COMMISSIONER'S DECISION

OBVIOUSNESS: Vial of Collogenase for Treating Herniated Discs

The invention is related to the discovery of a new and unobvious use for a known enzyme. The problem centered on how the invention might be claimed, since the enzyme is not novel, and methods of medical treatment are unpatentable. A claim was permitted for a vial containing collegenase specially adapted to the new use.

Rejection: Modified

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated December 20, 1974, on application 050,156 (Class 167-103). The application was filed on April 30, 1969, in the name of Bernard J. Sussman, and is entitled "Treatment Of Herniated Intervertebral Discs Of Mammals." The Patent Appeal Board conducted a Hearing on June 30, 1976, at which Mr. D. Watson, Q.C. represented the applicant.

The application relates to an allegedly new and unobvious utility in the discovery of a treatment for a herniated intervertebral disc with an injection of lyophilized collagenase. The applicant does not seek a monopoly on the method of use, but on a vial containing the known substance packaged in a manner, according to the applicant, to take advantage of the discovery made, in the form of a novel practical application of that discovery.

In the Final Action the examiner rejected claims 1 to 4 for failing to define patentable subject matter. In that action he stated (in part):

> The rejection of claims 1 to 4 is maintained and the reason for such rejection is that the claims do not define a patentable subject matter. Collagenase is known and the source of production is known (Clostridium Hystolyticum). See, "Isolation and Charaterization of Proteinase and Collagenase from Clostridium Hystolyticum", J. Clin Invest., 32, 1923 (1953) article by MANDL et al. Further the method of purifying collagenase to insure its essential freedom from proteolytic and elastolytic activity is known. See, "Clostridium Hystolyticum Collagenase its Purification and Properties", Archives of Biochemistry and

Biophysics, 74 465-475 (1958) article by MANDL et al. Also applicant acknowledges that its mode of operation is known i.e. the activity of purified and free of proteolytic and elastolytic activity collagenase to attack collagen and its degradation products and its inability to attack protein substrates which makes the use of collagenase harmless to blood vessels, muscles and adjoining bones.

It is accepted that applicant discovered a new method of use of collagenase, which utilizes the existing knowledge of the specific properties of a purified collagenase, and which under the present state of law would be unpatentable if presented.

Claims 1 to 4 in the present application refer to a small amount of an old compound, having a known activity and in a known purified form and therefore are directed to a subject matter that is deemed to be obvious.

Claiming of a vial containing a specific amount of a known medicament is nothing more than claiming a quantity of the medicament itself. The claiming of a quantity of a known material is surely equivalent to claiming a known substance. But known substances are in the public domain. Claiming a quantity of a substance in a vial is not equivalent to claiming a composition.

Moreover claiming a quantity of a material in a vial is an unacceptable way around the claiming of a method of medical treatment (Tennessee).

Applicant's attention is directed that claim 4 is further rejected as failing to comply with the requirements of Rule 54(1).

The applicant in his response dated March 18, 1975 to the Final Action stated (in part):

...

It is submitted that the Examiner's rejection can be upheld only if a person skilled in the art without knowledge of the Sussman invention would find it obvious to do what is claimed. It is clear that this is not the case. Indeed, the Examiner concedes that "it is accepted that applicant discovered a new method of use of collagenase..." None of the references relied on disclose the idea of using collagenase for intervertebral treatment of a herniated intervertebral disc. Therefore it would not occur to a person skilled in the art without knowledge of the Sussman invention that he should place collagenase in a form in which it would be suitable for this purpose, by providing a vial as a vehicle and placing in such vial a measured amount

appropriate for a single intervertebral injection and lyophilizing the collagenase in a sterile condition and purified so as to be essentially free of elastolytic activity and proteolytic activity against a protein other than collagen.

...

There is a further aspect of the invention as defined by claims 2 and 3 which does not seem to have received consideration by the Examiner, namely, the selection of a vial which when the seal is broken is adapted to receive a quantity of an aqueous medium sufficient to take up the lyophilized collagenase in the form of a solution at a concentration of 0.1% or less. Here there is a selection of the quantity of collagenase and the capacity of the vial so as to make it possible to subject the solution to lyophilization in the vial to produce the collagenase in a dry sterile solution within the vial in the concentration appropriate for the intervertebral treatment of a herniated disc.

...

In the Tennessee-Eastman case the Supreme Court held that claims for a method of chemical treatment were unpatentable because the Court construed the term process as not including the use of a medicine which would be otherwise unpatentable because of Section 41(1) and as not including surgical procedures, but none of the claims now presented are for a method and therefore the reasoning of the Tennessee-Eastman case is inapplicable. It is submitted that there is nothing in the Tennessee-Eastman case that would hold that merely because one form of claim for a particular subject matter is not within the statutory definition of patentable processes, that other types of claim to protect the invention must necessarily be refused. In this connection, attention is drawn to the Hewlett-Packard case in which at page 17, it was emphasized that the applicability of Section 41 must be determined on the basis of the popular meaning of "chemical process". Reference was made to the fact that the process in question involved only a mixing of the ingredients. It is submitted that in this instance, the preparation of the vial would be regarded as being a physical step analogous to mixing and not a chemical process.

...

Another objection that could be overcome by amendment is that if, contrary to applicant's submission, the Commissioner should consider the claims are somehow contrary to Section 41(1) in view of the Tennessee-Eastman decision, then they could be amended to include claims in the form of claims 3 and 4 of the British patent which were reproduced above, and which are for a method of providing collagenase in a pharmaceutically acceptable form and which in applicant's submission would certainly be patentable on the basis of the Ciba decision, even if Section 41(1) were applicable. Claims for the pharmaceutical preparation itself could be placed in dependent form.

The question which the Board must consider is whether the applicant has made and properly claimed a patentable advance in the art.

Present claim 1 is directed to a package in the form of a sealed vial containing a predetermined measured amount of lyophilized collagenase appropriate for a single intervertebral injection, the collagenase being purified so as to be essentially free of elastolytic and proteolytic activity.

At the hearing Mr. Watson gave a cogent interpretation of the jurisprudence pertaining to the instant subject matter. He also made it clear that the invention is related to the discovery of a new and unobvious utility of a known compound (collagenase).

The examiner stated at the hearing that he fully agrees with that proposition (re the discovery), but was only concerned with the form of claims presented when he made his rejection on obviousness.

The Board finds no reason to disagree that the inventive step, having the element of unobviousness, is in the discovery of the new properties of the known compound.

Invention must, however, be differentiated from discovery. Discovery may add to existing knowledge, but without anything further cannot amount to a useful invention. A discovery, just as the apprehension of a desideratum, may be the basis for and progenetor of an invention and, once perceived, the method of applying the discovery to produce a new and useful result is what constitutes invention. The application of the discovery may be quite simple once the discovery was made. As Lord Simonds observed in Raleigh Cycle Co. Ltd. et al v. H. Miller & Co. Ltd., (1948) 1 All, E.R. 308 at 311:

> The patentee, having made this discovery, proceeded to make an article which gave effect to it. It achieved...an immediate commercial success, and, though, I think, no great ingenuity

> was needed for the construction of the article, I am not prepared to dissent from the view taken by the Court of Appeal that here there was subject-matter to support a patent. The discovery was the inventive step which gave to the invention the necessary merit. (emphasis added.)

On the same subject Rinfret J. in Electrolier Manufacturing Co. Ltd. v. Dominion Manufacture Ltd. (1943) S.C.R. 436 at 442, stated:

> The merit of Pahlow's patent is not so much in the means of carrying out the idea as in conceiving the idea itself (Fawcett v. Homan (1896) 13 R.P.C. 398). He produced an improved thing as the result of the ingenious application of a known elastic material (Gadd and Mason v.Mayor, etc., of Manchester); and, to our mind, there was just as much inventive ingenuity in his discovery as there was in the adoption of tubular wire braids in making bristles, held by the House of Lords to have been good subject-matter of a patent (Thomson v. American Braided Wire Company), the result attained being a complete article, effective and capable of being assembled cheaply and expeditiously. The advance may have been slight - although, as pointed out by Fletcher Moulton on Patents (p.22), "the general tendency of the mind is to minimize the difficulty of a discovery after it has been made" - but there was a real inventive step upon "what went before"; and the new result which was obtained was of sufficient importance to make it a genuine invention. It follows that the patent should be held good and valid.

The Board is satisfied that in the situation where an unexpected utility of an old substance is discovered, claims directed to"a novel composition of that substance," and to "a method of use" would be found acceptable, provided of course that the method of use was not related to a form of medical treatment.

In the instant application it follows that the method of use would be directed to a form of medical treatment and would be unacceptable. The applicant has, however, cancelled all the claims to the method of use.

We are therefore persuaded, in the present circumstances, that "the method of applying the discovery to produce a new and useful result is what constitutes invention." (Vide, Raleigh Cycle v H. Miller, supra)
The specific question then is what form of claim, if any, can be accepted to represent a novel practical application of the discovery made.

Of pertinence to the present decision, and to the form of claim which may be accepted, is the rationale of the Supreme Court of Canada in Continental Soya Company vs Short Milling Company Canada Limited (1942) S.C.R. 187 at page 190, where Chief Justice Duff held as follows: (quoting from the treatise on Patents and Inventions by Lord Justice Luxmoore, H. Fletcher Moulton and A.W. Buruyer in the second Edition of Halsbury at p. 591.)

> The difference between discovery and invention has been frequently emphasized, and it has been laid down that a patent cannot be obtained for a discovery in the strict sense. If, however, the patented article or process has not actually been anticipated, so that the effect of the claims is not to prevent anything being done which has been done or proposed previously, the discovery which led to the patentee devising a process or apparatus may well supply the necessary element of invention required to support a patent. This is certainly the case if it can be shown that, apart from the discovery, there would have been no apparent reason for making any variation in the former practice. (emphasis added)

On this basis, claims were held to be valid, even though they were for a bleaching agent found in nature, but in a purified form. An example of one of the claims held to be valid and which appears analogous to the claims which could be in issue here, is found in the decision of the Exchequer Court in Short Milling vs Weston (1941) Ex. C.R. 69 at page 79 and which reads as follows:

> A vegetable agent for bleaching flour, which agent consists solely of vegetable material having a strength sufficient to bleach unbleached wheat flour while being formed into dough and when used in amounts too small to perceptibly add its own colour to the mixture.

An interesting new decision, re Ciba-Geigy AG(DÜRR'S) applications (Fleet Street Patent Law Reports - 1976), has come to our attention. This case was heard by the Court of Appeals in Great Britain before Lord Justice Russell, Lord Justice Scarman and Mr. Justice Thompson. It relates to: "Claims to a known compound in a container bearing instructions for use as [a] weedkiller."

The court, in dismissing the appeal, held that "there was nothing inventive in parcelling up a known material in a convenient package or container having written thereon the information that it can be used for the stated purpose in the stated loci; there was therefore no manner of new manufacture involved in the two claims to which objection had been made on that ground."

Lord Justice Russell gave the judgement of the court and quoted Graham J. (Patents Appeal Tribunal) as follows:

> Graham J., after discussing the cases of L'Oreal [1970] R.P.C. 565 and Organon [1970] R.P.C. 574 and Dow Corning [1974] R.P.C. 235 and after referring to a passage from the opinion of Lord Roche in the Mullard case (1936) 53 R.P.C. 323 with a comment thereon with which we agree, summarised his decision as follows:
>
> > "Applying the principles of those cases...it seems quite impossible to say that by the claim [claim 12] ...the applicants here are doing any more than claiming any package of any shape or size which will not in any way be modified by any instructions also included, that pack containing only a well-known and admittedly old material...they have not by the words used in any way modified their pack or qualified it so that it has a particular shape or construction or is particularly suitable for the purpose for which the material is intended to be used. It is really in effect only claiming the old material as such." (emphasis added.)
>
> We find ourselves entirely in agreement with the decision of the Patents Appeal Tribunal....

The Board therefore is convinced that, in the present circumstances, the limitation made in any acceptable claim must modify the pack or qualify it so that it has a particular shape or construction or is particularly suitable for the purpose for which the material is intended to be used. In other words the limitations in the claim must have a qualifying effect on the container or package.

It was argued that the vial and its contents (package) represents the novel and practical application of a new discovery for the use of collagenase. Claim 1 of this application reads as follows:

> A sealed vial containing collagenase in a predetermined measured amount appropriate for a single intervertebral injection for the treatment of a herniated intervertebral disc of a mammal, said collagenase being lyophilized in a sterile condition and purified so as to be essentially free of elastolytic activity and proteolytic activity against a protein other than collagen.

We are satisfied that it would not occur to a person skilled in the art, without the knowledge of the instant discovery, that one should place collagenase in a form which would be suitable for the new purpose. The applicant provides a sealed vial of a measured amount of lyophilized sterile collagenase in a quantity sufficient for a single intervertebral injection which is adapted to reconstitution with a quantity of aqueous solvent in an amount to fill the vial, wherein said collagenase occurs at a concentration of approximately 0.1% or less, said collagenase being purified so as to be essentially free of proteolytic and elastolytic activity against a protein other than collagen.

We find however, that claim 1 as presented does not satisfy the above considerations. For example, it does not give the concentration which, in our view, is an essential feature for a practical application of the invention. The vial also should be adapted to receive a quantity of an aqueous solvent sufficient to make a specific concentration for a single intervertebral injection. The vial should be particularly suitable for the purpose for which the material is intended to be used, and the modification must be introduced by some limitation in the claim.

Mr. Watson made it clear at the hearing that he was willing to consider amendments to the claims, or he would accept claims similar to that allowed in Great Britain.

The Board believes that a claim drawn along the lines set out below would be acceptable.

Proposed claim 1 reads:

> A sealed vial containing a measured amount of lyophilized collagenase purified so as to be substantially free of proteolytic or elastolytic activity and adapted to reconstitution with a quantity of suitable aqueous solvent in an amount to fill the vial, wherein said collagenase then occurs in a sterile solution at a concentration of approximately 0.1% (by weight) in said solvent in a quantity sufficient for a single intervertebral injection.

The above claim leads to something which, in our view, had never been done before. The claim clearly would not prevent anything being done which had been done or proposed previously. (Vide, Continental Soya v Short Milling Co. supra.) We consider such a claim would be directed to a novel and practical application of a new discovery for the use of collagenase; that is, the limitations in the claim qualify the pack so that it is particularly suitable for the new purpose for which the material is intended (Vide, DÜRR'S application, supra). The claim therefore relates to new and useful "subject matter" which defines a patentable advance in the art.

Claim 2, presently on file, would be redundant in view of proposed claim 1.

Claim 3 would be allowable if made dependent on proposed claim 1.

Claim 4, as was agreed, refers to subject matter from the "supplementary disclosure." This claim would be allowable if presented as claim 3, dependent on claim 1, under the heading of "claims supported by the supplementary disclosure."

One final question is whether or not Section 41 of the Patent Act applies. It follows that if Section 41 does not apply then the rationale of the Supreme Court in Tennessee-Eastman v Commissioner of Patents 1974 S.C.R. 111, is satisfied. That decision was concerned with a "kind of process" viz. "a new use for surgical purposes of a known substance." In the instant application we are not concerned with a process.

The proposed claim, therefore, would not offend any of the ramification of Section 41 of the Patent Act.

We recommend that the decision in the Final Action be withdrawn.

J.F. Hughes
Assistant Chairman
Patent Appeal Board

I am in agreement with the recommendations of the Patent Appeal Board. Accordingly, I withdraw the Final Action, and return the application to the examiner for resumption of prosecution. The applicant has six months to submit claims drafted along the guide lines set out in this decision.

J.A. Brown
Acting Commissioner of Patents

Dated at Hull, Quebec
this 16th. day of July, 1976