COMMISSIONERS DECISION

Subject Matter - Section 2 - Bovine Cell Line

Applicants claim to a continuous cell line useful to produce insulin was rejected as to unpatentable subject matter, being a form of living matter. The claims were allowed for the reasons advanced in C.D. 933. Rejection reversed.

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Patent application 291870 (Class 195-46), was filed on November 28, 1977 by Connaught Laboratories Ltd., of Willowdale, Ontario, assignee of the inventors George M. Healy et al. It is directed to a "Continuous Bovine Beta Cell Line." Claims 1-7 were rejected on October 10, 1980. The rejection was reviewed by the Patent Appeal Board, which held a Hearing on April 15, 1981 to consider the rejection. At the Hearing Connaught Laboratories was represented by Mr. Michael I. Stewart, of the firm of Sim & McBurney.

In claims 1-7 of the application, the Applicant is claiming a new bovine cell line useful to produce insulin. These claims were refused under Section 2 of the Patent Act for being directed to living matter. Claims 3 and 4 are typical.

> 3. A cell culture of a continuous bovine beta-cell line for the production of insulin in association with a nutrient culture medium, said cell line having a morphology very similar to that of beta cells of the bovine pancreas, the diploid number of chromosomes for the bovine species, a generation time of not more than 24 hours and is capable of producing insulin.
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> 4. The cell culture of claim 3 wherein said cell line is one as deposited with the American Type Culture Collection under accession number ATCC CRL 1407.

The issue is whether such claims are patentable. Mr. Stewart presented several convincing reasons why they should be allowed, but we need not go into them extensively. In another case heard shortly before the present one, the same question arose. That involved patent application 257177 of the Abitibi Company, for which a Hearing took place on March 11, 1981. Mr. David Watson, Q.C.,

represented Abitibi. The arguments both of Mr. Stewart and of Mr. Watson, together with the results of our own investigation of the development of patent law throughout the world, have brought us to the conclusion that we can no longer be satisfied that at law a patent for a microorganism or other new life forms would not be held allowable by our own courts. That is the criterion specified in Section 42 of the Patent Act, without which the Commissioner ought not to reject an application.

The decision in the Abitibi case was taken on March 18, 1982, and is now a public document. It is consequently not necessary to repeat here all the ratiocination developed there. However it may be useful to repeat from it the requirements which we think should be met by an Applicant before claims such as 1-7 of the application should be allowed. In it we said:

> 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, Nov. 1980):
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> > The standards state that microorganisms, such as yeast, mold, fungi, bacteria, actinonomycetes, unicellular algae, virus or protozoa, can be the subject of patent protection.
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> 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:
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> > 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...
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> ...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 meet 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 22nd. day of June, 1982

Agent for Applicant

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