

COMMISSIONER'S DECISION

Subject Matter - Sec. 2 - Activated Sludge

The rejection of claims to a fungal culture because they would protect living matter was withdrawn. Following the lead in the U.S. Chakrabarty case, and in other cases, it was decided to allow claims to new life forms provided they meet the other requirements of patentability. This is a change from earlier Office practise. Rejection reversed.

Recently the United States Supreme Court ruled in the Chakrabarty case (Diamond v Chakrabarty, June 16, 1980) that certain new life forms are patentable under American patent law. The decision has provoked considerable controversy, and raises the question as to whether under the Canadian Patent Act the same subject matter is also patentable. The issue has now come before the Patent Appeal Board for consideration, but with this difference. Whereas Chakrabarty sought to protect a mutant strain of bacteria, we must consider a somewhat higher life form, viz a mixed fungal yeast culture system.

The question has come to a head in an application for patent made by the Abitibi Company of Toronto for a Foam Flotation Activated Sludge Process. Abitibi is the assignee of the inventors, James E. Zajic, Martha A. Hill, Donald F. Manchester, and Karel Muzika, who carried out their work at the University of Western Ontario in London. The application was filed on July 16, 1976 under serial number 257,177, and put in class 362, subclass 16. When the application was rejected by the Examiner, the Applicant requested an oral Hearing before the Board, and that took place on March 11, 1981, at which time Mr. David Watson, Q.C., represented the Applicant.

The invention is for a process for biodegrading spent sulfite waste liquor from the manufacture of wood pulp. The process claims have been found by the Examiner to be allowable. He has, however, rejected claims 4 and 5, the latter of which reads as follows, and is illustrative of what is refused:

5. A microbial culture system acclimatized to SSL and having five principal components, all fungi, which have been identified through isolation and accepted taxonomical procedures as the following:

1. Phialophora jeanselmei (Langeron) Emmons (ATCC 20,482)
2. Phialophora richardsiae (Nannfeldt apud Melin & Nannf.) Conant (ATCC 20,483)
3. Hyalodendron lignicola Diddens (ATCC 20,484)
4. Trichosporon infestans (Moses & Vianna) Ciferri & Redaelli (ATCC 20,485)
5. Candida tropicalis (Castellani) Berkout (ATCC 20,486)

(The abbreviation "SSL" stands for spent sulphite liquor)

It may be noted that the species of yeasts listed as components of the mixture are both old and known. What the inventors have done is to take the known microbial culture from domestic sewage and modified or acclimatized it to sulfite liquor. The acclimatized culture can then be used to digest spent sulfite liquor from pulp plants, thus purifying it, so the effluent liquor can be discarded without contaminating waste streams. The new culture is particularly effective with foaming wastes, which previously have been difficult to purify. It will reproduce itself on spent sulfite liquor, and thus supplies are maintained.

The Examiner rejected the claims to the yeast culture under Section 2 of the Patent Act, holding that living or viable matter is not patentable subject matter within the meaning of that section.

For his part, the Applicant contends that the yeast culture is a man-made product, and thus satisfies the reference in Section 2 both to a "manufacture" and a "composition of matter." He relies heavily upon the recent U.S. jurisprudence in Chakrabarty, supra, and in re Bergy, a decision of the United States Court of Customs and Patent Appeals, decided March 29, 1979. He further makes an extensive submission relative to the patentability of processes in which living matter is involved, suggesting that since processes

using microorganisms are patentable, the microorganisms themselves should be accepted.

When the Statute of Monopolies, from which modern patent systems developed, was enacted in 1623, it was intended to encourage and protect the manufacturing industries, which at that time were thought of as relating to the production of inanimate objects such as textiles, machinery, soap, tools and the like. It was not until 1926 in the Commercial Solvents case (Commercial Solvents v Synthetic Products 1926 RPC 43, in which Weizmann's process for using bacteria to produce acetone was held valid), that bacteriological processes using living organisms were considered patentable in the United Kingdom. In 1956, in Szuec's Application, 1956 RPC 25, a process to grow mushroom tissue was held allowable. The bar still stood firm however, against patents for living organisms themselves, such as bacteria or plants. By 1960, in the General Electric case, 1961 R.P.C. 21 at 22, the U.K. Patent Office said:

The Office has always set its face against the treatment per se of the higher or more advanced forms of life. Claims have, however, been allowed for novel methods of preparing hormones, vaccines, &c., which include as a preliminary step the treatment of a living animal. In the case of the lower forms of life, claims have been allowed for the cultivation and treatment of yeast, and of moulds to be used for antibiotic production. Also, Mr. Watson referred to Szuec's Application (1956) R.P.C. 25 in which the cultivation of edible mushroom tissue was approved.

I feel that the Office, on the whole, has acted liberally in construing "manufacture" to include living matter, even though of a low order. Practice has, in fact, been taken further than that regarded as acceptable in the matter of Commercial Solvents Corporation v. Synthetic Products Company Ltd. (1926) 43 R.P.C. 185, which is often cited as the authority for the grant of patents relating to bacteriological processes; therein, as I understand the matter, the claims of the patent which was held to be valid were for the production of chemical compounds (acetone and butyl alcohol) by a process based on the use of bacteria. As I have indicated, patents have, in fact, been granted for bacteriological, &c. processes wherein the product of the process claimed is not inanimate matter, but a living substance, the justification for this being, I think, either that the substance would be regarded by the ordinary man as something to be bought and sold and used as are most other commodities, yeast, as I have said, being a case in point, or that it is to be employed directly for the manufacture of something vendible.

I feel, however, that this should be the limit of construction of "manufacture" in this field, for I think that it is straining the term too far to include therein artificial mutants of living organisms not specifically associated with manufacturing processes.

On appeal, the Patent Appeal Tribunal said (ibid, p.25):

It is plain therefore that this appeal illustrates one more facet of the difficult problem of the content of the expression 'manner of manufacture' and is in part made more difficult because of the employment in the process of living organisms. A long established Patent Office practice has prevented the acceptance of claims directed to the treatment of the more advanced forms of life, a practice applied substantially by rule of thumb methods, derived from a time when the many gradations of living forms were not as fully apprehended as is now possible. More recent developments, such as the identification of the active constituents in materials commonly used in manufacturing processes, for example, yeast, and the increasing use of bacteria in the production of commercially saleable materials, for example, acetone, have demonstrated the inapplicability of the rule to all living matter if the statutory requirement of "manner of manufacture" is not to be part denied. In consequence, Hearing Officers have apparently been disposed to seek some dividing line by which a division between higher and lower forms of living matter could be drawn with precision and thus to render this "rule" more convenient of application.

For my own part, I can find no advantage in the adoption of any test other than that which the Act and its predecessors have consistently laid down. Nor, in the present case, could such other be applied with advantage. For if it be conceded, as it is, that the mutation of lactic streptococcus cannot be excluded from a properly drafted claim, there can be no justification for regarding comparable micro-organisms as unsuitable for inclusion.

This lead D.M. Gaythwaite to say in Patents for Microbiological Inventions in the United Kingdom, as reported in Industrial Property Law 1977 at p.466:

Historically the approach taken by the Patent Office was that 'manufacture' could not include living matter or methods involving the treatment of living organisms (G.E.C.'s Application 60 R.P.C.1).

By 1973 we come to the American Cyanamide v Berk Pharmaceutical decision (1973) Fleet Street Reports, 487, where the High Court held that a process for production of an antibiotic using certain microorganisms is patentable subject matter. At the present time the U.K. Patent Office will accept claims to microbacterial strains and mutants and even to isolates of naturally occurring strains (Gaythwaite, supra, p. 467).

Historically United States Patent Practise had also stood against patents for new life forms. See, for example, H.C. Wengers remarks in Product Protection for Novel Microorganisms, I.I.C. (International Review of Industrial Property & Copyright) Vol. 3, 1974, p.285.

...due to the "product of nature" prejudice developed in large part from the dicta of Mr. Justice Douglas in Funk Brothers Seed Co. v. Kalo Inoculant Co. claims of this type [microorganisms] have generally not even been presented;

We refer also to W. Behringer's comments in Microorganism Patents, J. Chartered Institute of Patent Agents, London, Vol. 10, No. 2, November 1980 (Also reported in 63 JPQS Mar. 1981 at 128):

The Chakrabarty decision marks the first time that the High Court has focused on the question of whether living organisms might be claimed in utility patents [i.e. patents of inventions] in the United States, and it lays to rest the popular conception that that was not possible under the patent statutes. (p.48) (underlining added)

and at p.49

The Patent Office's insistence that bacteria are not patentable subject matter was based largely upon its reading of the history and tradition of U.S. patent practice (underlining added).

Indeed the Chakrabarty application itself was rejected by the Patent Office, and for eight years shuttled back and forth between the U.S. Court of Customs and Patent Appeals and the Supreme Court before the Higher Court settled the issue. Even then the opinion was divided 5-4, with the dissenters holding that the decision of the majority

...Extends the patent system to cover living material even though Congress plainly has legislated in the belief that sec. 101 of the Patent Act [does not encompass living organisms]. It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is expressly true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

In Canada, processes using microorganisms have been considered patentable for many years, both by the Patent Office and the Courts. See American Cyanamid v Frosst, Ex. C.R. 1965, 47 CPR 215, & Laboratoire Pentagone v Parke-Davis 1968 S.C.R. 307 55 CPR 111; In J.R. Short Milling v George Weston 1940 Ex. C.R. and 1942 S.C.R. 187 certain enzyme products, which border upon living matter, were held to be patentable, though the question of whether that type of matter is patentable was not really questioned or considered. The

court limited its attention to other matters, such as obviousness, anticipation and Section 41. To date, however, the Canadian courts have not faced the issue head-on. The present Applicant has been able to point to certain instances where Canadian patents have issued with claims to living or near-living matter, viruses, enzymes, attenuated vaccines, etc. but the long-standing Office approach has been that such subject matter is not patentable (See Manual of Patent Office Practise, Sec. 12.03-01 (a).) It was based on such prior U.K. precedents as In re Rau (1935) 52 RPC 362; R.H.F.'s Application (1944) 61 R.P.C.; Leonard's Application 71 R.P.C. 190; in re H.V. Philipps' Gloelampenfabrieken (1954) 71 RPC 192; in re Goldhaft 1957 RPC 276; in re Canterbury College, 1958 RPC 85; in re American Chemical Paint (1958) RPC 47; and GEC's Application 1961 R.P.C. 21.

Now, however, the Chakrabarty decision casts doubt upon the correctness of that practise. Four of the Chief Justices reached the conclusion that new microorganisms are unpatentable, but the remaining 5, the majority, found that the scope of the terms "manufacture" and "composition of matter" does extend to newly created microorganisms, and that Chakrabarty's invention is patentable because it is a nonnaturally occurring manufacture or composition of matter - "a product of humans ingenuity having a distinctive name, character and use."

We also have before us an Australian precedent in re Ranks Hovis McDougall Ltd. which appears in the Australian Official Journal of Patents, Trade Marks and Designs, Oct. 21, 1976. We find at p. 3918:

In respect of the invention claimed by claim 2, what has 'the inventor' done? What contribution has he made? He has discovered a naturally occurring microorganism and, by altering its conditions of growth, he has changed its morphological characteristics. If that is all that he has done, he has made no useful contribution to the art. On the other hand, I think the situation is quite different if, in producing the variant by some man controlled microbiological process, he has produced a new microorganism which has improved or altered useful properties. To suggest that a patent should be not granted for such an invention would in my opinion hardly accord with the views clearly expressed in the decision in National Research Development Corporation v. Commissioner of Patents. An objection that a claim to a new microorganism, being something living, is not a manner of manufacture is based, in my opinion, on too restricted a view of the meaning of manufacture in section 6 of the Statute of Monopolies.

Since that decision the Australian Office has granted patents on newly created microorganisms (as distinct from newly separated organisms which previously existed in nature).

In Germany two decisions of the Federal Supreme Court are relevant. In ex parte Schreiner, the "Rote Tauber" or "Red Dove" case, Mar. 27, 1969, (see the discussion in IIC Vol. 1, Nov. 1, 1970), it was held that biological processes, including the breeding of animals, may be patentable if the process is reproducible. In a subsequent decision, In re Koninklyke Nederlandsche Gest- en Spiritusfabriek N.V., Mar. 11, 1975 (see the report in 1975 IIC Vol. 6 No. 2, 208 ff), the "Baker's Yeast" case, it was concluded that microorganisms may be patented if the inventor shows a reproducible way to produce it. Furthermore the court held that the microorganism must be reproducible by the method used in the first instance. The requirement would not be met by reproduction from the organism itself (See Patenting Nature's Secrets - Microorganisms, Harold C. Wegner, IIC Vol. 7, 1976, No. 2, p.255 at 244), as, for example from a sample deposited in a culture collection. Strangely enough, the Court allowed a claim to a pressed form of the microorganism, relying upon the culture of the mutant to supply the starting material for the pressing process, since the specification taught how that could be converted to the pressed form.

Finally it may also be noted that other leading Patent Offices, such as those in Japan, now allow patents for microorganisms.

Obviously the answer to the question before us, which once had seemed so clear and definite, has become clouded and uncertain. Throughout the world various judicial bodies, without changes in legislation, have gradually altered their interpretation of statutory subject matter to adapt it to new developments in technologies, and current concepts of industrial activity. The Canadian courts have not stood entirely aloof from this current of change (vide American Cyanamid, supra) and Laboratoire Pentagone v Parke, Davis 1968 S.C.R. 307, 55 C.P.R. 111. Whether this was proper without legislative amendment may be arguable, but on viewing the foment of uncertainty

that has been stirred up, we can no longer be satisfied that at law a patent for a microorganism or other life forms would not be held allowable by our own courts. Since that is the criterion set down on Section 42, without which an application should not be refused, we recommend that the rejection of claims 4 and 5 be withdrawn.

It is of some importance, we think, to recognize how far our recommendation, if accepted, will carry us, and we believe clear guidelines should be set down for the benefit both of applicants and examiners. Certainly this decision will extend to all microorganisms, yeasts, molds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics. That is, for example, the working standard of the Japanese Patent Office (see Japan Patents & Trademarks, No. 27, the Suzuye Report, Nob. 1980):

The standards state that microorganisms, such as, yeast, mold, fungi, bacteria, actinomycetes, unicellular algae, virus or protozoa, can be the subject of patent protection.

We can see no justifiable reason for distinguishing between these life forms when deciding the question of patentable subject matter. Whether it reaches up to higher life forms - plants (in the popular sense) or animals - is more debatable. Certainly the U.S. Court of Customs and Patent Appeals and the U.S. Supreme Court shied away from that extrapolation. For example in the first Bergy decision, In re Bergy et al, U.S.C. CPA, Oct 6, 1977, Judge Kashwa, concurring, said:

I agree with the result and the reasoning of the opinion by Judge Rich joined by Chief Judge Markey. Nevertheless, I wish to emphasize, out of a super-abundance of caution, that I read the majority opinion as setting forth an extremely limited holding. While the PTO and the dissenting opinion raise the specter of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition. Each case must necessarily be considered on its own facts. On the facts of this case, I join the narrower confines of the majority opinion.

The majority opinion stated (at p. 18):

...The nature and commercial uses of biologically pure cultures of microorganisms ... are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses...

...they have come to be used to produce a vast variety of chemicals and drugs such as alcohols, ketone, fatty acids, amino acids, vitamins...and enzymes... In short, microorganisms have come to be important tools in the chemical industry... and when a new and useful tangible industrial tool is invented which is unobvious, so that it complies with the prerequisite to patentability...we do not see any reason to deprive it or its creator or owner of the protection and advantage of the patent system... As for the board's fears that our holding will of necessity, or "logically," make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far fetched."

We ourselves are not persuaded that the idea is so far fetched or so illogical.

If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will, and it is useful (for example to destroy the spruce bud worm), then it is every bit as much a new tool of man as a microorganism. With still higher life forms it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently.

One of those requirements is that the application satisfy Sec. 36. That section requires applicants to describe their inventions fully so

...as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it....

That axiom of patent law has been stressed repeatedly in our jurisprudence.

It was quoted by the Supreme Court of Canada in Western Electric v Baldwin (1934) S.C.R. 570 @pp. 571-573 and repeated as recently as January 19, 1982, by the Federal Court of Appeal in Beecham & Calgon v Proctor & Gamble, at p.9

...the patentee must particularly describe and ascertain the nature of his invention. In order that, after this privilege is expired, the public may be able to do what the patentee has invented, he must particularly describe and ascertain the manner in which the same is to be performed. (22 Hals. 161, Cert. 338)

Section 36 requires that the application should set forth the steps of making the invention, in this case the new microorganism. Now the creation of a new microorganism by mutation, or by other means, is fraught with considerable difficulty, and it is by no means certain that the inventor, or others following his directions, will be able to produce it again using the original method of manufacture. However a microorganism, being living matter, will reproduce itself on the proper culture medium, so that the inventor can maintain his supply indefinitely. If he places samples of the organism in a culture collection to which others have access, they too will be able to reproduce the organism, and thus have access to his invention, and use it once the patent expires. The question will consequently arise: is the deposition of the invention in the culture collection sufficient to satisfy the requirements of Section 36?

We do not see why it would not be. It would certainly permit others to make the invention, i.e. the microorganism. It will enable the public "to do what the patentee has invented," as called for by Sec. 36, i.e. to make the microorganism, and in most instances by the easiest, most certain, most efficient and best mode. This, we think, satisfies the requirement of the Act.

This is indeed the solution accepted by the House of Lords in the case of the American Cyanamid Company (Dannis) Patent, 1971 RPC 42, which recognized that deposition of a microorganism in a national culture collection would be an adequate description of the invention in question because a person of ordinary skill could put the invention into practice.

If deposition of a microorganism in a culture collection is sufficient disclosure of it when an applicant claims a process utilizing that organism, it seems strange indeed to hold it is inadequate when the organism itself is claimed.

In both instances the public needs the organism to work the invention, and in both instances it has it, through the culture collection. What we should be concerned with is making the invention available.

Certainly the inventor should describe his original method of production, and with such clarity that if it can be repeated others could do so. But if the organism can subsequently only be reproduced from itself, we do not see why the inventor should be deprived of his reward provided, by deposition, he makes it available to others. Indeed where it is possible we believe he should make use of both methods of disclosure to reduce the danger of his invention being lost to mankind.

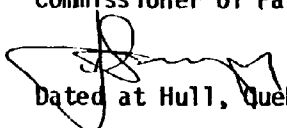
The organism, to be claimed, should not of course have existed previously in nature, for in that event the "inventor" did not create it, and his "invention" is old. It must also be useful, in the sense that it carries out some useful known objective, such as separating oil from sand, producing antibiotics or the like. It cannot be a mere laboratory curiosity whose only possible claim to utility is as a starting material for further research. And it must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity. In the present case we believe the product claims meets these tests, and the objection should be withdrawn.



G.A. Asher
Chairman
Patent Appeal Board, Canada

I have reviewed the prosecution of the application and considered the recommendations of the Patent Appeal Board. I concur with the reasoning and findings of the Board. The rejection is withdrawn. The application is remanded to the Examiner for further prosecution consistent with this decision.

J.H.A. Gariepy
Commissioner of Patents



Dated at Hull, Quebec

this 18th. day of March, 1982

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