

COMMISSIONER'S DECISION

Patentability of Kits, Aggregation - Radio isotopic Scanning Agents

Applicant discovered that phospholipids are particularly suitable carriers for technetium radio isotopes used in radio analysis of liver organs. Because of the short half life of the mixture, it must be prepared immediately before use, and cannot be sold premixed. Consequently applicant wished claims to a package of the separate ingredients, said ingredients to be mixed when used. It was held that under the circumstances existing the claims should not be rejected as aggregative, or because they are directed to a package or kit of ingredients. However the application was remanded to the examiner to consider the application of Section 41, since the ingredients were claimed in per se form.

Application 241,628 (Class 167-48) was filed on December 12, 1975 for an invention entitled "Labelled Phospholipid Spheres for Organ Visualization". The inventors are Abram Petkau and Stanley D. Ploskach. On May 8, 1979 the examiner, in a Final Action, refused some of the claims. A hearing was requested originally, but applicant subsequently withdrew that request.

The subject matter involves the use of a phospholipid carrier for radioisotopic scanning agents. Phospholipids have proven to be particularly suitable carriers for radioisotopes to be administered to patients to permit radioanalysis of various organs, such as the liver. Nineteen claims directed to a process for mixing the radioisotopes with phospholipids, and to the resulting admixture were considered by the examiner to be allowable. However he refused the last eight claims 20 to 27, in which the applicant claimed a package or kit of the separate ingredients used to carry out the process and prepare the phospholipid-radioisotope composition. He considered that the latter claims were directed to a mere aggregation of ingredients which do not inter-react until taken from their separate containers and used in the process.

Claims 20 to 27 are limited to a particular radioisotope of the element technetium. Because of its short half life there is a particular need to prepare it just before use. Claim 20 covers a kit of the various ingredients used to prepare the injectable material when it is needed. The injectable material itself cannot be readily sold as such since it would deteriorate seriously before it reached the user. Claim 20 reads as follows:

20. A combination yielding medical scanning agents labelled with short-lived radioisotope ^{99m}Tc , comprising:

- (1) a ^{99}Mo radioisotope generator yielding pertechnetate anion $^{99m}\text{TcO}_4^-$ in solution,
- (2) a concentrated reducing agent for obtaining from $^{99m}\text{TcO}_4^-$, ^{99m}Tc in multivalent cationic form, said multivalent cationic form of ^{99m}Tc forming a firmly-bound complex when contacted with phospholipid of (4)
- (3) a buffering reagent for the solution of ^{99m}Tc in multivalent cationic form,
- (4) an aqueous colloidal dispersion of phospholipid material having a predetermined particle size so as to localize at preselected organs after injection, and
- (5) kit means to separately contain until use predetermined amounts of at least (2), (3) and (4).

(Tc is the radioactive element technetium).

The examiner rejected the refused claims on the grounds that that they were directed to a mere juxtaposition of parts, and as such amounted to an aggregation rather than an active combination.

Through the years the definitions of "combination" and "aggregation" as used in the patent field have been many and varied. A few are represented here as examples.

Combination - a collection of inter-communicating parts so as to arrive at a single and not complex result (British United Shoe V.A. Fussell & Sons (1908) 25 R.P.C. 631)

- where the old integers when placed together have some working inter-relation producing a new or improved result then there is patentable subject matter in the idea of the working inter-relation brought about by the collocation of the integers (British Celanese v. Courtaulds (1935) 52 R.P.C. 171 at 193)

Aggregation - it is accepted as sound law that a mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination (British Celanese decision supra)

- each functions independently...no common result (Lester v. Commissioner of Patents (1946) C.P.R. 6 at 3)
- mere juxtaposition of parts is insufficient for patentability. The elements must combine for a unitary result. If any element in the arrangement gives its own result, without any result flowing from the combination, then there is no invention (Domtar Ltd. V. MacMillan Bloedel Packaging Ltd. (1977) C.P.R. 33 182 at 189)

As examples of aggregation may be cited the well known toy pistol-whistle (Lester decision supra) and the more recent non-cooperating elements of the rectangular container for beer bottles (Domtar decision supra).

In any event, the indispensable prerequisites of utility, novelty, and inventiveness required of patentable inventions must be met.

Using the above as a basis we must turn to the subject matter of claims 20 to 27 in order to determine whether the kit falls into the broad category of combination or that of aggregation.

The claims broadly describe a three (or more) component system with each component being separated from the others until use, when they are mixed. This could conceivably be accomplished by placing individual components in separate stoppered test tubes or bottles one of which serves as mixing vessel when the agent is prepared; another possibility would be a multi-compartmented vessel where the components are kept separate until mixed by transfer from one compartment to another or by breaking barriers between compartments. The previous is conjecture; however, any such contrivance would serve the purpose of the claim.

The applicant does not disclose a new apparatus for keeping components separated until use. It is clear that such a contrivance has not been invented in this application.

Further, it is clear that each component of the kit is known separately and not one of these components is claimed separately.

The method of preparing the radioactively labelled phospholipid particles and the product thereof appear to be allowable and the use of such for medical treatment appears to be inventive albeit non-patentable.

It is held that the association of components as defined in claims 20 to 27 (three or more separate entities associated in the spaced relationship of a kit) is not allowable in view of the above.

There is no inter-communication or working inter-relation between the components. The components are merely placed side by side, each maintaining its individual character, remaining independent, not influencing or being influenced by the others. The relationship of the components is not that of a result or product but rather that of starting materials. Certainly the product of end use of the kit could be a patentable combination because the labelled phospholipid product is a unitary result which is not the mere sum of the components but rather the result of their interaction. The kit claimed herein could well be compared with a kit to a new apparatus, i.e. an assemblage of parts or components with instructions as to how the parts fit together; surely this is not patentable.

In his response to the Final Action, applicant said:

In the Final Action, the Examiner has provided some quotations from jurisprudence relating to patentable combinations and to aggregations.

It is submitted that the quotations presented by the Examiner relating to combinations are applicable to the present claims. For example, one of the quotations is from "British United Shoe v. A. Fussell & Sons" (1980) 25 R.P.C. 631 which reads "--- a collocation of inter-communicating parts so as to arrive at a single and not complex result ---". The combination presently being claimed has a "collocation" of components adapted to "inter-communicate" and when it is put into a "single result" is obtained and the whole definition fulfilled. The combination is used to produce one end result, not several unconnected results as, for example, the aggregation of a pencil and its eraser.

It is further submitted that the quotations relating to an aggregation do not apply to the present claims, as is revealed on examination of them. One of the quotations, for example, is from the decision British Celanese v. Courtaulds (1935) 52 R.P.C. 171 wherein it was stated that "It is accepted as sound law that a mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination". It is quite evident from the present specification as a whole that the combination of components which is being claimed is not a mere placing side by side of old integers so that when put into use performs its own proper function independently of any of the others. The components of course do not "perform" any function until put into use by the user but when used the function is that of a combination which yields a novel and inventive result.

Another quotation made by the Examiner relating to an aggregation is "Domtar Ltd. v. McMillan Bloodell Packaging Ltd". (1977) C.P.R. 33, 182 at 189 wherein it was stated that "Mere juxtaposition of parts is insufficient for patentability. The elements must combine for a unitary result. If any element in the arrangement gives its own result, without any result flowing from the combination, then there is no invention". Again, this quotation does not describe the present invention as claimed in proposed claims 20 to 27 in that when the components are used, the elements do combine to produce a unitary result. Again, we can refer to a typical example of an aggregation as being a pencil and its eraser.

His contentions that the claims to the "kit" represent a patentable combination are as follows:

The claims to the combination describe components adapted to produce a patentable result when used. Thus, it seems to us that a true combination is involved by virtue of the intended use. This is the commercial embodiment of the invention and the purchaser is not going to buy it unless it is going to be used for its intended use. The combination as such has no other utility. Granted, each component taken separately has its own utility which may be for a number of other purposes but no one is going to purchase the combination to use those components separately for other reasons. In this respect, of course, the Examiner

states that each component is known and none are claimed separately. It is quite true that the components are not being claimed separately but this is the whole point. There is an interrelationship between the components when they are put into use, which is the only conceivable use of the combination. The parts or components are not being sold separately nor are they being claimed separately. It is the combination that must be considered.

In fact, we do not know of any jurisprudence which precludes the claiming of a set or combination such as is the subject matter of the claims in dispute. To our knowledge, the specific point has not been ruled upon. However, we can refer to some Commissioner's decisions for consideration.

As far as the proposed revised claims are concerned, it is to be emphasized that there is a sequential relationship of the components which is very significant. The components, as they are listed, are for sequential use in preparing scanning agents according to the invention. There is the radioactive pertechnetate anion in solution, which is then reduced by means of a concentrated reducing agent in order to obtain radioactive technetium in multivalent cationic form, a buffering agent is then used and finally the radioactive material is added to an aqueous colloidal dispersion of phospholipid material. Dependent claims list other components which fit into this sequence. This sequence of preparation of the scanning agents is quite clear from the disclosure and reference can be made for example to pages 11 and 12 wherein the preparation of a scanning agent is exemplified.

Applicant then went on to discuss two recent Commissioner's Decision, which he alleged were definitive with regard to Office Policy on aggregation. His arguments on that point, are reproduced here:

As the components in combination interact in sequence to yield a novel and inventive result, it is contended that the Examiner's position is contrary to Office Policy as set forth in the Commissioner's decision regarding the application that is now Canadian Patent No. 984,296, the decision being reported in the Canadian Patent Office Record, 13 July 1976, page xiii. In that decision, claims to a package of contraceptive pills so arranged as to be adapted to the use of which they were to be put were held to be patentable. The significance of the claims to the package was that by special construction of the package and/or indication to ensure that the pills were taken in the right order, the proper ratio of two types of pills would be taken and in the proper sequence. It was held that this

constituted a novel application of the discovery made by the Applicant with the pills so arranged as to take advantage of that discovery. Thus, it was considered that the Applicant had discovered a new method and that the method of applying that discovery was what was patentable even though the application of the discovery might be quite simple once the discovery had been made. Thus, by this decision, claims directed to a package containing individual pills or capsules containing the two types of steroids were obtained, the components having an interrelationship taking effect when the package was utilized by the purchaser.

It is believed that this decision is analogous to the present situation. In the present case, there is also a novel and practical application of a new discovery, the new discovery being the particular scanning agents and the method of making them. However, because a short-lived radioisotope is used for labelling the scanning agents, these agents are not suitably prepared until just prior to use. Thus, the components for preparing the scanning agents are sold in combination and this is the novel and practical application of the discovery of the products and the method of making them. Thus, to repeat, it is believed that if the proposed revised claims are not accepted, then this is counter to Patent Office policy expressed in the aforementioned decision.

We can also refer to another Commissioner's decision which related to an application which is now Canadian Patent No. 1,051,713 and was reported in the Canadian Patent Office Record on 15 May 1979, p. iv. The application in question related to a process and apparatus for the manufacture of coffee extracts. The claims to the process were not at issue in the appeal as it was agreed that those claims defined patentable subject matter. The claims, in question, related to apparatus, which the Examiner had rejected as being a mere mechanical juxtaposition of conventional units of apparatus to implement a given process, even though the process was considered patentable. The Applicant stated that a unitary result was achieved which was the ability of the apparatus system to carry out the inventive process and argued that apparatus and process were different aspects of the same invention. It was held that the claims to the apparatus were to a combination in that a unitary result could be produced, the unitary result being the coffee extract produced in a more expeditious manner than previously. It was held that all the elements of the apparatus contributed their part to produce the unitary result.

As the individual parts of the apparatus in the aforementioned application were apparently conventional, surely the unitary result emphasized in the decision could only be achieved when the apparatus was used to carry out the method. It is believed that this is analogous to the present situation where the combination comes into complete effect when the components are used to prepare the scanning agents just prior to use. The components are, however, by their nature specially adapted to provide the end result.

It is believed that these two Commissioners' decisions substantiate the position taken by the present Applicant that the claims as proposed define patentable subject matter and ought to be allowed in accordance with Patent Office policy as expressed in those decisions.

Applicant submitted additional arguments about the patentability of the kit claims as follows:

There are other reasons for submitting that the proposed claims ought to be allowable. A patentee is entitled to claim all aspects of his invention and a commercial form of that invention is surely one aspect which is believed to be suitable for patent claiming. As pointed out previously, the commercial aspect of the present invention is the combination of components ready for use in preparing medical scanning agents.

Although claims to the preparation of the scanning agents and to the products so produced have been indicated as allowable, these claims are in practice virtually impossible to police as the method would be carried out by the user only prior to scanning tests and thus manufacturers are not going to be making and selling the scanning agents. The claims to the method of preparation of the scanning agents and the products so produced would only be infringed by health practitioners, who are individuals against whom one would not normally claim patent infringement damages. Thus, the claims presently under consideration are the only real protection afforded the Applicant by way of protection for the commercial embodiment of the invention. The Examiner agrees that an invention and an advance in the art have been made by his indication that the process and product-by-process claims are allowable. As the claims now in dispute are vital to the Applicant, we believe they ought to be allowed in the absence of relevant prior art.

Finally, applicant discussed the inconsistent nature of the present practice in the Patent Office with regard to kit or package claims, particularly in the chemical arts. We present his view of this practice below:

In our view, there is no precedent in jurisprudence for rejecting claims of the present type and we are not aware of any established precedent for rejecting claims of this type in the Patent Office practice. It is understood that in the mechanical arts, claims to kits of cooperating integers are frequently granted. Obviously, the present situation is analogous.

Also, we direct attention to Canadian Patent No. 1,012,449 of Cohen issued 21 June 1977. That patent contains claims to a kit for use in determining nitrogenase activity in soil. There is also Canadian Patent No. 1,056,729 of Clarke et al issued 19 June 1979. This patent contains claims to a two-pack container or syringe, one part containing dry amoxicillin trihydrate or sodium amoxicillin and the second part containing a sterile mixture of water and a water-miscible pharmaceutically acceptable alcohol. The pack is to be used to prepare a solution of the amoxicillin suitable for injection just prior to use. Even though the particular end solution is disclosed as having enhanced utility, it is still most practical to avoid problems by preparing the solution just prior to use. There are also claims in the patent directed to the end solution and the process of making it. It is our view that the claims in this patent are analogous to the present situation and it must be pointed out that the prosecution of the application which became Canadian Patent No. 1,056,729 was handled by the Examiner who is in charge of the present application. Thus, if the present claims are refused, everything else aside, there is not consistency of examination before the Patent Office.

Applicant summarized his arguments as follows:

In summary, therefore, we believe that there is no precedent in jurisprudence or in Patent Office practice for rejecting claims of the type under discussion here. Furthermore, it is believed that any contention that the claims in question are directed to an aggregation is untenable in view of the reasons presented including recent Commissioner's decisions.

We do not think too much weight should be given to what is or is not the alleged practice of the Patent Office, or upon what patents may have been issued or refused. In our view we must look at the application itself and see if it complies with the patent law as stated in legislation, and as interpreted in jurisprudence by the courts.

The case before us raises the interesting question of whether an applicant is entitled to claim ingredients used to prepare a new and patentable composition where those ingredients are assembled together in a unitary package, and when the ingredients are separately old and known in the prior art. The same question would arise in a mechanical case where an inventor claims a box of selected standard and known parts which if assembled according to his instructions would produce a new and patentable machine. In both cases we must ask ourselves whether the parts properly define the invention as required by Section 36 when the invention is something made from those parts. We must also determine in the present case whether the requirements of Section 41 are being circumvented. When it was pointed out to applicant during the prosecution of this application that Section 41(1) governed the new composition being claimed, he made those composition claims dependent on the process for preparing them. See present claim 17, for example. We do not know whether there are other ways of preparing the desired product from the same ingredients than that covered by applicants process claims, but by claiming the ingredients used independently of any process claims, applicant effectively blocks all possible routes to the scanning agent using those ingredients, and there may indeed go beyond what is permitted by Section 41(1). He has not particularly described what those other processes may be, and his protection would be broader than a product made by the process of claim 1.

This is, we believe, comparable to the situation which arose in Commissioner of Patents v. Farbwerke Hoechst, 1964 S.C.R. 47, where the applicant attempted to claim per se a new medicine in a carrier. Mr. Justice Judson remarked, at p. 53

If a legal impediment exists against a patent claim for the new medicinal substance, namely S. 41(1) of the Patent Act, that legal impediment is equally applicable to the diluted substance.

and at page 54:

The decision under appeal is of extreme practical significance. It gives effect to form rather than substance. The claim to a pharmaceutical composition with which the present application is concerned is free from the limitations imposed by S. 41(1) and a person who obtained a patent in this way could assert such claims against anyone using the pharmaceutically active ingredient constituting the substance of the invention regardless of the process by which it was produced. Furthermore, it might affect compulsory licensing applications under S. 41(3).

In a later case, Tennessee Eastman v. Commissioner of Patents, 1974 S.C.R. 111 to 118, Mr. Justice Pigeon said:

Section 41 was enacted for the purpose of restricting the scope of patents "relating to substances prepared or produced by chemical processes and intended for food or medicine. The same principle proclaimed is that in the case of such inventions, "the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described in the claim or by their obvious equivalents". In my view, this necessarily implies that, with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, its use however prepared could be claimed as a method of treatment. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in S. 41(1).

It is thus clear that the courts are concerned about the effective circumvention of Section 41 by the use of per se product claims for something one step removed from the crux of the invention. In the two cases just

cited the crux of the invention was the chemical compound, and the applicants wished to project patentability forward to something coming later, in the one case a process for using the compounds, in the other to mixtures containing the compounds. However the court recognized that this would effectively avoid Section 41, and held the claims to be unpatentable. In the present case applicant is projecting from the composition backward to the ingredients used to make the compounds, and claiming those ingredients without any process limitation. Claim 20 furthermore, would protect those ingredients no matter what use they may be put to.

In a similar case, In re Dow Corning, 1974 R.P.C. 235 the Patent Appeal Tribunal was also considering claims to packs containing known substances, and submitted that the claims were in fact a disguised form of claim to a process for the medical treatment of human beings, and could not be allowed. In the present case, it can equally be said that the claims are a disguised form of claiming a medicinal substance.

We are not satisfied, however, that claims to "packs" or "kits" are always objectionable, or aggressive in nature. In the matter of Organon Laboratories Ltd.'s Application (1970 R.P.C. 574) it was concluded that there might be invention on placing pills (where the ingredients were old) upon a card in a particular order, which new order was suitable for a newly discovered method of treatment, even though it was already known to arrange other packs or cards to make it easier for the public taking treatment to select the appropriate pill at the appropriate time. The rationale for allowance was that a particular order was necessary to permit the pills to be used for a newly discovered method of treatment. As explained in the Dow Corning case, supra the effect of the Organon decision would not secure to the patentee a monopoly for their discovery of medical treatment, since others would be free to take the pills in the prescribed order provided they did not use the cards to select their pills.

In the matter of L'Oreals' Application, 1970 R.P.C. 565 the applicant sought to patent a pack containing two components for use in a process of treating hair, it being essential to keep the components apart until just before treatment of the hair. The claims were wide enough to cover the case where the ingredients to be made were placed in separate bottles in the same box, subject to the limitation that each container should be of a size sufficient for one treatment of hair. The claims were rejected by the Tribunal, it being found that

- (1) the composition to be prepared by mixing together the contents of the two containers in the pack was well known (though for a different purpose)
- (2) It was well known that the composition could be prepared from the ingredients
- (3) It was well known to make two component pack when circumstances demand it, e.g. when the components should be kept apart until they are used.

Under those circumstances, the court made some interesting observations:

From L'Oreals' Application 1970 R.P.C.

By their present application the applicants seek to secure claims to a, so-called, "two-component pack". In such a pack the ingredients for the hair treatment process are sold to the public in separate containers. The reaction components are thus kept separate but ready for admixture by the user immediately prior to the application to the hair.

The desirability of such a claim from the applicants' point of view is self-evident. Treatments of the kind envisaged will be carried out by hairdressers or by members of the public at home. If the only claims which can be alleged to be infringed are process claims, as already secured, the applicants are likely to be put in the possibly difficult and certainly undesirable position of having to sue potential customers. If other manufacturers do no more than sell competing "two-component packs", it is, to say the least, uncertain on the law as it at present stands, whether an action against them on the process patent would succeed.

It is accepted by the applicants that, if their claim is allowed, they would be able to stop anyone carrying away from a chemist shop two small bottles containing the ingredients and done up in one parcel for whatever purpose he required them. The applicants say however that in practice no proceedings would ever be taken on such a case as we have just postulated, which they describe as unreal, and they further say that in any event they ought to be entitled to sue such a man. Why it is said that they should be entitled to sue such a man is not entirely clear to use. The case cannot be described as wholly unreal. A man might well want to use materials suitable for the hair treatment process, and in similar quantities, for other purposes for which they had already been proposed or might be found useful. In general it would appear to us to be wrong to prevent the public buying or processing known ingredients for making a known compound in any quantities they like. If anyone uses the compound made from the known ingredients for treating hair they may well of course infringe the applicants' process patent.

What then are the proper considerations to be taken into account when deciding whether the application should be refused because the invention claimed is quite plainly obvious and there is no possibility that it involves any inventive step so as to add something to human knowledge? The first and fundamental matter is of course to establish the proper construction and scope of the claim, and it should be noted that the applicants wish this case to be approached on the basis that their claim is not further limited than we have indicated above. It is thus clearly seen to be so broad that the invention includes the mere wrapping together in a paper bag of two small bottles of the previously known ingredients which will make a known compound irrespective of the purpose for which it is used. Is such an invention so obvious and so clearly lacking in inventive step that it should be refused and what considerations are involved in deciding the question? Obviousness is a question of fact which must be decided objectively. It has been said to be a sort of jury question and was always so treated specifically when patent cases were tried by a judge and jury. Being a jury question, it is right that the jury should, in deciding it, take into account all the relevant circumstances. That, however, does not mean that the question can be decided by taking into consideration matters which, as a matter of law, are not relevant and which should not therefore be given any weight in deciding the question.

Here it is clear that, if the jury in considering whether the combined pack is an invention are entitled to take into consideration and give weight to the fact that the applicants allege that they have discovered a new method of treatment, which on the material before the Comptroller is not shown or admitted to be obvious, or if for some other reason it seems it may not have been obvious to associate the benefit of the doubt and allow them to have a claim to the combined pack. The reason is that it can then be justifiably said that no one would have thought of the combined pack unless they had already conceived the idea of the treatment in question, and the applicants are entitled to full protection for their discovery. It thus seems to us that the vital question here is this: is one entitled to take into account the fact that the treatment

for which the pack is ancillary is new and not obvious, or is there present some other reasons why it may not be obvious to associate the ingredients in one pack? If it is proper to take the first of these matters into account or if there is some other reason for non-obviousness present, then the claim should be allowed, but if not the claim should be refused.

The correct conclusion thus may well depend, and in our judgement in this case does depend, on the form and scope of the claim under consideration construed in the light of the relevant surrounding circumstances. In this case the claim is so wide that it covers the mere association of two bottles of the known basic ingredients, known as useful when mixed together for purposes other than the treatment of human hair, in one pack. The article covered by the claim must, in our view, be tested without reference to the discovery that the compound resulting from the combination of the basic ingredients is very suitable for the treatment of human hair. It is not suggested that there is any reason why an ordinary member of the public wishing to use the product of the known ingredients when combined, such product also being known to be useful for other purposes, should not buy two bottles of the ingredients and wrap them up together. Whether the claim could have been limited in such a way as to cover a pack or product which would be, from its construction or otherwise, for practical purposes only suitable for the treatment of the human hair is another matter. It is not so limited and, in our judgement, refusal in such circumstances is the inevitable consequence.

The applicants claim a pack consisting of two known ingredients suitable for producing a known compound. The ingredients and their product being known, the applicants have added nothing - whatever to human knowledge and have not given the consideration necessary to support a grant of letters patent in the form which they seek. The proposed claim covers no more than another example of a form of combined package in itself well known. It would be an unwarranted restriction upon the freedom of the public to grant a monopoly which would prevent them buying or producing such a package. In our view, the mere putting up of two ingredients in separate containers in one pack, the ingredients being intended to be mixed together before use to produce a known compound, cannot prima facie amount to a manner of new manufacture. It can only do so if some ground for non-obviousness of the proposal, which it is permissible to take into account, is apparent or may well exist. On the facts admitted here, no such ground is present and the person making the proposal for the pack in question has contributed nothing to the stock of human knowledge and to grant such a person a monopoly would be both hurtful to trade and generally inconvenient.

The present case is, of course, distinguishable from that in L'Oreal because the composition to be prepared was not known previously, since it contains phospholipid materials added by the applicant for a specific purpose.

In another case, Ciba-Geigy, 1977 R.P.C. 83, Applicant wished to claim a known substance in a container with instructions for a new use for that substance as a weed killer. The application was refused on the basis that there is nothing inventive in parcelling a known material in a convenient package or container having written thereon the information that it can be used for a new purpose. We quote from pp 88 and 89:

It is known that by crop-spraying with particular compounds dicotyledinous weeds can be destroyed without damage to monocotyledinous crops. The appellants have by research and experiment discovered that if you spray the locus of certain crops with a known compound it is possible also to destroy monocotyledinous weeds (for example grasses) without damage to the monocotyledinous crops. This discovery qualifies as an invention on the basis of N.R.D.C. case (1961) R.P.C. 134. This confers upon the appellants the monopoly of the use of this compound for this purpose in respect of such crops. However, since the compound is a known compound, the monopoly may be of little value, and the appellants' research and experiment little rewarded, because of the difficulty of "policing" the unlicensed exercise of the discovered method of selective weed eradication. Apart from the manifest difficulties of policing, it is commercially invidious to sue potential purchasers from the appellants (or their licensees) such as farmers and crop-spraying firms. They want to be able to prevent or discourage rival manufacturers of the known compound from selling it with instructions that it is suitable for application according to the appellants' discovery. It is on authority questionable whether they can do this as a matter of general principle. However, materials such as this will in the ordinary course be sold with instructions for their use on the sack or other container.

For this reason, the appellants seek to claim in their complete specification as follows, to take one of the two instances under review: "12. A compound of the formula defined in claim 1 in a container which bears instructions for use in selectively combating weeds at a locus comprising wheat, barley, rye, oats, rice, maize, cotton or soya".

The examiner concluded that it is customary, in presenting a substance for sale, to place the substance in a container with a written indication of the use to which it is intended the substance be put, and that the claim was not confined to an invention, was clearly lacking in subject-matter and devoid of any invention or manner of new manufacture. The Patents Appeal Tribunal (Graham, J.) considered that it was impossible to say of claim 12 that the appellants were thereby doing more than claiming the contents in any package of any size or shape, and not one modified or qualified in shape or construction so as to be particularly suitable for the purpose for which the contents were intended to be used: and upheld the decision. From this the appellants appeal, with leave.

At the outset of the argument we were startled by the proposition that it can be an invention to state in writing that which has been discovered; that is to say, that the known material can be used to combat selectively weeds in the loci described. It is however clear that if the claim can be sustained so that rival manufacturers of the substance cannot without infringement or licence sell in containers bearing the information in question, it will contribute greatly to the solution of the policing problem. 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) R.P.C. 323 with a comment thereon with which we agree, summarized 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".

We find ourselves entirely in agreement with the decision of the Patents Appeal Tribunal. We cannot see that it can sensibly be said that there is any invention involved in claim 12, any manner of new manufacture. The invention is the discovery that this known substance may be used without harm to the stated crops for the purpose of selectively combating weeds. There seems to us to be nothing inventive about parcelling up the known material in any and every convenient package or container having written thereon the information that it can be used for the stated purpose in the stated loci. There is no interaction between the container with its contents and the writing thereon. The mere writing cannot make the contents in the container a manner of new manufacture. There is nothing novel in the mere presentation of information by ordinary writing or printing on a container.

The United States Court of Customs and Patent Appeals has also shed some light upon this question in its decision In re Venzici 189 U.S.P.Q. 149 (1976). In it the applicant wished to claim a kit of interrelated parts to be used to splice cables. The normal way in which the invention would be marketed was as kits, the parts to be assembled in the field when cables were to be joined. The U.S. Patent Office had rejected the claims on the ground that they did not properly define the invention, which it considered to be the splice itself. The court held that the claims were not indefinite, and said:

We do not believe the words in question (manufactures) are to be so narrowly construed. To hold that the words "any manufacture" exclude from their meaning groups or "kits" of interrelated parts would have the practical effect of not only excluding from patent protection those "kit" inventions which are capable of being claimed as a final assembly (e.g. a splice connector), but also many inventions such as building blocks, construction sets, games, etc., which are incapable of being claimed as a final assembly. We do not believe Congress intended to exclude any invention from patent protection merely because it is a group or "kit" of interrelated parts. We therefore hold that a group or "kit" of interrelated parts is a "manufacture" as that term is used in section 101.

We are consequently persuaded that it is both legally and judicially sound to permit claims to disassembled inventions or "kits" in certain cases. It would be permissible, for example, where there is inventive novelty in the manner in which the kit is constructed (as in the Organon case). It would also be permissible when the invention would normally be marketed in the disassembled form or indeed that is the only way in which it could be marketed and the contents of the kit had not been assembled before (for other purposes). There must of necessity be both ingenuity and novelty in what has been done. It would not be permissible to cover the mere placing together of ingredients previously known to be useful for other purposes (cf L'Oreals). Nor to claim an old material packaged with instructions for a new use for the old material. Nor to circumvent other provisions of the Patent Act. It must comply with Section 36, for example, by being directed to what really is the invention.

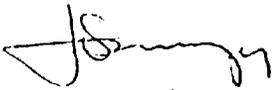
In the present case, there appears to be present both an element of novelty and one of ingenuity in the claims rejected, and we do not believe the rejection should proceed on the grounds relied upon in the final action. We are satisfied from the cases cited that kits are not necessarily aggregations nor can it be said applicants claims are directed to an aggregation.

We do believe however that the requirements of Section 41 should be considered.



G.A. Asher
Chairman
Patent Appeal Board, Canada

Having reviewed the recommendation of the Patent Appeal Board, I reverse the rejection on the grounds relied upon, and remand the application to the Examiner to consider whether Section 41 should be applied, or other objections made.



J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec

this 13th. day of January, 1981

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