Obviousness: Suture Storage Package

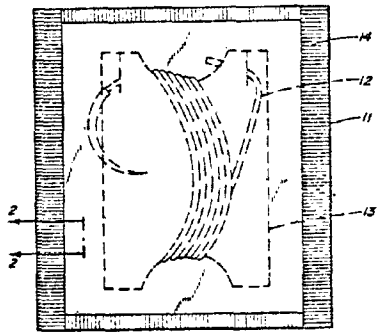
Conventional packaging of polyglycolic acid sutures is unsatisfactory because if stored the sutures disintegrate too quickly when subsequently used in the human body. Research by the applicant disclosed the cause of the problem. The sutures must be thoroughly dried and kept in a dessicated state in hermitically sealed containers which have themselves been dessicated before use and which are completely impermeable to moisture.

Final Action: Modified.

****

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated December 8, 1975, on application 086,315 (Class 217-36). The application was filed on June 23, 1970, in the name of Arthur Glick, and is entitled "Storage Stable Package For Absorbable Polyglycolic Acid Sutures, And Process For Preparing Same." The Patent Appeal Board conducted a Hearing on November 23, 1977, at which Messrs. D. Sim, Q.C. and I. Brameld represented the applicant. Also present were Dr. J. Richards and Mr. J. McPherson, representatives of American Cyanamide.

This application relates to the packaging of polyglycolic acid sutures so that the sutures are stable during storage. This is accomplished by desiccating sutures and container prior to sealing. Figure 1 of the application which illustrates the invention is shown below:



In the Final Action the examiner rejected claims 1, 2, 4, 5, 6, 7 and 8 for failing to define any patentable subject matter because of common knowledge and the following reference:

U.S. Patent 3,297,033 Jan. 10, 1967 Schmitt

The Schmitt patent, which is owned by the applicant company, describes a synthetic absorbable surgical suture of polyhydroxyacetic acid esters and absorbable surgical sponges or gauze of the same material. Monofilaments of the fiber are attached to surgical needles, sealed in transparent polyester-polyethylene packets, and dry sterilized by permeating the seal line with ethylene oxide. These sutures may be stored in a conditioning liquid such as alcohol-water mixtures.

In the Final Action the examiner stated (in part):

> The applicant, in the rejected claims, is predicating patentability on the broad idea of packaging polyglycolic acid sutures in a moisture free atmosphere. Accordingly claims 1 and 2 are directed to a method of packaging as is claim 4. Claims 5 to 8 are directed to a package. The claims under rejection are very broad and in reality merely define an idea that may have floated through someone's mind. Applicant, in fact, contends that his invention lies in the discovery or realization that even traces of water will seriously affect the suture.
>
> It is the Examiner's contention that this is merely expected skill to one skilled in this art. The sutures per se are known, the fact that moisture adversely affects the sutures is well known and conceded by the applicant. (see page 5, lines 23 to 26 of this disclosure). It is considered to be entirely obvious that if it is known that large amounts of water deteriorates the sutures that smaller amounts will also have a similar affect but perhaps to a lesser degree. The examiner contends that the skilled artisan would be unerringly led to this conclusion by the facts set forth above and therefore no invention was necessary.
>
> That being the case, and the applicant has not persuaded the examiner to the contrary by his arguments, the applicant's invention must be in a specific method of producing the moisture free package and a specific package per se. The examiner will not allow claims that merely set forth a package that maintains a suture in a moisture free manner as present claim 5 now does.
>
> The examiner, further, will not allow claims such as claims 6 to 8 herein. The gaseous contents of sealed containers have been evacuated for years and also non-reactive gases have been used widely. Aluminum foil packages have been in use for years and it is further submitted that this alone is not sufficient to give the applicant what he desires. Claims 6 to 8 are rendered obvious by almost all of the vacuum packs available today.

In response to the Final Action the applicant amended claims 1 and 5 to 7 by replacing them with new claims 1 to 5 and stated (in part):

The Examiner has construed the claimed invention as being based "on the broad idea of packaging polyglycolic acid sutures in a moisture-free atmosphere" adding that "the claims under rejection are very broad and in reality merely define an idea that may have floated through someone's mind". The Examiner appears to have appreciated the point made in applicant's previous amendment that the invention lies in the discovery or realization that even traces of water will seriously affect the suture. However, the Examiner comes to the conclusion that this is merely expected skill to one skilled in the art. He states that "it is considered to be entirely obvious that if it is known that low amounts of water deteriorates the sutures that smaller amounts will also have a similar affect but perhaps to a lesser degree".

At this point, applicant wishes to refer to method claim 1 which calls for the packaging of the suture in a water-vapor impervious container and requires that "substantially all of the water is removed from said suture and container". By contrast, former claim 5, although referring to a water-vapor impervious container, used slightly different language, possibly ambiguous, in regard to the freedom from water, i.e. "water-vapor impervious container having enclosed therein a sterile polyglycolic acid suture which is substantially free from water". In particular, it could be alleged that "substantially free from water" is more permissive regarding the quantity of water present than the method claim which calls for "substantially all of the water is removed". Moreover, the method claim makes it clear that this water is removed "from said suture and container" whereas former claim 5 did not make it perfectly clear that both the container and the suture are free from water. Proposed new claim 5, to take the place of former claims 5-7, is more specific in making it clear that absorbed moisture has been removed from the suture and from the (interior of) the container. Furthermore, proposed new claim 1 has been restricted in the interests of defining the invention more explicitly so that it now covers only the subject matters of claims 2 and 3. In other words, it still constitutes the necessary broad claim 1 to satisfy Rule 60 but it does not go beyond what is claimed separately in claims 2 and 3.

The point which applicant wishes to emphasize is that conventional dry packaging techniques for sutures are not sufficient in the case of polyglycolic acid sutures to prevent deterioration leading ultimately to unsatisfactory in vivo strengths. The whole argument has been set out clearly by applicant's expert, Dr. James Beverley McPherson, in affidavits filed in connection with the opposition by Ethicon Inc. to the grant of letters patent on applicant's corresponding U.K. specification Serial No. 1,263,217. Since portions of Dr. McPherson's affidavit evidence related to specific allegations in declarations filed by the U.K. opponent, there are quoted hereinafter only the portions of Dr. McPherson's affidavit which seem to be relevant to the present proceedings. If the Commissioner finds it necessary or desirable, a further affidavit could be obtained from Dr. McPherson specifically for the purposes of the present Canadian application.

A further response submitted October 21, 1977, was accompanied by an affidavit made by Dr. J. B. McPherson. Of the newly submitted claims 1 to 10, we informed the applicant prior to the Hearing that claims 1 to 4 and 7 to 10 were

acceptable. They cover a particular process for preparing the packages and certain specific packages which we are satisfied embody patentable features. At the Hearing, consequently, Mr. Sim limited his remarks to new claims 5 and 6. These claims are as follows:

> 5. A storage stable packaged polyglycolic acid suture comprising an air-tight sealed water-vapour impervious container, and within the container a dry, sterile polyglycolic acid suture, the gaseous contents of the container having been evacuated or replaced by a dry gaseous atmosphere non-reactive with polyglycolic acid, and the suture and interior of the container being substantially free of all absorbed moisture.
>
> 6. A storage stable, packaged polyglycolic acid suture according to claim 5 wherein said container is rendered moisture vapor impervious through the use of aluminum foil.

The issue to be determined is whether these claims represent a patentable advance in the art.

Claims of similar scope were rejected in the Final Action, in which the examiner stated that they "...are very broad and in reality merely define an idea that may have floated through someone's mind. Applicant, in fact, contends that his invention lies in the discovery or realization that even traces of water will seriously affect the suture...." To support his position the examiner argues that "sutures per se are known" and "the fact that the moisture adversely affects the sutures is well known and conceded by the applicant (see page 5, lines 23 to 26 of the disclosure)." He adds that "it is considered to be entirely obvious that if it is known that large amounts of water deteriorates the sutures that smaller amounts will also have a similar effect but perhaps to a lesser degree."

Dealing with these statements at the Hearing Mr. Sim agreed that "sutures per se are known." He disagreed with the allegation that the applicant concedes it was known that moisture adversely affects sutures. Page 5 of the disclosure (at lines 23 to 26) reads "it is known that when polyglycolic acid is contacted with water and particularly at high temperatures, that degradation of polymer will occur quite rapidly." According to the applicant this only acknowledges that degradation will occur in contact with water, particularly at higher temperatures but gives no indication as to what would be the effect of "moisture" at normal temperatures. Using gelatine as an example, Mr. Sim pointed out that it would deteriorate in boiling water, but it is stable to ambient moisture at normal temperatures.

Another issue raised by the examiner was that since it is known that large amounts of water affects these sutures, it would be obvious that smaller amounts will have a similar effect to a lesser degree. He contends all the applicant has done is to store the suture in a moisture free atmosphere. Responding to this objection, Mr. Sim stressed that conventional dry packaging techniques were not satisfactory for polyglycolic acid sutures, since conventional dry storage results in unsatisfactory in-vivo strength of the sutures if used after a relatively short storage period on the shelf. To support his position he referred to the affidavit of Dr. McPherson, which accompanied one of the responses to the Final Action. This affidavit sets out the circumstances in which the cause of poor in-vivo strengths were determined, and the subsequent steps taken to overcome the problem.

Upon reviewing suture development as outlined in Dr. McPherson's affidavit, we note that applicant's U.S. patent, 3,297,033 (Schmitt) represents the first synthetic surgically acceptable absorbable suture. This suture possesses superior properties to conventional catgut. Initially it was stored in the conventional dry packaging system used for other non-absorbable sutures of cotton, linen, silk, etc. It was found that polyglycolic sutures stored

for long periods of time had not suffered any significant loss in initial strength and had the appearance of being storage stable on tensile testing. However, animal implants revealed that the in-vivo strength deteriorated rapidly after prolonged storage before use. About this problem the affidavit states at page 5:

> At first we were puzzled by these facts and we considered whether the cause of the trouble might lie in oxidative degradation of the polymer or from progressive depolymerization resulting from the presence of small quantities of catalyst, or from the presence of excessive quantities of unreacted glycolide, or from the presence of glycolic acid residues or its dimer entering into transesterification reaction with the PGA polymer chain, or autocatalytic degradation from unidentified sources.
>
> 9. Intensive efforts in our laboratories eventually showed that although the sutures had been packaged "dry", nevertheless residual moisture present in the suture coupled with the moisture vapor present in the package were the culprits.

and on page 9:

> 15. To secure the advantages of the present invention three things must be achieved. One must vigorously remove absorbed moisture vapor from the suture material and container interior. One must keep the container interior and its contents in a desiccated state before sealing the container. Finally, one must hermetically seal the moisture vapor impermeable container.

The corresponding U.K. application was involved in opposition proceedings, during which it was attacked for obviousness. We were provided a copy of the Interim Decision of the U.K. Office following those proceedings, and quote the following from page 6 of that decision:

> Having considered all the evidence in this case it is my view that, while it was generally known that PGA was liable to undergo some degree of hydrolysis if immersed in water for a prolonged period, it was not generally understood that this material was so sensitive to minute amounts of water vapour absorbed from the atmosphere, as to make it unsuitable for use in surgical sutures after storage in conventional dry conditions. Whereas I accept the opponents' argument that in the case of a material for use in surgery it would be necessary to be particularly careful, I am not persuaded that it would be obvious to one skilled in the art that PGA sutures, already described as "dry" should be subjected to a further drying operation in order to preserve their tensile strength. (emphasis added)

It is clear that a stored polyglycolic suture using the conventional "dry" packaging method resulted in an unsatisfactory product. Consequently further research was necessary to discover the cause of the problem and its solution.

This discovery appears to constitute the basis for an inventive step which produces a new and useful result. On this point we refer to the comments of Lord Simmons in Raleigh Cycle vs H. Miller (1948) R.P.C. vol. LXV 141 @ 148:

> The patentee, having made this discovery, proceeded to make an article which gave effect to it. It achieved under the name of a "Dynohub" 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. [underlining added]

Similarly in Continental Soya vs Short Milling 1942 S.C.R. 187 @190 the Supreme Court said:

> The distinction between discovery and invention must, of course, be borne in mind. The relevant principle, in my opinion, is stated in the treatise on Patents and Inventions by Lord Justice Luxmoore, H. Fletcher Moulton and A.W. Bowyer in the 2nd 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 of 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.

We will now summarize the factors which can be considered as known with respect to polyglycolic acid sutures prior to the applicant's research:

> It is absorbable in body fluids over a period of time.
>
> It degrades when exposed to water, particularly water at high temperatures.
>
> It loses in-vivo strength if used after storage in conventional dry packages.
>
> Applicants cited U.S. Patent 3,297,033 recommended storage in an alcohol-water mixture.

As for catgut sutures, the following properties are known:

> They are absorbed in body fluids over a period of time.
>
> They degrade more rapidly when exposed to water, particularly at high temperatures.
>
> When packaged in an alcohol solution containing water it is stable.

The applicant discovered that removal of minute traces of moisture normally present in the suture, and from the atmosphere inside the package, is necessary to obtain a product which is stable when stored. In our view this is not obvious, and represents an inventive step.

At the Hearing there was considerable discussion about the terminology used in claim 5. The word "dry" in line three of this claim is meant to describe a "moisture-free" condition and the applicant suggested it might be more accurate to use the word "desiccated". We believe that such phrasing more accurately reflects the applicant's invention, and should be used here, and also in claim 1.

There was also some discussion about the term "dry" used in line 4 of claim 5 to describe the gaseous atmosphere present in the section. We think that a "dry gaseous atmosphere" could include traces of moisture, and the word "desiccated" should be employed here as well. Another term considered was "substantially", which is found in the last line of the claim. We believe that the word "essentially" would reflect the true nature of the invention more accurately.

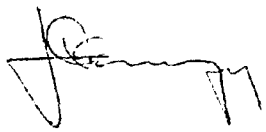
At the Hearing Mr. Brameld agreed to a further amendment to claim 5. Since the claim is for a product, but embodies certain process steps, it would be desirable to replace the process limitation by product limitations. We think such an amendment should be made.

To summarize, we recommend that claims 2 to 4 and 7 to 10 as proposed be accepted and that claims 1 and 5 would be accepted if amended as above. Dependent claim 6 would then be acceptable, also.

Gordon Asher
Chairman
Patent Appeal Board, Canada

Having considered the prosecution of this application, the recommendations of the Patent Appeal Board made subsequent to the Hearing, and the claims proposed subsequent to the Final Rejection, I confirm the rejection of existing claims 1, 2, 4, 5, 6, 7 and 8 for failure to describe the invention properly. I

further direct that proposed claims 2 - 4 and 7 - 10 received on June 8, 1976, be accepted, and that claims 1, 5 and 6 be accepted if amended in the manner called for by the Board. The applicant has six months to make such amendment, or to appeal to the Federal Court under Section 44 of the Patent Act.



J.H.A. Gariepy
Commissioner of Patents

Dated at Hull, Quebec

this 30th. day of December, 1977

Agent for Applicant

Smart & Biggar
70 Gloucester St.
Ottawa, 4, Ontario