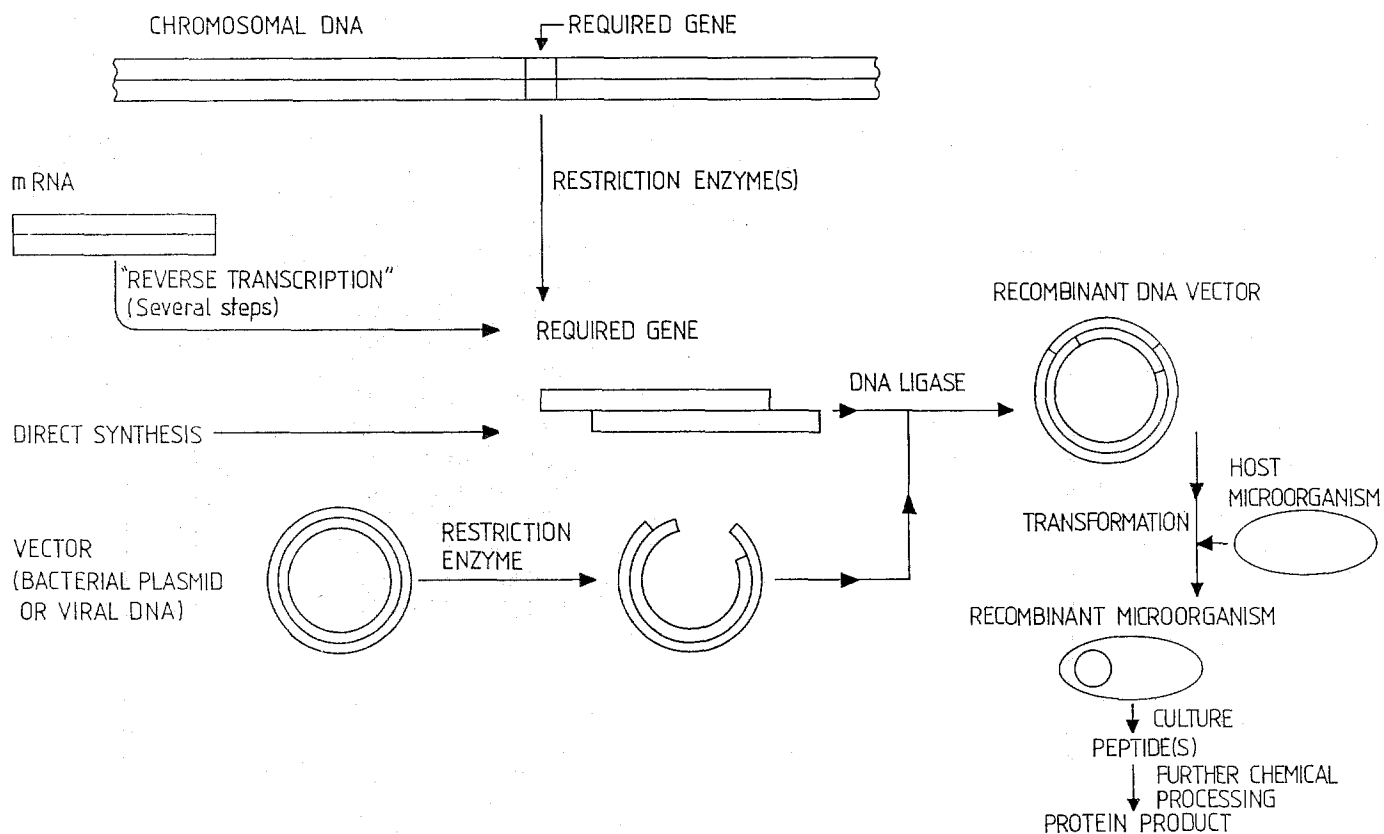
Similarly, inventions relating to new uses for products from microorganisms ought to be generally patentable.

Fermentation Processes and Procedures

Fermentation processes in general have been patentable for a very long time and no distinction needs to be drawn between processes using old microorganisms and those using new microorganisms including genetically engineered ones.

New Methods and Reagents

Recombinant DNA technology in general involves a formidable array of processes, procedures, and reagents including many reagents which are themselves products of living organisms whether natural or modified. The operative word here is "new"



natural or modified. The operative word here is "new" and methods and procedures which can be so qualified ought to be patentable in virtually all countries. They would certainly be in Australia.

The question gets a little more difficult when we are talking of new enzymic reagents, which are produced from naturally occurring microorganisms but which are discovered or found to be useful for the first time. Here again, however, the movement discussed above toward the granting of patents for newly discovered and isolated "products of nature" should allow patenting in this area eventually, if not now.

This brief discussion barely scratches the surface of some of the problems which are involved in the patenting of inventions in the general field of biotechnology and in the field of genetic engineering in particular. Most of the subject headings given above could form the subject for a book and many undoubtedly will.

I close on a hopeful note, with the words of a New Zealand court:

"The court must now take a realistic view of this matter in the light of current scientific developments and legal progress. The law must meet the needs of the age."

Amen.

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