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D E C I S I O N
of 17 August 1994

Case Number: T 0952/92 - 3.4.1

Application Number: 84201332.8

Publication Number: 0138252

IPC: G01T 1/204

Language of the proceedings: EN

Title of invention:
A mixture for use in the LSC (liquid scintillation counting) analysis technique

Patentee:
Packard Instrument B.V.

Opponent:
FISONS plc

Headword:
Prior use/PACKARD

Relevant legal provisions:
EPC Art. 54(1) and (2), 56

Keyword:
"Prior use (yes)"
"Analysability of a prior sold product (yes)"
"Inventive step (yes)"

Decisions cited:
G 0001/92, T 0093/89, T 0461/88, T 0206/83, T 0406/86

Headnote:

I. Whatever the means of disclosure (written description, oral description, use by sale, etc), availability in the sense of Article 54(2) EPC involves two separate stages: availability of the means of disclosure, and availability of information which is accessible and derivable from such means.

II. Information as to the composition or internal structure of a prior sold product is made available to the public and becomes part of the state of the art in the sense of Article 54(2) EPC if direct and unambiguous access to such information is possible by means of known analytical techniques which were available for use by a skilled person before the relevant filing date.

III. The likelihood or otherwise of a skilled person analysing such a prior sold product, and the degree of burden (i.e. the amount of work and time involved in carrying out such an analysis), is in principle irrelevant to the determination of what constitutes the state of the art.

IV. The novelty of a claimed invention is destroyed by the prior disclosure (by any means) of an embodiment which falls within the claim. The possibility of a complete analysis of a prior sold product is not necessary. The novelty of a claim is destroyed if an analysis of a prior sold product is such as to inform the skilled person of an embodiment of the product which falls within the claim.

V. The wording of a translation published in the Official Journal of the EPO of the official text of an opinion issued by the Enlarged Board of Appeal pursuant to Article 22(1)(b) EPC is legally irrelevant to the interpretation of such official text.

Case Number: T 0952/92 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 17 August 1994

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 19 August 1992 rejecting the opposition filed against European patent No. 0 138 252 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. D. Paterson
Members: R. K. Shukla
P. Krasa

Summary of Facts and Submissions

I. European patent No. 0 138 252 is based on an application claiming priority from September 1983. It relates to a liquid mixture for use in the Liquid Scintillation Counting (LSC) analysis technique, and has 5 claims.

The only independent claim has the following wording:

"A liquid, homogeneous mixture for use in the Liquid Scintillation Counting analysis technique, comprising a scintillation liquid, a scintillator and a surfactant, characterized in that said mixture also includes one or more mono- and/or di-esters of phosphoric acid, which phosphoric acid esters have been neutralized with an alkaline material having a pKa of at least 5 to a pH, at which the neutralization product comprises a mono- and/or diphosphate salt."

II. The patent was opposed on the grounds of lack of novelty and lack of inventive step. In support of these grounds the Opponent relied inter alia on the fact that a product (hereinafter referred to as "Supersolve") had been sold in the United Kingdom since 1980, and had a composition in accordance with Claims 1, 2, 4 and 5 of the patent. It was contended that the composition of the product had been made available to the public before the filing date of the patent, and was therefore part of the state of the art for the purpose of Article 54 EPC. In support of this contention the Opponent relied in the Notice of Opposition upon the following evidence:

D1: Excerpt from a catalogue issued in 1982 by Koch-Light Laboratories Limited (referring to Supersolve)
D2: Catalogue description of GAFAC PE 510 (a constituent of Supersolve)
D3: Data sheets relating to GAFAC PE 510

A Declaration by Mr R. V. Huggett

The Opponent also relied inter alia upon the following prior published documents:

D4: Liquid Scintillation Counting, volume 3 (1974), pages 220-234
D6: Liquid Scintillation Counting, volume 1 (1971) pages 1 to 14
D9: US-A-3 999 070

In response to the opposition, the patent Proprietor contended that the composition of Supersolve was not part of the state of the art at the priority date of the patent, and that the opposition should be rejected. A Declaration by Dr E. Ch. Th. Gevers was filed in support of the patent Proprietor's contention that the composition of Supersolve is too complex to allow a skilled person to analyze it without undue experimentation,

III. In response to a communication issued by the Opposition Division and to the Declaration by Dr Gevers, the Opponent filed a letter written by Dr Kremer, and a Declaration by Dr G. E. Taylor.

IV. The Opposition Division rejected the opposition pursuant to Article 102(2) EPC.

In its decision the Opposition Division considered that Supersolve could in principle have been analyzed before the filing date of the patent and that most of the claimed features of the invention were made available to the public. However, it held that from an analysis of this product a skilled person could not unambiguously derive the claimed feature that the "the esters have been neutralized with an alkaline material having a pKa of at least 5 to a pH, at which the neutralization product comprises a mono- and/or diphosphate salt", because Supersolve contained other anionic surfactants in addition to the phosphate surfactant, and from the determination of the cations present in such a mixture a skilled person could not draw a conclusion about the form (neutralized or non-neutralized) of the various constituents used to make up the final product. For this reason the Opposition Division held the claimed subject-matter to be novel.

The Opposition Division also held that the claimed subject-matter involved an inventive step in view of the cited documents. In particular, it was considered contrary to the teaching in the prior art to use a mono- or diphosphate salt in the liquid mixture in order to avoid luminescence, because the prior art (in particular D6 and D9) taught that in order to avoid luminescence the mixture should have a pH lower than 7. From such prior art the skilled person would thus be led to use a phosphate tenside in the acid form rather than in the form of the mono- or diphosphate salt in order to avoid luminescence.

V. The Opponent lodged an appeal against this decision and requested that the patent be revoked in its entirety. The following document and evidence were filed inter alia by the Opponent during the appeal proceedings:

D10: Fay et al, "Anionic Surfactants Based on Phosphorus" in Comun. Jorn. Com. Esp. Deterg. 12th, pages 295 to 309, Barcelona, Spain, 1981.

A declaration by Dr J. Emsley.

VI. The patent Proprietor requested that the appeal be dismissed and the patent maintained in accordance with a main request or one of the three auxiliary requests submitted 7 July 1993.

As main request, the patent Proprietor requested that the patent be maintained as granted. Claim 1 of auxiliary request 1 has the same wording as Claim 1 of the main request apart from the addition of a feature,"with the proviso that the alkaline material is not ammonia." at the end of the claim.

Claim 1 of auxiliary request 2 differs from Claim 1 of the main request in that the phrase, "neutralised with an alkaline material" is replaced by " neutralized with an organic amine ".

Claim 1 of auxiliary request 3 relates to the use of one or more mono- and/or di-esters of phosphoric acid neutralized with an alkaline material having a pKa of at least 5 to a pH at which the neutralization product comprises a mono- and/or diphosphate salt, in a liquid homogeneous Liquid Scintillation Counting mixture which

comprises a scintillation liquid, a scintillator and a surfactant, to improve the compatibility of the mixture with concentrated aqueous salt solutions or to reduce the chemiluminescence occurring with strongly alkaline samples.

VII. In a communication accompanying the summons to oral proceedings the Board gave its preliminary view that at least the subject-matter of Claim 1 of the main request seemed to lack novelty in view of the prior use of Supersolve. Oral proceedings were held on 17 August 1994.

VIII. In support of the request for the revocation of the patent, the Opponent submitted essentially the following arguments.

Novelty

According to the declaration of Mr Huggett, Supersolve was sold before the priority date and contained, inter alia, GAFAC PE 510, which (as disclosed in D2 and D3) is a phosphoric acid ester of an ethoxylated nonylphenol, and ammonium as a counter ion.

Supersolve could have been analyzed using techniques available before the priority date, as illustrated by the declarations of Dr Taylor and Dr Emsley. It is sufficient to destroy novelty if the skilled person by an analysis of the product would have discovered at least those features of the product which are comprised in the claimed subject-matter of the patent in dispute.

The possibility to analyse Supersolve is confirmed by the letter from Dr Kremer.

Since the feature that the "the esters **have been** neutralized with an alkaline material ...." is a process feature, Claim 1 of the patent in suit is a product-by-process claim. Clearly the obtained product will be the same whether the esters in question were neutralized prior to their addition to the mixture or were neutralized in situ by the addition of alkaline material directly to the mixture. Therefore, the above mentioned feature does not distinguish the claimed product from Supersolve.

Inventive step

Table 1 of document D4 discloses the utility of alkyl phosphate esters as reagents in scintillation mixtures. The subject-matter of Claim 1 differs from what is disclosed in D4 only in that the esters are neutralized.

Most surface active compounds can be obtained as acids and as salts, as stated on page 2 in the declaration by Dr Gevers. Furthermore, it is stated in D10, page 303, that anionic phosphate surfactants may be converted to a variety of metal and amine salts which makes them versatile enough to be useful in both oil and water based application.

Therefore, having selected a phosphate ester as surfactant as taught by D4, the skilled person would inevitably be drawn to neutralize the ester with an appropriate base. It is well known that scintillation

media have an optimal operating range of between pH 4 and 8. Hence, neutralization with a weak base capable of buffering the phosphate would be a routine optimisation.

Moreover, a lack of inventive step is supported by the fact that the patent Proprietor has not demonstrated any surprising advantage over the closest prior art, since no tests have been supplied comparing the claimed mixture with that disclosed in D4 or with Supersolve.

IX. The patent Proprietor submitted essentially the following arguments in support of his requests.

Novelty

Prior to the priority date of the patent in suit the chemical composition of Supersolve was not described in any published document.

The complex mixture of Supersolve could not have been analysed without undue burden in sufficient detail to allow the skilled person to understand and to reproduce it.

The requirement of analyzability before the priority date of the application means that the skilled person, **without knowing what to look for**, must be able to analyse the product in question.

Furthermore, according to Opinion G 1/92 (OJ EPO 1993, 277) it is required that the product can be **fully** analysed.

The declarations by Dr Taylor and Dr Gevers show that a total analysis of Supersolve would have required a lot of advanced equipment and the use of many different analytical techniques. Furthermore, an analysis such as described in Dr Taylor's declaration would normally not have been done, since this analysis starts with the removal of the solvents, and if the mixture is heated in order to remove the solvents also other components of the mixture may have been evaporated or destroyed. Moreover, the Fourier NMR method used according to the declarations by Dr Taylor and Dr Emsley was very expensive and not available for common analytical work before the priority date of the patent in suit. Also the HPLC method was not a common technique at that time. In addition to this, D10 states, page 299, that the analysis of alkyl acid phosphates presents many problems. Even in Dr Emsley's declaration, page 2, it can be seen that the analysis of phosphates is very complicated. This indicates that the analysis of Supersolve must have been much more complicated, since this product comprised many different compounds in addition to the phosphates.

Further submissions of the patent Proprietor relating to novelty are set out in the Reasons for the Decision.

Inventive step

The problem solved by the present invention is that known Liquid Scintillation Counting mixtures are not compatible with strong alkaline samples, since they suffer from background noise owing to chemiluminescence. Although D10 discloses the possibility of neutralized anionic phosphate

surfactants, there is no indication that such surfactants should be used in a Liquid Scintillation Counting mixture. On the contrary, it was believed at the priority date of the patent that in order to avoid the problem with chemiluminescence in connection with alkaline samples, either the sample should be neutralized or the LSC mixture should be acidified. This is exemplified both by D6 and D9. Also, in D4 there is no indication that the esters should be used in a neutralized form.

Furthermore, the results of a comparative test, given in the letter dated 7 July 1993, show that the neutralized LSC mixture of the invention has a surprising superior counting efficiency in the case of neutralized or acid samples as compared with the counting efficiency of a mixture comprising phosphoric acid esters in their free acid form.

Auxiliary requests

Even if the composition of Supersolve is considered as having been made available to the public, this is not relevant to the issue of inventive step in respect of the auxiliary requests, since the availability of the product per se does not disclose anything beyond its composition or internal structure. Supersolve does not disclose any possible advantage of its use; in particular it does not disclose the reduction of chemiluminescence in connection with alkaline samples. The person skilled in the art has therefore no reason to change the composition of Supersolve, e.g. to use an amine instead of ammonia, in order to further improve the product when used with alkaline samples.

Furthermore, since none of the available documents discloses that the problem of luminescence in connection with alkaline samples can be solved by using a neutralized phosphoric acid ester, there is no reason to modify Supersolve or the mixture known from document D4 in order to solve the problem of chemiluminescence in connection with alkaline samples.

X. At the conclusion of the oral proceedings the decision was announced that the patent would be maintained on the basis of the first auxiliary request of the patent proprietor.

Reasons for the Decision

1. *Novelty: issues raised*

1.1 The first main issue in this appeal is whether the prior sale of Supersolve by Koch-Light Laboratories Limited deprives any claims of any of the patent proprietor's requests of novelty, and if so, which claims.

In this connection certain matters are not in dispute between the parties. First, the process step in Claim 1 (that "phosphoric acid esters have been neutralised"), which make this claim a "product-by-process claim", is not a distinguishing feature for the product per se. In the Board's view this process feature is irrelevant to the issue of novelty.

Furthermore, as set out in the Notice of Opposition and supported by evidence filed at the same time, the

product Supersolve was sold in the United Kingdom from 1980 onwards, and therefore before the priority date of the patent in suit.

Furthermore, as set out in the Notice of Opposition and supported by the declaration by Mr Huggett, the product Supersolve had a composition within Claims 1, 2, 4 and 5 of the main request. In particular, **the mixture** which was sold contained GAFAC PE 510 surfactant, which according to documents D2 and D3 is a mixture of mono and di-esters of phosphoric acid. According to Mr Huggett's declaration the mixture was neutralised with aqueous ammonia (having a pKa of between 5 and 12), so that it contained a mixture of mono- and di-phosphate salts.

However, Claim 3 of the main request requires that "the organic phosphoric acid ester is neutralised with an organic amine", and Supersolve did not have a composition falling within such claim.

1.2 During the proceedings before the Opposition Division, the Opponent originally submitted in the Notice of Opposition that such Claims 1, 2, 4 and 5 lacked novelty simply having regard to the fact that Supersolve had been sold before the priority date and had had a composition falling within such claims. In reply, however, the patent Proprietor submitted inter alia that such fact (i.e. "the mere availability of a product satisfying the claims") does not destroy the novelty of such claims, because it is "a prior use which does not allow a skilled person to find out how the product can be made". In response to this, the Opposition Division issued a communication in which the

Opponent was "requested to comment in detail on the question whether it would have been possible to analyze (Supersolve) prior to the priority date of the contested patent". In connection with this question, the patent proprietor filed the declaration by Dr. Gevers, which supported the patent proprietor's view that the chemical composition of the Supersolve product was "too complex to allow skilled persons to analyze it without undue experimentation"; and the Opponent filed the declaration by Dr. Taylor, as well as the letter from Dr. Kremer, supporting the Opponent's view that it would have been possible to analyze Supersolve before the priority date.

Before the Opposition Division the patent proprietor relied primarily upon Decisions T 93/89 (OJ EPO 1992, 718) and T 461/88 (OJ EPO 1993, 295), as well as Decision T 206/83 (OJ EPO 1987, 5), in support of contentions to the effect that there was no motivation for a skilled person to analyze Supersolve and furthermore that such an analysis would not have been possible without an undue burden of experimentation, and was not possible with a reasonable investment of time and money.

Since the issue of the Opposition Division's decision, the Enlarged Board has issued its Opinion G 1/92 (OJ EPO 1993, 277), which overruled the finding in Decision T 93/89 that "If the composition of a commercially available product can be established only by a chemical analysis, the ingredients of the product have not been made available to the public unless there was reason for experts to investigate it".

1.3 In the light of the Enlarged Board's Opinion G 1/92, during the appeal proceedings the patent proprietor raised a number of questions as to what has to be proved by an Opponent in a case such as the present, in order to establish lack of novelty of a claimed invention having regard to the prior sale of a product having a composition in accordance with the claimed invention. These questions can be summarised as follows:

(i) Is it necessary for an Opponent to prove that a skilled person could have analyzed **without undue burden** the product which was sold before the priority date, and could thereby have known that the composition of such product was in accordance with claims of the patent, in order to establish lack of novelty of such claims?

(ii) Is it necessary for an Opponent to prove that a skilled person could have carried out a complete analysis, without undue burden, of the product which was sold, and to be able to reproduce such product **exactly** without undue burden, in order to establish lack of novelty of the claimed invention?

(iii) As a factual matter, has it been established by the Opponent in the present case that Supersolve could have been analyzed before the priority date so as to prove lack of novelty of the claimed invention?

1.4 In relation to questions (i) and (ii) above, the patent Proprietor requested that if the present Board did not

intend to decide, or hesitated to decide, in favour of his submissions, questions along the following lines should be referred to the Enlarged Board of Appeal under Article 112(1)(a) EPC:

(a) "Is the chemical composition of a product made available to the public by virtue of the availability to the public of that product when said chemical composition could be determined by analysis of the product, but not without undue burden?"

(b) "Does the availability to the public of a product, the chemical composition of which could not be determined so completely as to allow reproduction of the said product, nevertheless destroy the novelty of an invention if at least the presence of the essential elements of said invention could be determined from the product?"

(c) "What are the considerations which should be taken into account when determining whether a prior sold product could have been analyzed and reproduced 'without undue burden'?".

The Opponent did not object to questions such as set out above being referred to the Enlarged Board of Appeal, if the present Board thought it appropriate to do so.

2. *Novelty - main request: legal issues*

The main legal question in this case is: what was "made available to the public" and therefore part of the

state of the art for the purpose of Article 54(2) EPC, by reason of the prior sale of Supersolve?

To answer this question, as well as the other related questions set out in paragraph 2.3 above, it is necessary to consider briefly the relevant legal background.

2.1 In the first place it appears to be very well established in the case law of the Boards of Appeal that for a claimed invention to have been "made available to the public" in the sense of Article 54(2) EPC before the relevant filing date, information equivalent to the claimed invention must have been accessible to a skilled person. As stated by the Enlarged Board in Decisions G 2/88 and G 6/88 (OJ EPO 1990, 93 and 114), "The word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection". Similarly in Opinion G 1/92 (OJ EPO 1993, 277), the Enlarged Board stated that "Where it is possible for the skilled person to discover the composition or the internal structure of the product ... then both the product and its composition or internal structure become state of the art", and that "It is the fact that direct and unambiguous access to some particular information is possible which makes the latter available ...".

Furthermore, in Opinion G 1/92 the Enlarged Board emphasised that "Article 54(2) EPC does not make any distinction between the different means by which any information is made available to the public. Thus,

information deriving from a use is governed in principle by the same conditions as is information disclosed by oral or written description".

In other words, the disclosure of a written description is the information which a skilled person can learn by reading it, the disclosure of an oral description is the information that a skilled person can learn by hearing it, and the disclosure of a product which has been used is the information that a skilled person can learn from it, either visually or by analysis for example.

Thus whatever the means of disclosure (written description, oral description, use, etc.), availability in the sense of Article 54(2) EPC involves two separate stages: availability of the means of disclosure, and availability of information which is accessible and derivable from such means.

Furthermore, whatever the means of disclosure, as indicated in the passage of Opinion G 1/92 quoted above, a question may arise in any particular case as to what is "directly and unambiguously" derivable from such means. Both the result of reading a written description and the result of an analysis may be relatively unclear. This is a question of degree.

It follows from the above that in the Board's view the Opposition Division was correct to inquire into the possibility of analysis of Supersolve.

2.2 The further question to be considered (paragraph 1.3 above, question (i) and paragraph 1.4 above, question (a)) is whether the line between what is available to the public by analysing a prior used product and what is not so available is determined by the criterion of what can be derived from such an analysis "without undue burden". In this connection the patent proprietor relied upon the following passage in Opinion G 1/92: "Where it is possible for the skilled person **to discover the composition or the internal structure of the product and to reproduce it without undue burden**, then both the product and its composition or internal structure become state of the art" (emphasis added). The patent Proprietor submitted that the phrase "without undue burden" governed both the "discovery" of the composition or internal structure and its reproduction, and relied upon the official German translation as published in the Official Journal, which, it was submitted, made this clear.

The official text of Opinion G 1/92 is English and, in the Board's view, it is therefore the English text of the Opinion which has to be interpreted, without reference to the translated German text, which is legally irrelevant; the wording of the German text may have resulted from a misunderstanding by the translator of the intention underlying the English text.

In the Board's view the above-quoted passage of the Opinion is not entirely clear as a matter of grammar, since the phrase "without undue burden" could qualify just the reproduction of the product, or it could qualify both the discovery of its composition or internal structure and its reproduction. In support of

the latter interpretation, the patent Proprietor submitted that the analysis of the composition of the product went together with the possibility of reproducing it, and that since both analysis of the product and the possibility of reproducing it were necessary for the composition of the product to have been "made available", the phrase "without undue burden" necessarily applied to both analysis and reproduction.

In the Board's view it must first be noted that the questions which were referred to the Enlarged Board and which were the subject of Opinion G 1/92 did not raise the question of the applicability of the concept "without undue burden". The referred questions concerned whether it was necessary for particular reasons to be identified which would cause a skilled person to analyze a prior used product or to search for information from such a product; as mentioned in paragraph 2.2 above, such referred questions arose from the finding in Decision T 93/89 that the composition of a prior used product is not "made available to the public" unless there are reasons for a skilled person to analyze it.

Thus the reference in Opinion G 1/92 to "without undue burden" in the above-quoted passage was not strictly necessary for providing an answer to the referred questions, and therefore cannot have been intended to alter or add to the existing law concerning what constitutes "the state of the art".

The concept of reproduction of a product "without undue burden" is traditionally associated with the question

of "sufficiency" of a description of an invention in a patent specification: that is, whether the invention which is the subject of the patent has been described in the patent specification "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" (Article 83 EPC). In this context, the skilled person knows what it is that he is trying to reproduce: namely, the subject-matter which is claimed in the patent and which is therefore to be protected by the patent, and the invention which has been disclosed in the description of the patent. Thus in this context, the phrase "without undue burden" is an explanation of the words "sufficiently clear and complete" in Article 83 EPC.

The concept of reproducibility "without undue burden" has also been extended by analogy to cases concerning novelty, where a prior document describes a product such as a chemical compound which is the subject of a claim in a patent. As held in Decision T 206/83 (OJ EPO 1987, 5), such a description of a product does not render the product "available to the public", and thus does not destroy the novelty of such a claim, if a skilled person is unable to make the product, using his common general knowledge and "without undue burden" (in other words, in the absence of an "enabling disclosure").

However, the extension of application of the concept "without undue burden" from reproduction of what has been described in a prior document to the discovery of what is not yet known about a previously sold product (namely, its composition or internal structure) would involve very different considerations, and the Board

does not accept either that that was intended by the Enlarged Board of Appeal in Opinion G 1/92, or that it is legally correct.

Thus in the present case the patent proprietor argued that because the product Supersolve only had mediocre properties and was "nothing special", it followed that the cost of analysing Supersolve would far outweigh any benefit that could be expected from such analysis, and for this reason the carrying out of an analysis of Supersolve would be an undue burden on the skilled person. In the Board's view, such an approach to the determination of novelty is essentially equivalent to the approach set out in Decision T 93/89, which was overruled in Opinion G 1/92, for example in the following passage: "It is the fact that direct and unambiguous access to some particular information is possible, which makes the latter available, whether or not there is any reason for looking for it".

The Board does not accept the further submission of the patent Proprietor to the effect that the criterion of analyzability of a prior used product without undue burden has always been applied by the Boards of Appeal, as evidenced for example by Decision T 406/86, which is referred to in and implicitly approved by Opinion G 1/92, and in which it was held that the composition of a product is "made available" if it can be "determined without any difficulty" by chemical analysis. Such a finding is not the same as saying that, for the composition of a product to be "made available" it must be analyzable "without undue burden".

In the Board's view, to apply the concept of "without undue burden" to the determination of the composition or internal structure of a prior used product which cannot be ascertained visually (for example by analysis) would introduce a subjective element into the determination of novelty, which was specifically rejected by the Enlarged Board in Opinion G 1/92 (see paragraph 2.1). On the contrary, following what is stated in such Opinion as quoted above, in the Board's view it is the fact that direct and unambiguous access to information concerning the composition or internal structure of a prior used product is possible, for example by means of analysis, which makes such composition or internal structure "available to the public" and thus part of the state of the art for the purpose of Article 54(2) EPC. If such an analysis is possible in accordance with the known analytical techniques which were available for use by a skilled person before the relevant filing date, the composition or internal structure thereby is available to the public.

This conclusion is in accordance with what was stated in Decision T 406/86, referred to above, and is also in accordance with the principles set out in paragraph 2.1 above. In particular, the analysis by a skilled person of a product which has per se been "made available to the public" by means of prior sale for example, using available analytical techniques, can be considered as equivalent to the reading by a skilled person of a written description in a document which has per se been "made available to the public". The likelihood or otherwise of such a skilled person either reading such a written description, or analysing such a prior sold

product, and the degree of burden (i.e. the amount of work and time) involved in such reading or analysing, is in principle irrelevant to the determination of what constitutes the state of the art.

2.3 The next question to be considered (paragraph 1.3 above, question (ii), and paragraph 1.4 above, question (b)) is whether, if the composition of a prior used product is to be "made available", a **complete** analysis of such product must be possible, so that, as submitted by the patent Proprietor, such product could have been **exactly** reproduced. This requirement was said to follow in particular from the statement in paragraph 1.4 of Opinion G 1/92 that "An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use **a given product** ..." (i.e. to be able to reproduce it), and that "Where such teaching results from **a product** put on the market, the person skilled in the art will have to rely on his general technical knowledge to gather all information enabling him to prepare **the said product**" (emphasis added).

While this Board agrees that on a strict literal interpretation, this paragraph of the Opinion in isolation could be understood to mean that a complete analysis of a marketed product, sufficient to enable it to be exactly reproduced, is necessary if the composition of the product is to become part of the state of the art, nevertheless, bearing in mind also that this paragraph is only indirectly related to answering the questions which were referred by the President of the EPO to the Enlarged Board, in the Board's view having regard also to the previous case

law of the Boards of Appeal, such a literal interpretation was not what was intended by the Enlarged Board.

According to the established jurisprudence of the Boards of Appeal, the novelty of a claimed invention is destroyed by the prior disclosure (by whatever means) of an embodiment which falls within the claim. Thus in the Board's view, the novelty of a claimed invention is destroyed by the prior use of a product, for example, sale of a product, if an analysis of a product using available analytical techniques is such as to inform the skilled person of an embodiment of the product which falls within the claim of the patent. The Board therefore does not accept the patent proprietor's submissions to the effect that a **complete** analysis of a prior used product must be possible, so as to enable an **exact** reproduction of such product, in order to destroy the novelty of the claimed product.

3. As to questions (a) and (b) in paragraph 1.4 above which were put forward by the patent proprietor for possible referral to the Enlarged Board of Appeal, the Board decided not to refer such questions, because in the Board's view the answers to the questions which are discussed and set out above follow clearly from previous case law of the Boards of Appeal, whereas the answers to such questions which were put forward by the patent proprietor, although perfectly arguable as such, are contrary to such previous case law and appear also to be contrary to the main gist of Opinion G 1/92.

In view of the answers to questions (a) and (b) as set out above, question (c) in paragraph 1.4 does not arise.

4. As to question (iii) set out in paragraph 1.3 above, the factual question to be answered in the present case is essentially as follows: has the Opponent established that Supersolve could have been analyzed before the priority date of the opposed patent, using known analytical techniques which were available for use by a skilled person at that time, so as to inform such skilled person that the composition of Supersolve was in accordance with the invention claimed in the opposed patent?

4.1 The declaration of Dr Taylor, an expert in the field of analytical chemistry, describes with reference to published articles analytical procedures that a skilled person would have followed in the analysis of Supersolve, using techniques available before the priority date of the patent-in-suit. Thus, according to the declaration, after the removal of the volatile components of the Supersolve which could be identified by their boiling points, an elemental analysis or inductively coupled plasma (ICP) source spectrometry of the residue would have indicated the presence and the amount of phosphorus in the residue; high pressure liquid chromatography (HPLC) or gas chromatography (GC) of the residue would have identified 2,5 - diphenyl oxazole (PPO) and 1,4 - bis (o-methylstyryl) benzene (bis-MSB) which are commonly used scintillant in the art; and a ^{31}P NMR at a relatively higher pH would have indicated the presence of monoester and diester of phosphates since at higher pH the resonance shifts of

the two species are quite distinct. Moreover, according to the declaration, using a cation-exchange column all the cations including ammonium would have been separated and then identified by classical means.

Similarly, in the declaration of Dr Emsley, an expert in the field of analytical chemistry and the chemistry of phosphorus, it is stated that using inductively coupled plasma source (IPC) spectrometry and Fourier Transform (FM) ^{31}P NMR, it would have been possible to measure the amount of phosphorus and also identify mono-and diester of phosphorus in Supersolve. Also, according to the declaration, the pH of a solution of phosphate esters would have indicated that they were not in the free acid form.

In the declaration by Dr Gevers, an expert in the field of chemical analysis by chromatography and spectroscopy, it is stated that whereas an identification of solvents and nonionic surfactant in Supersolve would be straight- forward, an isolation, and therefore, identification of all the surfactants present in the Supersolve would be complicated and time consuming. Moreover, according to the declaration, the amount of phosphorus present is at the detection limit of elemental analysis and a ^{31}P NMR analysis to detect the presence of phosphates would require a comparison with more than 150 known phosphate surfactants under identical conditions. With regard to the cations present in Supersolve, it is stated by Dr Gevers that although identification of cations would be possible, it would be impossible to tell which cation originally belonged to which anion or whether the cations were added as inorganic salts or bases, so that it was not

possible to conclude whether salts of surfactants or a mixture of acids, bases and/or salts was used to compose Supersolve.

Although the patent Proprietor does not disagree with Dr Taylor's final conclusion that it would have been possible in 1983 to carry out an analysis of Supersolve, it nonetheless disputes that (a) an elemental analysis would have automatically revealed the presence of phosphorus, since the skilled person had no reason to expect its presence in an LSC mixture, and (b) that an average analytical laboratory would have possessed around the year 1983 all of the advanced equipment and apparatus necessary to perform the analysis according to Dr Taylor's suggestion. Referring to the Declaration by Dr Gevers, it has been further submitted by the patent Proprietor that (c) a complete analysis of the Supersolve would be so complicated and time consuming that it would be impossible in practical terms.

4.2 As to submission (a), the Board considers that it was well within the competence of a skilled person to identify the presence of phosphorus by subjecting the Supersolve residue (after the evaporation of volatile components) to an elemental analysis. Also in the Board's view, the use of Fourier Transform ^{31}P NMR technique (which has been known since 1960's) in the case of dilute solutions would have sufficiently enhanced weak signals so that it would have been possible to identify the presence of mono and diesters of phosphates in Supersolve, as explained by Dr Taylor and Dr Emsley in their declarations. Concerning the submission by Dr Gevers that it was not possible to

conclude whether phosphoric acid esters or a mixture of phosphoric acids, bases and/or salts was used to compose Supersolve, this is not relevant to the issue of novelty in the present case. As to the possibility of identification of solvent and scintillators in Supersolve, this has not been disputed by Dr Gevers, and the Board is also of the view that isolation and identification of solvent Pseudocumene would have been possible by evaporation, whereby Pseudocumene would have boiled at its boiling point of 168°C, whereas the HPLC or GC technique would have identified the presence of PPO and bis-MSB which are commonly used scintillators in the art.

4.3 As to submission (b), the Board considers that it is irrelevant whether or not all the necessary analytical equipments were available in one laboratory. What is crucial is whether all the necessary equipment and techniques were available to a skilled person before the relevant date so that he was able to inform himself of the composition of the Supersolve to the extent that the composition was in accordance with the claimed subject-matter. In the present case the Board is satisfied that this is so for the above reasons.

4.4 As to submission (c), as already stated in paragraph 2.3 above, the Board does not accept that a **complete** analysis of Supersolve is required to take away the novelty of the claimed subject-matter, but merely an analysis which is sufficient to inform a person skilled in the art that Supersolve had a composition falling within the terms of the claimed subject-matter. As discussed in paragraph 4.2 the Board is satisfied that

in the present case such an analysis of Supersolve was possible.

5. Thus, the Board considers that in the present case,all the necessary means and analytical methods were available to the notional skilled person at the priority date of the patent in suit which allowed him to identify Supersolve as a product falling within the scope of Claim 1 of the main request. Therefore, in the Board's judgment, the subject-matter of Claim 1 of the main request lacks novelty within the meaning of Article 54 EPC.

6. *Novelty - auxiliary request 1*

The LSC mixture according to Claim 1 of this request is distinguished from Supersolve in that the phosphoric acid esters have been neutralised **but not with ammonia**, as in the case of Supersolve. The mixture as a result contains cations of an alkaline material other than those of ammonia. The subject-matter of Claim 1 is thus new.

7. *Inventive step - auxiliary request 1*

7.1. The subject-matter of the patent addresses the problem of incompatibility of the known LSC mixtures e.g. LSC compositions known from D9 and US-A-4 001 139 with strongly alkaline samples which are known to produce a strong and prolonged background noise due to chemiluminescence.

The data provided in Examples I and III of the patent for the determination of chemiluminescence, in the

Board's view, demonstrate that an acceptable level of chemiluminescence (in comparison with a background level of about 35 counts per minute - see page 3, lines 24 to 25, and page 4, line 35 of the patent) is obtained in the case of neutralised scintillation mixtures according to Claim 1 (mixtures B) containing mono or diphosphate salts even when used with alkaline samples. Thus, the Board is satisfied that the above technical problem was credibly solved by the composition as set out in Claim 1.

7.2 Although the applicability of Supersolve as a liquid scintillation mixture in general was made available to the public, in the Board's view its other extrinsic properties, and in particular its chemiluminescence property when used with alkaline samples, had not been made available to the public before the priority date of the patent in suit.

7.3 The scintillation mixtures disclosed in Table 1 and on pages 228 and 229 of document D4 comprise organic solvents, a butyl-PBD scintillator and alkyl phosphate esters as a surfactant. Although this document is mainly concerned with the development of design principles of LSC mixtures with a view to providing highly efficient scintillants with good capacity for a wide range of samples (see page 230, last but one paragraph), it does not deal with the problem of chemiluminescence encountered in case of strongly alkaline samples. Therefore, the skilled person confronted with the above technical problem could not gain any relevant information from this document.

7.4 Document D9 discloses LSC mixtures which comprise an aromatic hydrocarbon solvent, an ethoxylated alkyl phenol surfactant, a scintillation solute, a substituted ethoxylated carboxylic acid and optionally a tertiary amine salt or a quaternary ammonium salt of such acid (see the ABSTRACT and columns 2 to 6). The document teaches to reduce chemiluminescence caused by the addition of an alkaline sample by using carboxylic acid in free acid form. Tertiary amine salt or a quaternary ammonium salt of the acid is used to enhance the water miscibility of the mixture (see column 4, lines 61 to 65; column 5, lines 25 to 35). Thus, document D9 contains no pointer either that the compositions now claimed could solve the existing technical problem.

7.5 In document D6, the problem of chemiluminescence in liquid scintillation counting technique is discussed in detail. It is reported that organic peroxides react in an alkaline medium to produce chemiluminescence (see the sentence bridging pages 5 and 6); mixtures of benzoyl peroxide, basic solubilising agents and scintillation cocktails produce very intense chemiluminescence (see page 6, third paragraph) and that an alkaline medium is essential for the chemiluminescence reaction in standard scintillation solutions and addition of an acid to a neutral pH or lower than 7 generally stops luminescence (see the paragraph bridging pages 6 and 7). Also it follows from "CONCLUSION" (see items 3 and 4) on page 9, that in order to avoid chemiluminescence, the biological samples, which had been digested in basic solubilising agents, should be neutralised (or acidified) by the addition of an acid, and that if the scintillation

mixture is alkaline, it should be checked for chemiluminescence and stored until the luminescence has decayed to a tolerable level.

7.6 Having regard to the above disclosures of documents D6 and D9, the Board agrees with the patent Proprietor's submission that in the art of liquid scintillation counting, it was generally considered at the priority date that to prevent or reduce chemiluminescence in the case of an alkaline sample, the alkaline sample had to be neutralised (by the addition of an acid) previous to its addition to the LSC mixture or the LSC mixture had to contain a free acid.

7.7 In view of the above, in the Board's view, a skilled person would not have considered neutralising alkyl phosphate esters in the LSC mixture of document D4 to form mono- or diphosphate salts with a view to reducing chemiluminescence in alkaline samples. The disclosure in document D9 relating to reduction of chemiluminescence is contrary to the teaching of the patent in suit and leads away from the use of mono- or diphosphate salt in the LSC mixture according to document D4.

Similarly, it would have been contrary to the understanding of chemiluminescence in the art to employ Supersolve (which was known to be neutral) in the case of alkaline samples. The skilled person concerned with reducing chemiluminescence would have neutralised or acidified the sample prior to its addition to Supersolve or would have considered acidifying Supersolve. In the Board's view, as the skilled person

was not aware of the chemiluminescence property of Supersolve in relation to an alkaline sample, he had no reason to replace ammonia in Supersolve by any other alkaline material.

8. For these reasons, in the Board's judgment, the LSC mixture according to Claim 1 of auxiliary request 1 was not obvious to a person skilled in the art and therefore involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The Decision of the Opposition Division is set aside.

2. The case is remitted to the first instance with the order to maintain the patent with Claims 1 to 5 as set out in auxiliary request 1 filed on 7 July 1993, and with the description to be adopted to such claims.

3. The request for referral of questions to the Enlarged Board is refused.

The Registrar: The Chairman:

M. Beer G. D. Paterson