Philosopher's paradise: Should a microorganism the product of a microbiologist be patentable?*

by

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> Bacteria, yeasts, moulds, algae, protozoa and viruses constitute a seemingly heterogeneous group of biologic entities but they resemble one another in small size and relative simplicity of structure and organisation, and hence are called microorganisms or, as some authorities prefer, *protists* (Greek: *protista* the very first). . . . Microorganisms perform the same fundamental activities within their single cells as 'higher' organisms do within their many-celled structures: utilization of food and energy, formation of protoplasm, reproduction. It is important to remember that microorganisms are essentially the same biologically as other organisms.[1]

Microbiologists are now able to "cause to exist" (to use a neutral phrase) microorganisms that probably would never arise in the course of evolution.

The issue of the subject of this paper can be stated very simply: Should such microorganisms be patentable? The simplicity of the statement belies the extreme difficulty of the issues of law, science and ethics which must be considered in resolving the problem. Such issues will be dealt with in this paper in the context of recombinant DNA technology.

"Genetic engineering" has become an accepted term to use in relation to recombinant DNA research. When addressed to the layman it is almost invariably accompanied, by way of illustration, with emotive phrases such as "tampering with evolution",[2] and "creation of life experiments".[3] Perhaps it is the random and often inaccurate use of this kind of language which is largely responsible for promoting the major public controversy which surrounds these microbiological

[1] Carpenter, *Microbiology* (3rd ed. 1972).
[2] "Questions raised by right to patent life forms" *New Zealand Herald,* 7 July 1980, p.6.
[3] Rogers, *Biohazard* (1977) 196 quoting the *New York Times* and *Washington Post.*

experiments.[4]

In order to discuss the role of law, in particular the patent system, in resolving the difficult social and ethical considerations associated with the issue it is necessary to substitute for the emotional slogans and colourful Frankenstein-type visions, some hopefully accurate explanation of underlying scientific principles. This task is by no means easy—the issue has aptly been described as "one of the most baffling technical mazes of the century".[5]

All living organisms possess structures called chromosomes which are composed of genes, these determine the organism's characteristics.[6] In the scientist's vocabulary "genotype" means the fundamental hereditary make up of an individual organism. The word "genome" denotes the self-replicating portion of a cell—a complete set of hereditary factors. The observable characterists of an organism—the way the genes "read out" in the real world is called its "phenotype".[7]

Before the recent recombinant DNA techniques man could alter genomes (1) by selective cross breeding—producing change over many generations or (2) by mutation—a gene is capable of changing to a different form so that it determines a somewhat altered characteristic. The change may be brought about by exposing a genome to radiation (a process achieved in nature itself by cosmic rays) or to chemicals.[8] The result of this external interference is evident in the next generation.

Genes are made of DNA or deoxyribonucleic acid. The DNA molecule was described by James Watson and Francis Crick as recently as 1953. It is a double helix—"a winding spiral staircase of four different organic bases".[9]

Every organism is made up of proteins. A living cell is a protein factory. Different kinds of cells make different proteins. The DNA—of which genes are composed—within a cell directs the assembly of these proteins. By varying the order in which the four DNA "rungs"—*nucleotides* appear nature provides each gene with a code for the manufacture of a specific protein or piece of protein—for example a gene may be coded to produce insulin or growth hormone.

The DNA code is transcribed on to messenger RNA or ribonucleic acid which takes the information obtained to a subcellular unit the 'factory' of the cell called the ribosome. Transfer RNA carries the

[4] *Ibid.*, 177-205.
[5] *Ibid.*, 196.
[6] Pelczar Reid and Chan, *Microbiology* (4th ed. 1977).
[7] *Ibid.*, 211; Hawker and Linton, *Microorganisms: function, form and environment* (1979), 41.
[8] Hawker and Linton, *op. cit.*, 221; Rogers, *op. cit.*, 9-10.
[9] Rogers, *op. cit.*, 28.

necessary biochemicals or raw materials from within the cell to the ribosome which manufactures the specified protein ordered by the original DNA segment.[10]

Special enzymes called restriction endonucleases are the tool of the genetic engineer. They cleave DNA molecules at specific sites. Another enzyme, DNA ligase is used to join DNA molecules.

Plasmids are small circular units of extrachromosomal DNA. Plasmids can be eliminated from the cell by various treatments without lethal effect on the cell.[11] Stanley Cohen successfully used plasmids derived from the bacterium *E. coli* as vehicles to carry units of foreign DNA back into the *E. coli.*[12]

This tool kit of special enzymes, plasmids and specialised techniques makes it possible to isolate one of the million-odd genes of an animal cell to fuse that gene with part of a bacterial gene and to insert the combination into bacteria. As those bacteria multiply they make millions of copies of their own genes and of the animal gene inserted among them. If the animal gene is fused to a bacterial gene in such a way that a bacterium can treat that gene as one of its own the bacteria will produce the protein specified by the animal gene.[13]

The last few sentences attempt to summarise the results of some of the most exciting biological research of the century. This research has been intensive and has taken place on a world-wide scale. The collective application of the individual discoveries and principles is best illustrated by way of example.

In mid-1979 Genetech and a team of scientists from the University of California, two rival groups, simultaneously announced the synthesis of human growth hormone using recombinant DNA techniques.

In the recombinant DNA technique restriction enzymes are used to isolate a DNA gene strand from a human cell. The strand is then removed and hooked onto another piece of DNA—called a plasmid—taken from the bacterium *E. coli* in the human intestine for example. The plasmid, with its transported DNA strand is then incorporated into the *E. coli* bacterium and *E. coli*'s genetic machinery begins to follow the genetic code of the new DNA and manufacture a protein totally foreign to that it would normally produce.

The starting point for the synthesis of human growth hormone was the pituitary gland where the hormone is manufactured naturally. Baxter and the others first isolated RNA from the pituitary glands and then used it as a pattern to make a copy of the DNA gene, which was then inserted into an *E. coli* plasmid. The plasmid was returned to *E. coli* which began to synthesise the hormone and the laboratory was soon filled with dishes of a new man-made growth hormone.[14]

The potential benefits of this new technology are immense. Genes

[10] Gilbert and Villa-Komaroff, "Useful Proteins from Recombinant Bacteria" Scientific American, April 1980, 74; Rogers *op. cit.*, 28-30; Villee Dethier, *Biological Principles and Processes* (2nd ed. 1976) 20-22; Carpenter, *op. cit.*, 179-183.

[11] Brock, *Biology of Microorganisms* (3rd ed. 1979) 374, 395-398; Gilbert and Villa-Komaroff, *loc. cit.*, 74; Hawker and Linton, *op. cit.*, 48-49; Rogers, *loc. cit.*, 32-42.

[12] Rogers, *op. cit.*, 41.

[13] Gilbert and Villa-Komaroff, *loc. cit.*, 74.

[14] Stockton and Symans, "On the brink of the secret of life". *The Bulletin,* 10 June 1980, 59.

from human or other animal cells are able to be introduced into bacteria to obtain the production, on a commercial scale, of products coded by the human or animal genes. For example insulin, a protein needed in the regulation of blood sugar levels and which is required for the treatment of diabetes, has in the past been obtained at great expense from the tissue of higher animals. The genes for insulin can now be inserted into an appropriate bacterial host.[15] A culture of this recombinant bacteria which can be grown easily and at low cost thus serves as an efficient factory for the production of this protein.

The bacterium, *E. coli* has already been genetically re-engineered, using the technology explained, to produce interferon—a protein made by cells to block viral infections quickly. Interferon appears to be the body's first line of defense against viruses. It may also have a therapeutic effect in some cancers.[16]

Recombinant DNA could well be *the* future of the pharmaceutical industry. Antibiotics are the obvious example. Since the initial discovery by Sir Alexander Fleming in 1928 of a fungus which excreted a bacterial killing substance (pencillin) there has been a continuous search for new strains of microorganisms which could either produce larger quantities of known antibiotics or else produce new ones altogether. Streptomycin and aureomycin, for example, two of the early antibiotics were the products of intense research involving soil samples from all over the world.[17]

Having found a 'useful microorganism' man has not been absolutely limited by its inherent genetic abilities in utilising it. As explained, genes may be mutated by chemicals or radiation. Drug companies have, in the past, done considerable work with various mutagens in the hope that some subsequent mutation will increase the microorganisms' antibiotic yield.[18]

If, however, the gene sequence for a given antibiotic could be isolated and de-coded the information could be utilised to produce a recombinant microorganism which could manufacture that antibiotic at high efficiency and low cost.[19]

Genetic engineering techniques are not limited in their application to medicine. The Department of Scientific and Industrial Research for instance, is currently working on a genetically engineered microorganism for the fixation of nitrogen—essential in agriculture. Improvement of biological nitrogen fixation systems will lead to a direct reduction in dependence on fertiliser. Commercial fertiliser is

[15] Gilbert and Villa-Komaroff, *loc. cit.*, 74.
[16] *Ibid.*, 94.
[17] Rogers, *op. cit.*, 140.
[18] *Idem.*, Pelczar Reid and Chan, *op. cit.*, 223.
[19] Rogers, *op.cit.*, 141.

produced by the Haber process. This fixes nitrogen and hydrogen under high temperature and pressure. Natural gas has been used to obtain the necessary hydrogen but as the supply of natural gas inevitably diminishes and the price rises the price of commercial fertiliser will rise correspondingly.[20] The necessity for an inexpensive alternative provides the incentive to succeed in the application of recombinant DNA techniques in this area.

The list of possible applications goes on.[21] It has been suggested that organisms may be developed to assist in the disposal of industrial waste and to degrade metals and other materials.[22]

Microorganisms are already used to produce single cell protein (a protein supplement in food) on a commercial scale. It was recently announced that these microorganisms have been made more carbon efficient by an application of recombinant DNA techniques.[23]

Microorganisms may well be the ultimate solution to the world's energy problem. The (USA) National Science Foundation's adviser on recombinant DNA has been quoted as saying:[24]

> Theoretically any process occuring in nature can be harnessed for man's use. We could even learn how to duplicate photosynthesis the basic energy converting process in green plants.

The commercial potential of these techniques was recognised even in the very early stages of their development.[25] The research and experimentation outlined earlier has not been confined to university laboratories. Major industrial concerns, notably the pharmaceutical companies, have kept apace with the achievements of the academic biologists. Although secrecy, (particularly on the part of the pharmaceutical companies) makes it difficult to gauge the exact extent of the private sector's involvement in this work it is significant that a meeting called in the very initial stages of research to discuss safety guidelines for laboratories conducting recombinant DNA experiments, attracted no less than twenty-five representatives from such companies as Eli Lily, Upjohn, General Electric, Monsato Chemical and Union Carbide. Britain's science giant, Imperial Chemical Industries, announced very early on, a collaboration with the University of Edinburgh to investigate the potentials of recombi-

[20] Terzaghi, "An attempt to Engineer a Nitrogen Fixing Symbiosis", *New Zealand Science Teacher*, Number 24, March 1980, 14.
[21] Examples given in: Stockton and Symons, *loc. cit.*, 60; Brock, *op. cit.*, 398; Gilbert and Villa-Komaroff, *loc. cit.*, 93-94; DeMott, "Test-Tube Life: Reg. U.S. Pat. Off." *Time* 30 June 1980, 38.
[22] "Eleventh hour for biotechnology in Britain", Nature vol. 284, 10 April 1980, 499; DeMott, *loc. cit.*, 38; Irons and Sears, "Patents in Relation to Microbiology", 29 Ann. Rev. of Microbiology 319 (1975).
[23] Walgate, "Single cell protein organism improved", Nature vol. 284, 10 April 1980, 503.
[24] DeMott, *loc. cit.*, 38.
[25] "Eleventh hour for biotechnology in Britain", *loc. cit.*, 499.

nant DNA engineering.[26] Their achievements in relation to the production of single cell protein have already been mentioned.[27]

Clearly millions of dollars have already been invested in the development of this biotechnology and much more will be required before the realisation of any significant commercial profit from its application.[28] The following will perhaps indicate the magnitude of investment—both financial and intellectual. The Chairman of Cetus Corporation, America's largest biotechnical enterprise has stated that " 'Cetus is now investing millions of dollars of its own money, and comparable amounts on behalf of major company clients,' in biotechnology. New Companies like Cetus will move biotechnology forward, thinks Cape, but new companies are not necessarily small. Cetus has 250 employees—and eighteen projects in five industries, all with potential markets of billions of dollars. 'Biotechnology is no longer cheap' says Cape."[29] Criticising the budget recommendations made by a committee convened in Britain to investigate the establishment of a biotechnology firm for exploiting commercially the scientific enterprise of the British Universities and organisations such as the National and Agricultural Research Councils, Dr Cape stated that £2 million a year for five years is too little to invest in such a new biotechnical firm. He suggested that £50 million over five years would be the minimum 'if you are not going to waste your cash'.[30]

The technology has proceeded to the point where researchers now wish to patent the products of their work: the microorganisms themselves.[31]

It is appropriate at this point to consider the absolutely basic question: What is the function of the Patent system?

The Report of the Committee to Examine the Patent system and Patent Law (Britain) contains the following statement:[32]

> The primary intention of the patent system is the encouragement of industries in the country. The theory of the present British system is well defined by Mr T.A. Blanco White Q.C. in his book *Patents for Inventions* as follows: The basic theory of the patent system is simple and reasonable. It is desirable in the public interest that industrial techniques be improved. In order to encourage improvement, and to encourage also the disclosure of improvements in preference to their use in secret, any person devising an improvement in a manufactured article, or in machinery or

[26] Rogers, *op. cit.*, 138-139.
[27] Ante, p
[28] DeMott, *loc. cit.*, 39; "Eleventh hour for biotechnology in Britain", *loc. cit.*, 499.
[29] "Spinks offers too little", Nature vol. 284, 10 April 1980, 503.
[30] *Idem.*
[31] "Awaiting the outcome of the General Electric Appeal are patent applications for at least 100 different kinds of organisms or processes to make organisms. All the products of genetic engineering activities in more than a dozen companies and countless University laboratories in the United States and abroad". DeMott, *loc. cit.*, 38; Wade, "Supreme Court Hears Argument on Patenting Life Forms". Science vol. 208, 4 April 1980.
[32] *The British Patent System, Report of the Committee to Examine the Patent System and Patent Law,* (1970); Cmnd 4409), 1.

> methods of making it, may upon disclosure of his improvement at the patent office demand to be given monopoly in the use of it for a period of sixteen years. After that period it passes into the public domain: and the temporary monopoly is not objectionable, for if it had not been for the inventor who devised and disclosed the improvement nobody would have been able to use it at that or any other time, since nobody would have known about it. Furthermore, the giving of the monopoly encourages the putting into practice of the invention, for the only way the inventor can make a profit from it (or even recover the fees for his patent) is by putting it into practice: either by using it himself, and deriving an advantage over his competitors by its use, or by allowing others to use it in return for royalties.

A previous committee discussed the theory on which the patent system is based in the following terms:[33]

> . . . the opportunity of acquiring exclusive rights in an invention stimulates technical progress, mainly in four ways: first, that it encourages research and invention; second that it induces an inventor to disclose his discoveries instead of keeping them as a trade secret; third it offers a reward for the expense of developing inventions to the stage at which they are commercially practicable; and fourth that it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously.

It would appear then, that the intention behind the patent legislation is to protect and encourage exactly such research as has been pursued by the microbiologists: the investment that has already been made and is yet required is considerable; although the stage has yet to be reached (in a number of areas) where the use of these microorganisms is commercially practicable, it is undeniable that their widespread beneficial use in industry will be a reality in the near future; patent protection would ensure the disclosure of new useful bacterial strains developed by private companies. However, applications for patents on microorganisms have received less than favourable treatment by patent offices.

Clearly it is not sufficient that any new technology merely appear to come within what is generally considered to be the intention behind the patent system. The requirements of the Patents Act must also be fulfilled.[34] It is these requirements which are now considered.

Under the Patents Act 1953 an application may be made for a patent for an "invention". Section 2(1) of the Act defines invention as:

> . . . any manner of new manufacture the subject of letters patent and grant of privilege within section six of the Statute of Monopolies and any new method or process of testing applicable to the improvement and control of manufacture; and includes an alleged invention.
>
> The Statute of Monopolies means the Act of the twenty-first year of the reign of King James the First chapter three intituled "An Act concerning monopolies and dispensations with penal laws and the forfeiture thereof.

In *Wellcome Foundation Limited* v. *The Commissioner of Patents*[35] Davison CJ, applying the principles outlined in *National Research*

[33] A Departmental Committee on the Patents and Designs Act under the chairmanship of Sir Kenneth Swan Q.C. Second Interim Report (1946) Cmnd 7890:70.
[34] But see the discussion at 11 *post*.
[35] Supreme Court, Wellington, 13 December 1979. (A 215/77).

Development Corporation v. *Commissioner of Patents*,[36] described that decision as ". . . a landmark decision in patent law on the subject of the meaning of manufacture".[37] He also made it clear that the meanings given to the terms "invention" and "manner of manufacture" in the *NRDC* case were now accepted in Great Britain as correctly stating the legal principles to be applied.[38]

In the *NRDC* case the High Court of Australia pointed out that the corresponding Commonwealth provision to section 2 ". . . defines the word invention not by direct explication and in the language of its own day, nor yet by carrying forward the usage of the period in which the Statute of Monopolies was passed, but by reference to the established ambit of section 6 of that statute. The inquiry which the definition demands is an inquiry into the permissable subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of a concept which the law has developed by its consideration of the text and purpose of the Statute of Monopolies".[39]

In relation to "manufacture the Court commented:[40]

> The word . . . finds a place in our present Act not as a word intended to reduce the question of patentability to a question of verbal interpretation, but simply as the general title found in the Statute of Monopolies for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed. It is a mistake likely to lead to an incorrect conclusion to treat the question whether a given process or product is within the definition as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture'? It is a mistake which tends to limit ones thinking to the idea of making tangible goods by hand or by machine, because 'manufacture' as a word of everyday speech generally conveys that idea. The right question is: Is this a proper subject of letters patent according to the principles which have been developed for the application of s.6 of the Statute of Monopolies"? It is a very different question.

Patents have been recognised as being available for methods or processes of producing microorganisms (e.g. antibiotics).[41] Two decisions have recently dealt with the question of whether the microorganism itself is patentable. The first is the case of *Application of Chakrabarty*[42]

The United States patent legislation provides:[43]

> Whoever invents or discovers any new and useful process machine manufacture or composition of matter or any new and useful improvement thereof may obtain a patent therefore subject to the conditions and requirements of this title.

In June 1973 Dr Ananda Chakrabarty, a microbiologist employed

[36] [1961] R.P.C. 135.
[37] *Wellcome Foundation* v. *The Commissioner of Patents,* supra, 40.
[38] *Ibid.*, 40-41.
[39] *Supra,* 141.
[40] *Idem.*
[41] *Joseph Szevc's Application* [1956] R.P.C. 25; *Virginia-Carolina Chemical Corporation's Application* [1958] R.P.C. 35; *Ranks Hovis McDougall Limited* v. *The Controller of Patents, Designs, and Trade Marks* [1978] R.P.C. 588.
[42] 571 F. 2d. 40 (1978).
[43] 35 USC § 101.

by the General Electric Company, filed in the United States Patent Office an application asserting thirty-six claims related to his invention of "a bacterium from the genus *Pseudomonas*. . . ."

Prior to Chakrabarty's invention certain bacterial strains having the capacity to decompose crude oil had been identified. Any given strain could degrade only a particular component of the oil. For this reason biological control of oil spills had involved the use of a combination of different strains. For various reasons only a portion of any such mixed culture survived and the oil spill remained unattacked for a long period.

Chakrabarty determined that the genes responsible for the bacteria's ability to break up hydrocarbons were not in its chromosome but in its plasmids. By introducing compatible plasmids from three different bacteria into a fourth, *Pseudomonas*, a new strain of microorganism was created which had the capacity for degrading several different components of the crude oil at once.

The bacteria could theoretically be freeze-dried until required then introduced onto straw with which the oil spill would be covered. According to the inventor the bacteria would after the feast die for lack of oil.[44]

Chakrabarty's patent claims were of three types: process claims for the method of producing the bacteria; claims for an inoculum comprised of a carrier material floating on water such as straw, and the new bacteria; claims to the bacteria themselves. The Patent examiner allowed the first two types of claims but rejected the claims for the bacteria. His decision rested on two grounds: (1) that microorganisms are "products of nature" and (2) that as living things they are not patentable subject matter under 35 USC § 101.[45]

Chakrabarty appealed the rejection of the claims to the Patent Office Board of Appeals. The Board reversed the examiner on the first ground, agreeing with the appellant that the claimed bacteria were not naturally occurring, but affirmed the examiner on the second ground. The Board's conclusion that § 101 did not include any living organism rested on their belief that Congress did not so intend. This, they concluded, was evidenced by the legislative history of the United States Plant Patent Act 1930, in which Congress extended patent protection to certain asexually reproduced plants—indicating that it did not consider that living things were already covered by 101.[46]

On appeal the United States Court of Customs and Patent Appeals, by a divided vote, reversed the Board's decision.

[44] DeMott, *loc. cit.*, 38.
[45] *Diamond* v. *Chakrabarty*. Unreported judgement of the Supreme Court of the United States. No. 79-136, 16 June 1980.
[46] *Application of Chakrabarty*, supra, 42.

Rich C.J. accepted the appellant's statement of the issue before the Court:[47]

> In the instant appeal, appellants are seeking protection for a *new bacterium* admittedly alive, in which such changes have been effected as to produce in this bacteria new capabilities. The Board of Appeals has agreed that this organism is *not* a *"product of nature"*. If it be accepted that all things in our world are either products of nature or things produced by man, then by the process of elimination the Board of Appeals has agreed with the appellants contention that his new bacterium is a thing produced by man i.e. a manufacture. It should follow, therefore, that . . . appellant has *already* met the requirements of section 101. [emphasis added]

This argument was accepted in the Court's prior decision *Application of Bergy*,[48] (a patent application for a pure culture of the microorganism *Streptomyces vellosus* found to be useful in the production of the antibiotic linomycin), which Rich C.J. regarded as being the controlling precedent in *Chakrabarty*.

At the end of his opinion Rich C.J. pointed out that the only asserted objection to the patentability of the *Pseudomonas* microorganisms was that they were alive and for that reason alone not within one of the categories of patentable invention.[49] This objection was rejected in *Bergy* on the ground of public interest. It was recognised that microorganisms had become important tools in the chemical industry especially pharmaceutics:[50]

> . . . and when a new useful tangible industrial tool is invented which is unobvious so that it complies with the prerequisites to patentability other than the enumerated statutory categories we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from section 101 categories on the sole ground that it is alive. . . . We think it is in the public interest to include microorganisms within the terms "manufacture" and "composition of matter". In short we think that the fact that microorganisms as distinguished from chemical compounds are alive is a distinction without legal significance. . . .

A second ground for the rejection of this argument was based on the illogical situation which its acceptance would produce. A biologically pure *culture* would be unpatentable for the reason that it was alive yet the functioning of a living organism and the utilisation of its life functions in a *process* would not affect their patentability under section 101.[51]

Markey J., concurring, was of the opinion that the appellant's invention fell squarely within the language of the statute:[52]

> There are but two sources for manufactures and compositions of matter God (or nature if one prefers) and man. As presented to us, the invention is admittedly a manufacture by man.

The sole issue, therefore, was whether the appellant's invention, admittedly novel, useful and unobvious was unpatentable solely because it was alive. On looking at the purpose of the legislation: to recognise

[47] *Ibid.*, 43.
[48] 563 F 2d. 1031 (1977).
[49] *Application of Chakrabarty,* supra, 42.
[50] *Application of Bergy,* supra, 1038.
[51] *Ibid.*, 1037.
[52] *Application of Chakrabarty,* supra, 44.

the exclusive rights of inventors in their discoveries for a limited time to encourage progress in the useful arts, he concluded that it would defeat this fundamental purpose if the Court was to interpret the Statute as though it included the word "dead".[53]

Baldwin J. dissenting, defined the issue before the Court in somewhat different terms. Given that the unmodified organism would be unpatentable,[54] he saw the Court as being faced with the decision as to whether or not the appellant's modification of the microorganism *Pseudomonas* was sufficient to render it statutory subject matter.[55]

The majority based its decision on the premise that the modified microorganism must fall into one of two categories: man made or product of nature. If it could not be brought into the second then it must be man made and therefore a manufacture. Baldwin J. was of the opinion that merely because a thing is man made does not mean it is a manufacture.[56] He defined three categories: products of nature; things sufficiently modified so as not to be products of nature but not sufficiently modified as to be statutory manufactures; manufactures.

In deciding the amount of modification required to convert admittedly unpatentable subject matter into patentable subject matter he applied the test that the essential nature of the natural product must be substantially altered. The following sequence of 'logic' was then applied. Has there been a substantial modification of the essential nature of the organism? The essential nature of the organism is its animateness or life. The applicant has not changed the essential nature he *has not created new life.* Adding one extra plasmid thereby increasing the bacteria's efficiency at cleaning up oil spills does not exclude the new organism from the classification as a mere product of nature.[57]

The second case which dealt with this question was *Ranks Hovis McDougall Limited* v. *The Controller of Patents and Trade Marks*[58]

Two months after the *Chakrabarty* appeal the issue of whether microorganisms per se should be patentable, came before the High Court of Ireland.

[53] *Idem.*

[54] The same situation obtains in New Zealand. Patents Act 1953 s.10(7) provides "Where a complete specification claims a new substance no claim shall be construed as extending to that substance when found in nature". Even if it is argued that a microorganism is not a 'substance' it is submitted that a microorganism found in nature could not fulfil the requirements of the Statute that at the date of the application being filed the subject matter of the application be new or novel in New Zealand.

[55] *Supra,* 44.

[56] *Idem*: "Manufacture and man made are not synonymous for patent purposes".

[57] *Supra,* 45. Miller J. also filed a dissenting opinion based on the same reasoning as that adopted by the Board: that Congress did not intend patentability of such subject matter—evidenced by the legislative history of the Plant Patents Act of 1930.

[58] [1978] F.S.R. 588.

Section 6 of the Patents Act 1964 (Ireland) provides:

> An application for a patent may be made by any person who claims (a) to be the true and first inventor of the invention to which the application relates. . . .

Section 2 of the Act provides that the term "invention" means:

> . . . any new and useful art, process, machine, manufacture or composition of matter, and includes an alleged invention and also any new method or process of testing applicable to the improvement or control of manufacture.

Section 9 (7) of the Act provides:

> Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature.

The appellant's application requested the grant of a patent entitled: "Improvements in or relating to microorganisms". The applications related to strains of a microorganism: claim 1 of the specification being *"Fusarium graminearum schwabs"* deposited with the Commonwealth Mycological Institute and assigned number IMI 145425 and variants and mutants thereof"; claims 2-7 being for specific organisms with different deposit numbers and claim 13 being "Fungal cultures containing *Fusarium graminearum schwabs* IMI 145425 or mutants and variants thereof substantially as described with reference to any one of examples 6 to 11 hereinbefore set forth"; and also to methods or processes of production.[59]

While the appellant's method of production of the microorganisms is not detailed in the decision it is probable that the process of mutation explained previously was undertaken. McWilliam J. made the following statement:[60]

> The value of this microorganism is that it provides edible protein which it is hoped can be developed on a commercial scale to supplement the animal and vegetable sources of protein for food. The plaintiff produced this new strain of microorganism by techniques which were laborious and expensive. The process of producing this new strain has been described in the affidavits and correspondence before me but it is sufficient to say that it entailed the selection of a soil sample from which a microorganism was isolated and that the selected microorganism was then *altered* by varying the composition of culture media in which it was grown or 'cultivated'. The elaborate processes by which the final microorganisms were produced do not occur in nature and I accept that these microorganisms would not occur naturally and, when developed, could not serve the purpose of producing edible protein for consumption unless handled in laboratory conditions and provided with the correct nutrients. On the other hand, they are described in an affidavit filed on behalf of the plaintiff as "living cells' and I also accept that they are a form of life, albeit a very low form. [emphasis added]

The application was granted by the examiner in so far as the methods and processes of production were concerned but refused in so far as it related to the microorganisms themselves (claims 1-7 and 13).

On appeal to the High Court of Ireland, McWilliam J. determined as a preliminary point that, bearing in mind the provisions of section 9(7), the product at claim 1 of the specification was an unaltered

[59] *Ibid.*, 590.
[60] *Ibid.*, 591.

substance occurring in nature and should be excluded.[61]

On the central issue of whether the microorganisms fell within the statutory definition of "invention"[62] the judge, after referring to various dictionary definitions of "manufacture" and "composition of matter" (held to mean "put together", "made" or "constructed"), rejected that the microorganisms—albeit that they were provided with artificial conditions so that microorganisms that would not be found in nature were caused to exist—fell within either of these terms. He held that the microorganisms "grew" or had been "caused to grow"—grow being distinct from manufacture or composition of matter.[63]

In relation to the two American cases of *Bergy* and *Chakrabarty* McWilliam J. observed that these focussed entirely on the question of whether living matter was patentable and did not consider whether the microorganisms were "compositions of matter" or had been "manufactured". The *Chakrabarty* decision accepted that all things could be classed as man made or nature made. If the microorganisms did not occur in nature they were man made and therefore a manufacture. McWilliam J. concluded in *Ranks Hovis* that merely because a substance has been produced by man does not mean that it has been manufactured within the meaning of the Statute and that the microorganisms in question had not been manufactured they had been "grown".

The two matters emphasised by the majority judgement in *Chakrabarty*—illogicality and public interest—he did not feel obliged to take into consideration:[64]

> With regard to the former, it is to be noted that, in both the Irish and American Statutes, "processes" are not related to "manufacture" or "composition of matter", from which it would appear to follow that a new and useful process for a purpose other than manufacture or composition of matter may be patented and that there is a distinction in this respect between the grant of a patent for a process and the grant of a patent for the product of that process.
>
> With regard to the latter, I fully accept that it is or may be in the public interest to grant a patent for new microorganisms but, as was pointed out in the dissenting judgement in that case, this is a matter for the legislature and not for the Courts, and I have to decide what the legislature did enact and not what it intended to enact or ought to have enacted.

McWilliam J.'s criticisms of the *Chakrabarty* decision were answered in June of this year. On application of the Government, following the decision of the Court of Customs and Patent Appeals the Supreme Court of the United States granted a writ of certiorari

[61] *Ibid.*, 592. The judgement is in this respect ambiguous. The finding as to the applicability of s.9(7) was made only in respect of claim 1—presumably therefore, this claim was for the unaltered bacteria as originally isolated from the soil, although the claims as set out in the judgement do not appear to be substantially different.

[62] It was not contended that the subject matter was not both "new" and "useful".

[63] *Supra*, 592.

[64] *Ibid.*, 593.

"to determine whether a live, human made microorganism is patentable subject matter under 35 USC 101".

The issue was simply stated: "The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 USC 101 . . . specifically we must determine whether respondent's microorganism constitutes a "manufacture" or "composition of matter" within the meaning of the Statute".[65]

The decision was viewed with interest the world over. On it depended the outcome of a large number of applications for microorganisms, the products of genetic engineering activities in companies and university laboratories both in the United States and abroad.[66]

Beginning with the language of the Statute the Court read the term "manufacture" in accordance with its dictionary definition to mean "the production of articles for use from raw materials prepared by giving these materials new forms, qualities, properties or combinations whether by hand, labour or by machinery" and "composition of matter" to include all compositions of two or more substances and . . . all composite articles, whether by the results of chemical union, or of chemical mixture, or whether they be gases, fluids, powders or solids. . . ". In choosing such expansive terms as "manufacture" and "composition of matter" modified by the comprehensive "any", Congress, it was concluded, plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history up to the 1952 Act was outlined as indicating that a broad construction was intended. It was observed that the Committee Reports accompanying the 1952 Act indicated that Congress intended statutory subject matter "to include anything under the sun made by man".[67] However the Court added:[68]

> This is not to suggest that section 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. . . . Thus, a new mineral discovered in the earth or a new plant found in the wild is not a patentable subject matter. Likewise Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none'.
>
> Judged in this light, respondent's microorganism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character [and] use.

By way of reinforcement it was added:

> . . . the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature's handiwork but his own; accordingly it is

[65] *Diamond* v. *Chakrabarty*. Unreported judgement of the Supreme Court of the United States No. 79-136, 16 June 1980.
[66] DeMott, *loc. cit.*, 38; Wade, *loc. cit.*, 31.
[67] *Diamond* v. *Chakrabarty*, supra, 4.
[68] *Idem.*

patentable subject matter under [section] 101.

Is a thing found in nature but modified by man, man made—given that man does not create its original state of "being alive"? What if one introduces the additional premise that man modifies the living thing yet relies on that living thing's continuing life processes to give any beneficial effect to the modification—reproducing, thereby reproducing the modification, say? Could one justly conclude that there are now three categories of life: man made; God made; man-assisted-God-made? Philosopher's paradise one might say. All a bit metaphysical and absurd when one considers that the theoretical purpose of the Patents Act is to encourage "Practical Man".

There must surely be a more practical approach to deciding how the patent legislation itself is to be applied than embarking upon such ingenious semantic contortions as have been performed by the judges who have been faced with the issue thus far.

The answer *appears* to lie in the *NRDC*[69] case. That decision, recall, emphatically rejected the kind of approach subsequently adopted by McWilliam J. in *Ranks Hovis* and the Supreme Court in *Chakrabarty* of asking: Is this a manner or kind of manufacture? Rather, the correct question to ask is whether the invention claimed is a proper subject of letters patent according to the principles developed for the application of section 6 of the Statute of Monopolies.[70]

The word "appears" is stressed because in its judgement the High Court of Australia seemed to refer to two exceptions to the broad proposition they outlined. Firstly, processes for treating diseases of the human body (since dealt with by Davison C.J. in the *Wellcome Foundation* case[71]). Secondly,[72] towards the end of the judgement, the Court deals with ". . . the Commissioner's contention that even apart from the considerations which we have discussed agricultural or horticultural processes are by reason of their nature outside the limits of patentable inventions.[73] In relation to this the Court made the following statement:[73a]

It may be conceded however that if there were nothing that could properly be called

[69] *Supra.*
[70] Ante.
[71] *Supra.*
[72] One commentator has also concluded that there was a second category of exception he defined it in the following terms: "Processes in the field of animal husbandry and cultivation of plants where the end result is not a result of the process but the inevitable result of that which is inherent in the animal or plant" but he pointed out that the Court referred less clearly to this second category and that it was doubtful that his summation of the Court's views was correct: A.C. King Q.C., "Judicial Consideration of the Patentability of Methods and Processes since the *NRDC* case". Industrial Property Seminar conducted in the Law School at Monash University, 7 October 1972.
[73] *Supra,* 146.
[73a] *Idem.*

> a product of the process, even an ingenious new departure would be outside the limits of patentability. In *RHF*'s application Morton J. approved a statement of the examiner which had been made to illustrate that the vendible product test enunciated in the *GEC* case was not definitive. The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation do not result from a process which is a "manner of manufacture". This may be agreed. However advantageously man may alter the conditions of growth the fruit is still not produced by his action".

This would appear to be exactly the conclusion which McWilliam J. arrived at in the *Ranks Hovis* case: the resultant microorganism was not the product of a "manner of manufacture" but a result of something inherent in the organism—"it grew".

It is submitted that this point may justly be dismissed as academic. The Court's whole consideration of the Commissioner's contention was ambiguous and any attempt to apply it in the area of man-altered microorganisms (even assuming it would be just to categorize them with fruit and growing crops) is bound to lead one back into the labyrinth of philosophical thought. Its acceptance would signify a return to the kind of arguments considered in the *Ranks Hovis* and *Chakrabarty* cases.

The original question outlined must therefore be answered. Is this a proper subject of letters patent according to the principles developed for the application of section 6 of the Statute of Monopolies? In relation to this Davison C.J. in the *Wellcome Foundation* case stated:[74]

> But in applying the test as set out in the *NRDC* cases as to whether or not the present application is the proper subject for the granting of letters patent under the Act, it is not only the element of inventiveness that must be considered but also the purpose of the Act and the Statute of Monopolies. Section 6 of the Statute of Monopolies requires that the process concerned be not contrary to the law, or mischievous to the State, by raising the prices at home or hurt of trade, or generally inconvenient.

The outline of the scientific principles and techniques behind genetic engineering of microorganisms, previously given, must establish that the requirement of inventiveness is fulfilled. It has also been established that the research and resultant technology comes within that category of undertakings which it is the purpose of the patent system to encourage.[75] It could not be described as "contrary to law"—meaning anything designed to be used for an illegal purpose e.g. implements for housebreaking, picking pockets, locks etc.[76] It remains to be considered whether "genetic engineering" could be described as "mischievous to the State" or "generally inconvenient".

In the *Ranks Hovis* case it was argued that practical difficulties stand in the way of allowing patents for living organisms.[77] The examiner stated that he found it difficult to see how publication after acceptance could be effected. "How . . . may any interested person

[74] *Supra*, 44.
[75] Ante, 10.
[76] *Wellcome Foundation* v. *Commissioner of Patents*, supra, 44.
[77] *Ranks Hovis McDougall* v. *The Commissioner of Patents*, supra, 591.

obtain samples with a view to testing if the invention works or perhaps infringes some process he has protected with a view to opposition proceedings. . . ? It is also difficult to see how the invention is to become available to the public at the end of the term of the patent."[78] To these can be added the old contention that microorganisms cannot be the subject of a precise written description in a patent specification.[79]

These difficulties have to a large extent been overcome in foreign jurisdictions. At or before the time that the patent application is filed a culture is required to be deposited in an established culture collection where it is preserved for future verification.[80] This in itself creates problems.[81] Bearing in mind that third parties could abuse this procedure by acquiring a strain from the collection, producing some other strain e.g. by mutation, and using the latter on an industrial scale, the decision must be made as to when or under what conditions the microorganism should become available to third parties. The European Patent Office for example, has just modified its rules in this regard, removing some of the pre-existing inequities, by providing that access to the strain is to be limited to an independent expert acting on behalf of third parties. The expert, who must be on an official list of recognised experts, is also bound by certain conditions—including retention of the strain exclusively in his hands. His appointment must be by mutual agreement between the applicant and the party requesting the strain.[82]

The further objection—that microorganisms are unstable and fail to reproduce identically thereby creating uncertainty as to the patent claim coverages and therefore confusion on the issue of infringement,[83] also appears to be illfounded. It apparently arose before the current practice of placing a culture in a depository and was obviously inter-twined with the difficulty of identifying the precise microorganism described in a written specification where there was no sample available for verification. ". . . [T]he science of microbiology has sufficiently progressed that instability is no more a problem than it

[78] *Idem.*

[79] See Patents Act 1953 (N.Z.), ss.21(1)(9); 41(1)(h); 41(1)(b).

[80] See *The British Patent System, Report of the Committee to Examine the Patent System and Patent Law,* op. cit., 164-165, Irons and Sears *loc. cit.,* 323.

[81] Discussed in several papers at the Budapest Conference 1973 on industrial property: Proceedings of the Hungarian Association for the Protection of Industrial Property —*Conference on Some Topical Questions Concerning Protection of Industrial Property,* Ed. Takats: Szabo, "The scope and value of protection in the microbiological field" 426-429; Bellenghi, "The need for an international institute for the deposition of microorganisms" 437-439; de Brabanter, "Patentability of microbiological inventions in the Benelux countries" 410-411; Palagyi, "About the problems of patenting microbiological inventions in Hungary from the point of view of a practising patent attorney" 402.

[82] Crespi, "Patenting nature's secrets and protecting microbiologists interests". Nature vol. 284, 17 April 1980, 590.

[83] Irons and Sears, *loc. cit.,* 323.

is in other branches of technology. Microorganisms are routinely reproduced true to form. Indeed true reproduction is essential to industrial procedures".[84]

While these practical difficulties (for example arising out of the depositing of microorganisms in culture collections—accessibility to such microorganisms, and the necessity for independent verification) could aptly be described as "inconvenient", the inconvenience is to the Patent Office, the applicant, and the opponent and not a general inconvenience to the State, as it is submitted is envisaged by the language of section 6 of Statute of Monopolies.

There is, however, an adjunct to recombinant DNA technology which has not previously been dealt with in this paper and which could arguably come within the term "general inconvenience".

In September 1973 a letter from a group of Scientists working in this field was published in several leading scientific periodicals.[85] It recognised that, although no hazard had to that date been established, hybrid molecules, the product of recombinant DNA technology could prove hazardous to laboratory workers and to the public.

The letter provoked extensive discussion about the reconstruction of DNA molecules and their reintroduction into microorganisms that might, inadvertantly, be released from the laboratory. Fears of other potential hazards were expressed:

> The quickest way to build a library of cloned gene sequences is the controversial technique of shot-gunning—breaking up the entire genome of an organism with restriction enzymes, plugging the individual fragments into plasmids or phage, and then growing all of them up within suitable bacterial hosts. Shot-gunning was controversial. . . . Who could tell, went the argument, whether one of these random genes, introduced on a plasmid into something like *E. coli* might not suddenly render that bacterium hazardous to humans (or for that matter, some other unfortunate resident of the biosphere).[86]
>
> If DNA sequences were in fact so interchangeable, might a random bit of, say, toad DNA begin to reprogram, in some altogether unforseen fashion, a previously benign soil bacterium?[87]
>
> . . . There may well be a fairly crucial reason for the division of all living organisms into the two great groups of the lower prokaryotes and the higher, nucleated, eukaryotes. While prokaryotes, like bacteria, regularly wreak havoc with the internal functioning of eukaryotes, like human beings, Sinscheimer argued that there had never been, in the past, any real generic transfer between the two groups. If, hypothetically, some eukaryotic DNA control sequence was grafted into a prokaryotic parasite like bacteriophage, might it suddenly prove that such a modified phage, previously only a threat to bacteria, would find itself able to colonise human cells as well?[88]

The scientists simply did not know the answers to the questions. In fact some of the scientists themselves were among the critics of the course which recombinant DNA, and its attempted regulation, was

[84] *Ibid.*, 324-325.
[85] Science, 21 September 1973.
[86] Rogers, *op. cit.*, 136.
[87] *Ibid.*, 155.
[88] *Ibid.*, 198.

taking. They too were asking the questions: "Have we the right to counteract, irreversibly, the evolutionary wisdom of millions of years, in order to satisfy the ambition and curiosity of a few scientists? How far will we want to develop genetic engineering? Do we want to assume the basic responsibility for life on this planet—to develop new living forms for our own purposes? Shall we take into our hands our own future evolution?[89]

Recombinant DNA became a major controversy in the United States. Public hearings were called in many cities—in some cases accompanied by a moratorium on all recombinant DNA work while the subject was in issue. In retrospect it may be that the public failed to direct its questions at the potentially more dangerous aspect of recombinant DNA. To quote the words of one of the foremost scientists in the field:[90]

> Although it now seems likely that members of the scientific community who plan to do this research have accepted a set of guidelines that maximize benefits and minimize hazards it is far less certain that similar guidelines have been or will be established to guide the commercial applications of this technology or the misuse of the technology for the preparation of military weapons. For these reasons I remain apprehensive.

However, when the *Chakrabarty* decision went to the Supreme Court[91] the opponents of recombinant DNA research were once again presented with the opportunity to voice their concern. It is submitted that the answer given to their contentions by the Supreme Court is the answer which should be given to any objection, based on section 6 of the Statute of Monopolies that patentability of microorganisms, the products of recombinant DNA, would be "generally inconvenient" or "mischievous to the State" as encouraging potentially hazardous research the products of which could be disaster for the notorious "future generations". The passage is quoted at length as being probably the most worthwhile in the judgement:[92]

> To buttress its argument, the Government, with the support of *amicus,* points to grave risks that may be generated by research endeavours such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may product pollution and disease. That it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better "to bear those ills we have than to fly to others that we know not of".
>
> It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under section 101. We

[89] *Ibid.,* 194.
[90] Curtiss, "Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards" Ann. Rev. Microbial. 1976, vol. 30, 507, 531.
[91] *Diamond* v. *Chakrabarty* supra.
[92] *Ibid.,* 12.

> disagree. The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by lack of incentives but that is all.
>
> What is more important is that we are without competence to entertain these arguments—either to brush them aside as fantasies generated by fears of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the kind of investigation, examination, and study that legislative bodies can provide and Courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the government, the Congress and the Executive, and not to the Courts.

In short, the Patents Act does not provide the correct context and Courts are not a suitable forum for considering and passing judgement upon issues of such magnitude.

It is submitted that there is no reasonable ground for denying patent protection for microorganisms, the products of recombinant DNA research—even though there is some scepticism as to the practicality of such patents. It has been observed for example, that "it will be awfully hard to show uniqueness, to prove that one man's microbe is really different from another's".[93] "If an engineered microorganism such as the oil-spill eating *Pseudomanas* can survive in nature (i.e. successfully compete and reproduce) then what is to prevent someone from making isolations of that microorganism down-wind or downstream (for we all know how easily microorganisms can be transported) and taking the isolate elsewhere mutating or recombining the organism and claiming it is a natural isolete? What is to keep the organism genetically pure and recognisable? What is to prevent it recombining with other microorganisms and thereby reproducing a new lot of microorganisms with the desired property?"[94] One article appearing in a recent science periodical took the matter even further —quoting the following paragraph as an example of "the kind of speculation that lawyers get high on":[95]

> The familiar terms and concepts of the patent law are not easily adapted to the patenting of living microorganisms that reproduce themselves. The microorganisms themselves presumably would not infringe the patent by reproducing (and thereby manufacturing) themselves without a licence and a human being who himself becomes infected or whose plant or animal (or whose food, liquid etc.) becomes infected presumably would not become an infringer merely by providing the medium in which the microorganisms propagate (at least if he does so unintentionally and takes reasonable measures to curb the growth of the infection—and does not use the microorganisms in any way). But the very fact that living organisms may

[93] DeMott,*loc. cit.*, 39 quoting James Watson, Nobel laureate as co-discoverer of the structure of DNA.

[94] B. Terzaghi, scientist in the Genetic Engineering Plant Physiology Division of the DSIR commenting upon the appropriateness of patents on recombinant organisms.

[95] Wade. *loc. cit.*, 32.

reproduce in ways and places uncontrolled by the patentee or his licensees and perhaps in profusion suggests that patent grants on the organisms themselves would be unprecedented in scope.

There has obviously been very little experience to date in any large scale practical utilization of microorganisms, the products of recombinant DNA technology. There may ultimately prove to be some basis to the arguments outlined—that it would be impossibly difficult to police and enforce any patent in respect of a microorganism which is intended to be released into the environment, such as Chakrabarty's *Pseudomonas*. But it is submitted that in many other areas where these microorganisms will be used, e.g. the pharmaceutical industry, such difficulties, in practice, will not arise. In considering their patentability such microorganisms should be seen for what they are—useful industrial tools.

Many scientists are sceptical about the effect which patents will have on their work. They fear that bacterial strains will be kept out of circulation for considerable periods awaiting patent grants;[96] that fellow workers will be cautious about sharing information—they forsee genetic engineers from Universities, for instance, refusing to share research results with colleagues with an eye to the eventual commercial gain they stand to make as partners and stockholders in commercial genetic engineering companies;[97] some deprecate the emphasis which they consider that patentability of the microorganisms will place on money rather than learning, improving the quality of life, or environmental concerns.[98]

It is submitted that patentability would have a generally beneficial effect—encouraging continued research and the ultimate commercial application of recombinant DNA technology to the benefit of the general public. The Report of the Committee to Examine the Patent System and Patent Law (Britain) had this to say on the value of patents:[99]

> We have found general acceptance that the act of invention and the development of new ideas is inherent in the human mind and would continue without any legal protection for the results. As, however, a patent system increases the possibility of reward for the successful exploitation of inventions there can be little doubt that it does play a part in encouraging individuals to invent and organisations to create conditions in which inventions can be made. But the basic aim of a patent, and indeed its effect, is to encourage the successful industrial application of inventions. The man with the resources can normally be expected to put those resources to use without special assistance in established fields, where he can be reasonably assured that his factory will work technically and where the demand for his product is already known to exist. If, however, resources are to be put at risk to develop a new process or product, which has yet to be tested, then he will hesitate lest the expense of the development may prove to be irrevocable while his competitors can wait and.

[96] DeMott, *loc. cit.*, 39.
[97] *Idem*: "Questions Raised by Right to Patent Life Forms". *New Zealand Herald*, 7 July 1980, 6.
[98] Terzaghi see n.94; DeMott, *loc. cit.*, 39.
[99] *Op. cit.*, 10, para. 56.

> without equivalent expense, pick up and use the successful results. It is the knowledge that patent monopoly will enable him to hold off competition for a period which encourages him to take the risk and use the resources to develop new industrial inventions.

It is hoped that the consideration of this subject has at least demonstrated its importance. The magnitude of the implications of microorganisms and genetic technology could well stand on a par with mechanisation and the silicon chip.[1]

It is submitted that the subject merits a more discerning approach than has thus far been accorded by the judiciary or for the most part, the media.

Its solution does not lie in attempting to determine whether it is God or whether it is man who has "invented", within the terms of a Statute, any one microorganism but in an objective appraisal of the possible costs as opposed to the definite benefits of allowing patents to be granted for such subject matter.

Because this paper has touched on various aspects of science, law and philosophy it is perhaps fitting to conclude it in the same manner that a professor of international law commenced his address to the group of scientists who gathered to discuss the fears that they held as a result of the initial recombinant DNA experiments; A scientist and a lawyer are arguing about which of theirs is the older profession. The argument goes back and forth, from Pericles to Hippocrates to Maimonides to Hammurabi, until it reaches all the way back to God. God, the scientist states, must have been a scientist to have brought order out of chaos. Yes, the lawyer responds, but where do you think the chaos came from?[2]

[1] Chance for N.Z. Scientists to Try New Field". *New Zealand Herald*, 20 August 1980, p.6.
[2] Rogers, *op. cit.*, 77 per Capron, University of Pennsylvania.