

COMMISSIONER'S DECISION

Patentable Subject Matter - Phenotypic Concentration of Spermatozoa

Claims to a concentrate of mammalian spermatozoa were rejected on prior art and as being directed to unpatentable subject matter. It was held the claims failed to distinguish over subject matter disclosed in a prior French patent, but that modifications would clear that reference. It was also concluded that in the present circumstances there was present allowable subject matter.

Rejection: Affirmed and Modified.

Patent application 079973 (Class 209-69), was filed on April 13, 1970, for an invention entitled "Method And Means For Controlling The Sex Of Mammalian Offspring And Product Therefor." The inventor is Wallace Shrimpton. The examiner in charge of the application took a Final Action on June 21, 1976 refusing to allow it to proceed to patent. In reviewing the rejection, the Patent Appeal Board held a Hearing on August 9, 1978, and at which the applicant was represented by Mr. D.G. Finlayson. The inventor, Mr. Shrimpton, was also present.

The invention for which the applicant seeks protection is a means for controlling the sex of mammalian offspring. It involves separating the spermatozoa of the male into two fractions, one of which contains the male-producing sperm and the other the female-producing sperm. The female ovum is then fertilized with the male-producing sperm or with the female-producing sperm, according to the sex wanted in the offspring. The procedure is particularly useful in breeding cattle. If the ultimate object is milk herds, for example, one would wish to reproduce only females.

The general method is known, but the applicant has developed a new way to separate the two types of sperm utilizing differences in density between them. The sperm, which contains both the male-producing sperm (referred to as Y-sperm) and female-producing sperm (referred to as X-sperm), is introduced into the middle of a column of a liquid separation medium having a uniform density gradient from the lightest density at the top to the heaviest density at the bottom. The lighter Y-sperm rise more quickly,

and a concentrate rich in Y-sperm is skimmed off the top. Milk fractions have proven to be effective separation media, ones which do not harm the sperm, though other media, such as tomato juice, may also be used. Temperature and other conditions must be suitably controlled, but these do not form part of the question before us.

Claims 1, 15, 17 and 45 are representative of the invention claimed.

1. A method for separating X-sperm and Y-sperm according to phenotypic differences to make possible the control of the sex of mammalian offspring, the steps of mixing fresh sperm with a nutrient medium, cooling the mixture of sperm and medium to a temperature in the range of -5°C. to 2°C. to immobilize the sperm, introducing the cooled mixture of sperm and medium to a separation medium in the form of a separate body of nutrient medium to a separation medium in the form of a separate body of nutrient medium and maintaining the said temperature range in the separation medium, said separation medium having a uniform density gradient extending from a lightest density at the top to a heaviest density at the bottom, at least part of said separation medium being substantially equivalent in density to the density of said mixture, applying buoyant forces to the sperm introduced to said separation medium tending to separate the sperm at levels of suspension within the separation medium according to individual sperm density, and then separating a portion of the separation medium of known density containing a suspended sperm fraction of equivalent density and desired predetermined sex characteristics.
15. A method as in Claim 1 wherein said sperm is a member of the group consisting of primates, cattles, pigs, sheep, rabbit, buffalo, goat and horse sperm.
17. A method as in Claim 15 wherein said sperm is human sperm.
45. A composition of matter comprising deep frozen mammalian sperm in a nutrient medium wherein at least 90% of said sperm has chromosomes of one sex, said nutrient medium at 0°C. having a viscosity below about 1.0 poise, a density within the range from about 1.010 to about 1.044 grams per cc, a pH between about 6.0 and 8.0.

The examiner was ready to accept the process claims as being directed to a novel way to separate sperm, but rejected the product claims 45-50 (of which claim 45 quoted above is representative). The same claims had been refused in 1974 and "withdrawn without prejudice"

on July 29, 1974. The application was subsequently allowed, forfeited, restored and the product claims reinserted on December 22, 1975. The examiner's continued objections to them is that the product claims do not distinguish inventively from those taught in French Patent 1472775, issued to the SWB Corporation on January 30, 1967, and that since the sperm is living matter it is not patentable under Section 2 of the Patent Act. He said:

The reference teaches the separation of a sperm population into predominantly Y-chromosome or X-chromosome containing sperm fractions. Such fractions are used in insemination to increase the chances of obtaining offsprings of one sex over the other. The reference broadly teaches the use of various media including milk and glycerol as the separation media and more specifically egg yolk and glycine as the preferred medium. Further, the desired properties of the media taught in the reference are essentially the same as those claimed by the applicant. The "deep frozen" limitation recently added to instant claim 45 does not define further invention as applicant points out in his letter of April 28, deep freezing "is a common and accepted manner of storing and shipping products of this type".

Further, the product defined by claims 45 to 50 does not fall within the scope of section 2 of the Patent Act. Living or viable matter is not patentable. Mixing or diluting such matter with a nutrient medium and freezing said mixture does not confer patentability to said matter.

The applicant contends that his product distinguishes from that disclosed in the French patent because it is much more successful in producing the desired sex in offspring, and is viable when deep frozen. Further he says the product has commercial use in "the modern industry of providing animal protein for human consumption", is reproducible, and as such is patentable subject matter. An affidavit taken by the inventor was submitted as evidence of the differences between his product and that disclosed in the citation.

The applicant has also argued that the Patent Office allowed similar product claims in Canadian Patent 891017, which is the counterpart of the French citation, and that consequently he himself should be allowed similar claims so that "any subsequent determination of the correct patentee can be settled in the Canadian courts. We cannot, however, accept that particular argument. The other Canadian application is not in suit, and it would be improper for us to assess its patentability.

What we do have before us is application 079973, and we must determine whether we think the claims in it are patentable, divorced from any question of validity of claims in other patents.

In discussing the Canadian patent 891617, applicant says (p. 4, response of December 21, 1976):

As an application that patent was copending with the present application for twenty-one months and indeed the first Examiner attempted to apply that Canadian patent against the present application. The Canadian patent includes a number of product claims for the same viable commercial product and the limitations of that composition are not identical to the composition and qualities and characteristics of the composition in Claims 45, et seq. The applicant contends that a conflict should have been declared in the normal prosecution of these two applications and that while the present rejection is not on the basis of that Canadian patent, the Examiner has rejected Claims 45-50 as containing no patentable subject matter and yet the Patent Office issued a patent with claims for a similar type and parallel subject matter at a time when the present application had already been on file for more than a year and a half.
[underlining added]

We see these statements as an admission that the product claims in the Canadian patent [and also in the French patent] are the same as what applicant claims. Otherwise we do not see how applicant can contend conflict should have been declared. If the products are different (as applicant argues elsewhere) there would be no conflict.

For our part, we have been persuaded by the affidavits and evidence presented at the Hearing that applicant's product must indeed differ from that claimed in Bhattacharya's Canadian and French patents. Otherwise the results obtained using Shrimpton's product would not differ so greatly from that using Bhattacharya's product. Its higher pregnancy rate and viability demonstrated in applicant's arguments, affidavit, and the article in Nature August 20, 1966 indicate it is a significantly different product. Such a difference is more than a question of degree.

The difficulty, one recognized by Mr. Finlayson at the Hearing, is that the claims as now defined do not clearly distinguish from Bhattacharya, and in our view were consequently properly refused by the examiner because of his citation. Mr. Finlayson suggested that he should perhaps

add a process limitation to the claims to avoid this difficulty. We agree that this is indeed a proper case to include a process limitation as the only apparent way to properly define over the prior art. To overcome the rejection of anticipation we would consequently call upon the applicant to make such an amendment. We also think it would be proper to remove the term "deep frozen" from claim 45 as requested by Mr. Finlayson, since the product of claim 1 would not be deep frozen, and indeed would not be viable when deep frozen unless other additives are included. We further see no objection to amending the reference to 90% sperm of one sex to 70%, since on page 26 of the disclosure it is shown that at least 70-80% of the sperm should be of one sex for commercial purposes, and it is only "essential" to have 90% of one sex to obtain best results.

These amendments would, we are satisfied, clear the objections based upon anticipation in the French patent. We are still left, however, with the more thorny question whether the product is objectionable as not being directed to statutory subject matter.

At the Hearing Mr. Finlayson recognized the general prohibition against patenting living matter per se. It is a prohibition which also applies to animal breeding. We have, on earlier occasions, concluded that both are directed to non-statutory subject matter, not encompassed within the meaning of the word invention as used in Section 2 of the Patent Act. Most of the earlier decisions of the Commissioner unfortunately are unpublished, but we can refer to the Patent Office Record for Jan. 4, 1977 xiii (The Human Liver Cell Line Case), to Dec. 20, 1977 at p. xiv (the Wehrmeister decision; and to May 23, 1978 at xiv (the Miyairi case).

In reaching such conclusions we have had recourse to Tennessee Eastman v Commissioner of Patents 1973 C.P.R. 8, (2d) 202; N.V. Philips Application (1954) 71 R.P.C. 192; Lawson v Commissioner of Patents (1970) 62 C.P.R. 109; Commissioner of Patents v Farbwerke Hoechst (1964) S.C.R. 49; In re Rau G.m.b.H. (1935) 52 R.P.C. 362; R.H.F.'s Application (1944) 61 R.P.C.; Leonard's Application (1954) 71 R.P.C. 190; N.V. Philips' Gloeilampenfabrieken's Application (1954) 71 R.P.C. 192; In re A.D. Goldhaft et al 1957 R.P.C. 276; In re American Chemical Paint 1958 R.P.C. 47; Swift and Company's Application 1962 R.P.C. 37; In re Canterbury Agricultural College's Application

1958 R.P.C. 85; National Research Development's Application 1961 R.P.C. 131; the British Patent Act of 1977, Ch. 37, Part 3(b); the Convention for the Grant of European Patents, Article 53(b); J.R. Short Milling v George Weston et al 1941 Ex. C.R. 69 and 1942 S.C.R. 187; American Cyanamid v Frosst (1965) 2 Ex. C.R. 355; In re Virginia-Carolina Chemical 1958 R.P.C. 351; In re Hamilton-Adams (1918) 35 R.P.C. 90; and Standard Oil Development's Application (1951) 68 R.P.C. 114. In the United States a very recent ruling of the United States Supreme Court effectively denied patentability to new forms of microorganisms, In re Bergey, June 26, 1978, as reported in BNA's Patent, Trademark & Copyright Journal No. 385 June 29, 1978, page A, reversing the U.S. Court of Customs and Patent Appeals as reported in No. 349, Oct. 13, 1977 at p. D-1. Earlier United States decisions had held that living organisms and matter were not patentable. See for example Guaranty Trust v Union Solvents 54 F. 2d 400, 410; In re Arzberger 1940 C.D. 65, & 46 U.S.P.O. 32; In re Nancy 499 F. 2d 12 89, 1294; and American Fruit Growers v Brogdex, U.S. Supreme Court, 1931 C.D. 77, which while now an old case was relied upon in the dissenting opinions In re Bergey, supra, and In re Chakrabarty P.T.C.J. 3-9-78-p. D-1, which dissents were subsequently endorsed by the Supreme Court (supra).

In the present case applicant's claims stop short of the breeding steps, covering only materials to be used in breeding. The controversy will consequently turn upon whether the rejected claims should be refused for being "living matter," a "product of nature," or a "living organism."

There is no doubt that spermatozoa possesses certain attributes of life, including mobility and the ability to generate life when coupled with ova. On the other hand they cannot reproduce themselves, at least not directly, and really are only part of a living organism, much as a leaf or seed is part of a plant, or a heart is part of a human organism. In his dissenting opinion (subsequently tacitly endorsed by the U.S. Supreme Court) in the Bergey case (supra), Mr. Justice Miller said:

The nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions [which are patentable]. For example, both the microorganisms claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful product (lincomycin and honey, respectively).

This cannot be said of chemical compositions. I agree with the board [of appeals] ... that living organisms (e.g. plants and biologically pure cultures of microorganisms were not intended by Congress to be within the scope of 35 U.S.C.101 [which like the Section 2 of the Canadian Patent Act defines what is an invention]).

While there are obvious similarities between the applicant's subject matter and that in Bergy, there are also differences. The sperm do not reproduce sperm, nor do they themselves produce a "technologically" useful product.

In the Goldhaft decision, supra, we find:

Mr. Watson urged, however, that the Applicant's method was truly a "manner of manufacture", or, expressed in another way, that what I may perhaps call the sex-controlled egg was in fact a vendible product within the meaning to be given to that phrase when applying the G.E.C. rules. After careful consideration, I find I cannot agree with this contention. The fertilisation of the ovum, the production of the egg, its incubation and the hatching of the chick are steps in a process of nature, in a natural phenomenon. The Applicants' invention as claimed consists merely in the act of intervening, by the introduction into the egg of an appropriate chemical compound, in this natural process to alter the sex of the chick ultimately to be hatched, and to be hatched whether or not the applicants do so intervene. In my judgement, such an act is not a "manner of manufacture" within the meaning of the statute. Alternately stated a "sex-controlled" egg must, like fruit and growing crops, be excluded from the ambit of the phrase "vendible product" as used in the G.E.C. rules.

Again, in some respects the subject matter of the decision and that of the application are similar, but there are differences. The applicant's process is not a natural phenomenon, and there is no creation either of living matter or of a living organism. The separation carried out in the invention is completely artificial.

The last case to which we would refer is In re Rau, supra, quoting from p. 363:

In my opinion, the production by selective cultivation of seeds having the desired compositions set forth in Claims 1 to 4 cannot be held to be a manner of manufacture within the meaning of Section 93 of the Acts. Selective breeding of animals and cultivation of plants for the obtainment of improved stocks by the rigorous selection of and breeding from the few

individuals which are nearest the ideal has, as is well known, been practised from the earliest times as a part of agricultural or horticultural development, as for example in the production of improved flowers or fruit with desired characteristics in the progeny, and the exercise of art or skill in these directions has not been regarded as coming within the term 'manufacture'. I think that the subject of the present applications is clearly distinguishable from the invention considered in the case of Commercial Solvents Corporation v. Synthetic Products Co., Ltd. ((1926) 43 R.P.C. 185) referred to by Counsel, it seems to me that the process in the latter case is analogous to a chemical manufacturing process or operation, the cultured bacteria playing a part in the conversion of starchy bodies into acetone and alcohols similar to that of chemical reagents or catalysts.

As regards Claims 5 and 6, these claims simply refer to the ordinary known methods of extracting the oils or fats from oil-bearing seeds in general and to the usual use of the residues, and Claims 7-9 are the usual appendant product claims; there is no suggestion in the Specification that the seeds according to Claims 1 to 4 are to be treated in any but the ordinary manner of treating seeds to obtain oils, fats and fodder residues.

The present case differs from Rau's invention in that the vital steps present in cultivation are absent.

Jasper Utermann, in his article Reflections on Patent Protection of Products of Nature IIC Vol. 9 No. 5 1978, p. 409, has analysed objections based upon the view that products which occur naturally or are found in nature are unpatentable. The basis for such an objection is that products which occur naturally should remain freely available to the general public. That, of course, is not a factor in this case, since the synthetically separated sperm would not occur as such in nature.

While the present case is fraught with some uncertainty, we have reached the conclusion that the product of claim 45 (when properly amended) is not open to the usual objections based on living matter, living organisms, and products of nature, and that this is not one where the Commissioner could say with any certainty that the applicant is not by law entitled to be granted a patent, as referred to in Section 42 of the Patent Act. We would consequently recommend that the present objection against such claims when amended, be withdrawn.

We note that the present title of the application does not clearly express what the new claims would protect. Something such as "Phenotypic Separation of Spermatozoa" would, we think, be more appropriate.

Another matter was also discussed at the Hearing. The claims are broad enough to cover human sperm, and the disclosure specifically mentions that aspect of the invention. This raises some doubts as to whether in their broadest term the process and product claims are only commercial and industrial, but rather extend to the socio-medico sphere, encompassing methods for controlling human populations. Mr. Shrimpton also indicated at the Hearing that his work had really been limited to livestock, and there is some uncertainty as to its practicality (and therefore utility) with humans. To avoid these objections the applicant offered at the Hearing to exclude the human species from his claims, so there would be no need for the Board to consider such issues. First it was proposed the claims should be limited to "animals," but Mr. Finlayson argued that humans are often classified as an animal species. To avoid that problem it was agreed that all the claims would be limited to non-human mammals.

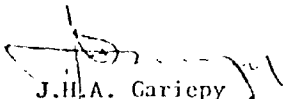
With that and the other amendments agreed upon, the Board recommends that the present objections be withdrawn.

Mr. Finlayson would also like to add certain claims dependent upon claim 45 to include glycerol and other additives which render frozen sperm more viable. We see no objection to that, but believe it is a question which can be more properly worked out with the Examiner when prosecution is resumed.



Gordon Asher
Chairman
Patent Appeal Board, Canada

Having reviewed the prosecution, I adopt the reasons, conclusions and recommendations of the Board. The rejection of present claims 45-50 is affirmed. The applicant should now proceed to make the amendments agreed upon at the Hearing within six months of the date of this decision, or to appeal under Section 44. The application is to be returned to the Examiner to resume prosecution.



J.H.A. Gariepy
Commissioner of Patents

Dated at Hull, Quebec
this 7th. day of March, 1979
Agent for Applicant
Meredith & Finlayson
77 Metcalfe Street
Ottawa, Ontario