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D E C I S I O N
of 18 June 1996

Case Number: T 0069/94 - 3.3.2

Application Number: 85105731.5

Publication Number: 0163178

IPC: A61K 9/18

Language of the proceedings: EN

Title of invention:
Pharmaceutical composition

Patentee:
BEECHAM GROUP PLC

Opponent:
HOECHST Aktiengesellschaft Zentrale Patentabteilung

Headword:
Pharmaceutical composition/BEECHAM

Relevant legal provisions:
EPC Art. 54(2), (3), 56

Keyword:
"Late filed requests - admitted"
"Novelty - yes 'Unit dosage form' represents technical feature"
"Inventive step - no - obvious to try commercially available product"

Decisions cited:
T 0176/84

Catchword:
-



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Boards of Appeal

Chambres de recours

Case Number: T 0069/94 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 18 June 1996

Appellant:
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 November 1993
rejecting the opposition filed against European
patent No. 0 163 178 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
J. van Moer

Summary of Facts and Submissions

I. European patent No. 0 163 178 was granted on the basis of seven claims contained in European patent application No. 85 105 731.5 designated for the contracting states BE, CH, DE, FR, GB, IT, LI, NL and SE. Claim 1 as granted reads as follows:

"1. A pharmaceutical composition comprising a freely flowable powder in unit dosage form, the powder comprising a porous, high absorption silica or silicate having a liquid absorption capacity of 100 to 300 ml per 100g of silica or silicate and a mean particle size of 30 to 500 μm in diameter, and having absorbed therein 40 to 75 % by volume of a liquid pharmaceutically active composition, based on the weight of powder plus liquid."

II. Opposition was filed under Article 100(a) EPC against the granted patent by the Appellant. Of the documents cited during the opposition, the following remain relevant to the present decision:

(2) "Hagers Handbuch der pharmazeutischen Praxis",
4. Auflage, 1977, Springer Verlag, pages 232 to
269,

(3a) booklet of the Degussa company
"Fällungskieselsäuren und Silikate", September
1983,

(5) EP-A-0158120,

(6) DD-C-36133

III. The Opposition Division rejected the opposition taking the view that the subject-matter of claim 1 as granted was novel and involved an inventive step with respect to the prior art. Although document (2) individually disclosed each of the claimed features, there was no disclosure of a particular silica or silicate comprising a combination of all of the claimed features. Document (3a) described the characteristics of a silicate as claimed, namely Sipernat 50, but did not refer to pharmaceutical applications and a unit dose form. The late filed document (5) to be considered under Article 54(3) EPC, did not teach the feature "in unit dose form". In agreement with the parties the further late filed document (6) was not discussed under Article 54 EPC.

According to the decision of the Opposition Division page 10, last paragraph of point 6.1, the Respondent (Patentee) stated that in relation to document (6) "his invention lies in the combination of achieving a high absorption while having a particle size which allows to obtain a free flowing powder".

Without referring to a particular document representing the closest state of the art, the Opposition Division considered that the problem underlying the patent in suit was to achieve a pharmaceutical composition which could provide a more rapid and complete drug release and which had high absorption capacity while still remaining flowable.

Since none of the cited documents suggested solving the said problem by a composition comprising a silica or silicate having a high absorption capacity and being a freely flowable powder, the skilled man would not be led to the subject-matter of claim 1 as granted without exercising an inventive step. It was particularly to be noted that in the light of the disclosures of

documents (2) and (3a) referring to a strong absorbance which might provoke an incomplete release of the medicinal substance, the skilled person would be discouraged from using the claimed silica or silicate. Furthermore, there was nothing in document (6) which suggested a method of how to increase the absorption capacity while maintaining a freely flowable powder.

Since product claim 1 was allowable dependent claims 2 to 6 and process claim 7 were also allowable.

IV. The Appellant lodged an appeal against this decision. Oral proceedings took place on 18 June 1996.

The arguments of the Appellant, both in the written procedure and at the oral proceedings, may be summarised as follows.

There was a contradiction between claim 1 characterizing the pharmaceutical composition as a freely flowable powder in unit dosage form and the description of the patent in suit on column 1, lines 58 to 60 relating to capsule and tablet formulations as possible unit dose formulations. This contradiction made the reasoning of the Opposition Division non-conclusive.

Document (5) did not disclose a unit dosage form of a pharmaceutical composition. However, taking into account the fact that in view of the said contradiction claim 1 comprised nothing more than a free flowable powder, this prior art destroyed the novelty of the claimed subject-matter.

At the oral proceedings the Appellant withdrew his objection under Article 54(1) EPC in regard to documents (2), (3a) and (6).

As regards inventive step, the Appellant argued that according to the worked examples of the patent in suit well known commercially available silica products such as "Sipernat" and "Wessalon" were used as absorbents. Having regard to the product specifications of these silicas as set out in document (3a), it was clear that the alleged invention was only based on the determination of the absorption capacity and mean particle size of a commercially available product by simply measuring these parameters.

There was also no prejudice in the prior art against using the said "Sipernat" or "Wessalon" silica products as absorbents. It was common general knowledge that different pharmaceutical compounds did not show the same absorption and desorption properties on silicas. Accordingly, the general hint in document (2) to pay attention to the rate of release of the absorbed active compounds also applied to the teaching of the patent in suit which was not restricted to a specific group of pharmaceutical active compounds.

Although document (6) expressly mentioned an absorbed amount of only 27.75 % by volume of a liquid pharmaceutical active compound, a value below the presently claimed range, it was clear that this value did not necessarily represent the maximum amount of absorbed pharmaceutical active compound which could be achieved. There was no reason for a person skilled in the art to assume that the silica material used in document (6) had to be restricted to a low absorption capacity.

Moreover, document (6) clearly made reference to several disadvantages when using adsorbents having a small particle size. Accordingly, it was not possible to base an inventive step on the use of an adsorbent material having a relatively large particle size.

Since claim 1 failed to meet the requirements of the EPC, it was also not possible to maintain claims 2 to 7.

The auxiliary requests 1 to 6 of 17 June 1996 were filed at such a late stage of the procedure that they should be not admitted by the Board of Appeal.

- V. The Respondent contested these arguments and submitted auxiliary claim sets 1 to 6 on 17 June 1996 and amended the so-called auxiliary claim set 5 at the oral proceedings.

Claim 1 of auxiliary claim set 1 differs from claim 1 as granted in that protection is sought for "A pharmaceutical composition providing more rapid and complete release than conventional drug containing formulations..".

Claims 1 of auxiliary claim sets 2 to 4 contain in addition to claim 1 as granted disclaimers relating to choline chloride and/or ethoxyquin.

Claims 1 of auxiliary claim sets 5 and 6 differ from claim 1 as granted in that the unit dosage form is defined as a tablet and a capsule respectively.

In response to the Appellant's arguments, the Respondent took the view that claim 1 clearly related to a pharmaceutical composition in unit dosage form made from a freely flowable powder. Accordingly, the unit dosage form clearly represented an essential feature of the claimed composition. Since document (5) undisputedly did not disclose a unit dosage form of the composition, the objection under Article 54(3) EPC with respect to this prior art could not be maintained. Document (6) disclosed a maximum adsorption capacity well below the minimum adsorption capacity stated in

present claim 1. Documents (3a) and (5) both did not refer to pharmaceutical compositions nor did they refer to unit doses. Document (2) did not contain any suggestion that the relevant physical parameters belonging to different silica or silicates should be combined. Accordingly, none of these documents could be prejudicial to novelty.

In rebutting the obviousness objection vis-à-vis the prior art, the Respondent emphasized in the letter dated 14 December 1994 on page 2, point (b) that the problem to be solved by the invention was "the provision of a pharmaceutical composition, ultimately in unit dose form which is made from a freely flowable powder comprising a silica or silicate with a particle size range enabling it to be easily formulated (300-500 micron) a high absorption capacity (100-300ml per 100g silica or silicate); a large amount of liquid pharmaceutically active composition absorbed into them (40 to 75% by volume)." It was furthermore necessary to take into account the fact that the overall composition was "suitable for use as a pharmaceutical composition in unit dose form, with the pharmaceutical component being rapidly and completely released upon administration".

Although the known silica product Sipernat 50 was used according to the examples of the patent in suit, it was in particular to be noted that this commercially available product had never been proposed for such a purpose before the priority date of the patent in suit. Moreover, the skilled person reading document (2), in particular pages 235 and 251 and document (3a) was discouraged from using the said Sipernat product because these documents gave the impression that slow or incomplete release of the active compound was to be expected. Attention was drawn to the fact that an increasing amount of material to be absorbed was in

inverse proportion to the rate of material to be released. It was furthermore to be noted that document (2) disclosed particle size ranges not suitable for producing a freely flowable powder and that the absorption of a food-stuff-additive exemplified in document 3a) did not give any incentive to absorb a pharmaceutical composition.

The Respondent furthermore took the position that document (6) was almost 20 years old when the present invention was filed and therefore could not be considered to be the closest state of the art. Document (6) clearly indicated difficulties in to preparing tablets containing more than 10% of a liquid active compound. Consequently, this prior art clearly comprised the teaching to use silica materials having a low absorption capacity. Furthermore, it was to be noted that according to this prior art the solvent was removed from the absorbent material before compacting the powder in the form of a tablet. Document (6) was also totally silent as regards the release properties of the tablet.

There was also no teaching in any other documents to use silicas as presently claimed for pharmaceutical compositions. Accordingly, claims 1 to 7 of the patent in suit must be upheld.

VI. The Appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained unamended as a main request, or, on the basis of one of auxiliary requests 1 to 4, and 6 filed on 17 June 1996 and auxiliary request 5 filed at the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. The late filing of six auxiliary requests containing six sets of claims raises the procedural problem of their admissibility. Claim 1 of auxiliary claim set 1 differs from claim 1 as granted by the functional feature that the pharmaceutical composition provides a more rapid and complete release than conventional drugs which feature was discussed in detail during the proceedings before the Opposition Division and at the appeal stage. This feature is disclosed on page 1, lines 24 to 29 of the original application document corresponding to column 1, lines 29 to 34 of the specification. Claims 1 of auxiliary claim sets 2 to 4 comprise in addition to the features of claim 1 as granted disclaimers with respect to prior art documents which were regarded as accidentally destroying novelty. The disclaimed compounds choline chloride and/or ethoxyquin can be found on pages 5 and 14 of document (3a) as well as on page 3, line 36 and examples 1 to 5 of document (5). Claims 1 of auxiliary claim sets 5 and 6 differ from claim 1 as granted by a definition taken from dependent claim 5 originally filed corresponding to dependent claim 3 as granted, namely the unit dosage form of the pharmaceutical composition as a tablet and capsule respectively. The remaining claims of the auxiliary requests correspond to the claims as granted and those originally filed. Accordingly, the Board is convinced that the auxiliary requests remain close to the granted one and represent bona fide attempts to overcome objections under Articles 54 and 56 EPC. Therefore, the Board has exercised its discretion so as to admit all six auxiliary requests into consideration.

3. Since the amendments according to the late filed six sets of auxiliary claims all have a basis in the originally filed documents and the claimed subject-matter is more restricted in relation to that granted, the requirements of Articles 123(2) and (3) EPC are satisfied.

4. Having regard to the objections of the Appellant, the novelty of claim 1 as granted *vis-à-vis* document (5), designated for the contracting states BE, DE, FR, GB and NL must be considered under Article 54(3) EPC. In this respect it was undisputed by the Appellant that document (5) relates to a freely flowable choline chloride silica powder and that this prior art does not disclose a unit dosage form of the composition. Having regard to the wording of claim 1 as granted "A pharmaceutical composition comprising a freely flowable powder in unit dosage form..." and the disclosure of the description of the patent in suit on column 3, lines 18 to 25 and the worked examples according to the patent in suit, however, clearly indicating that capsules or tablets as unit dose formulations are made by filling the freely flowable powder into a capsule shell or by compacting the freely flowable powder, the Board cannot see under which circumstances the said reference to a unit dosage form represents a contradiction to the description of the patent in suit. It is therefore not possible to follow the Appellants argumentation that the mention of a unit dosage form in the context of claim 1 as granted does not represent a feature distinguishing the subject-matter of the patent in suit from the prior art disclosed in document (5). Novelty over the disclosure of document (5) must accordingly be acknowledged for the claimed subject-matter as granted and therefore for the further restricted subject-matter claimed in the auxiliary requests.

None of the documents cited in the course of the procedure discloses the specific combination of a liquid pharmaceutically active composition and a porous silica or silicate defined in claim 1 as granted or the claims 1 according to the auxiliary requests. The Board is thus satisfied that each of the present requests relate to novel subject-matter. In any event, the novelty of documents other than document (5) was not questioned by the Appellant at the oral proceedings before the Board.

5. The patent in suit relates to a pharmaceutical composition in unit dosage form comprising a liquid pharmaceutically active composition absorbed in a porous silica. In the opinion of the Board, when discussing the main request and each of the auxiliary requests, the closest state of the art is document (6), which also relates to such a pharmaceutical composition in unit dosage form.

5.1 Article 54(2) EPC unambiguously indicates without any time restrictions that the **state of the art** shall be held to **comprise everything** made available to the public by means of a written or oral description, by use or in any other way **before the date of filing** of the European patent application. Document (6) neither relates to an antiquated technology no more used in industry, nor does it comprise a teaching which at the filing date of the patent in suit was disproved by those skilled in the art. Accordingly, the Board cannot accept the Respondents argumentation that a person skilled in the art would disregard document (6) only because of its publication date about 20 years before the filing date of the application documents forming the basis of the patent in suit.

Document (6) relates more particularly to a process for the preparation of stable tablets containing the active compound in liquid form. Reference is made to well known technologies using mixtures of the pharmaceutically active compounds for example with pulverized soap stone, milk powder and starch which allow tablets to be prepared containing only about 5% of a liquid substance. In the same context it is stated that a higher concentration of liquid active compounds may be achieved by using materials having adsorption properties to form a powder before a tablet or gelatin capsule is prepared as the final form to be administered. Highly dispersed silica is described to be a suitable adsorbent to soak up liquid active compounds to form a powder. In view of the fact that adsorbents having a particle size below 50 μm could be compacted to tablets only at high pressures by using high amounts of binder materials which process steps result in a delayed disintegration of the tablet, it is proposed that larger particles of 0.1 mm to 0.3 mm be used. Although these particles effect a good structural compactness of the tablet without having a negative influence on the disintegration properties, it is pointed out that a content of more than 10 % of liquid active compound will cause problems. It is observed that during the compacting procedure a leakage of the active compound out of the tablet surface takes place accompanied by a degradation of the active compound whereby the tablet surface becomes a mean appearance. To overcome these difficulties of the preparation process, document (6) proposes the use of a column of specified geometrical size, containing the silica adsorbent having a particle size of 0.1 mm to 0.3 mm, charging an active compound onto the column and uniformly distributing the active component by subsequently charging a solvent such as water and/or alcohol onto the column. The step of uniformly distributing the material is described as not causing a

wash out of the active compound. The tablet is then compacted according to a conventional method. It is indicated that the tablet may contain 10 % to 20 % of the active compound. The worked examples of document (6) relate to 1000 g Panthenol and 2000 g silica gel material respectively 1000 g Methylpentinol and 1500 g silica gel material. The adsorbate containing the active compound is dried, admixed with conventional additives and compacted (see the whole document comprising only two pages).

In relation to (6), the problem underlying the patent in suit - main request - is to provide a pharmaceutical composition in unit dosage form containing an increased amount of absorbed liquid pharmaceutically active compound.

The Board notes that the formulation of this problem is not in contradiction to the Respondent's point of view when analysing what is really achieved by the teaching of the patent in suit over that of document (6) (see above point III, second paragraph and point V, paragraph beginning "In rebutting..").

The problem is solved by the pharmaceutical composition comprising a silica or silicate having absorption properties as set out in claim 1 of the patent in suit.

Having regard to the worked examples of the patent in suit relating to the preparation of gelatin capsules containing drugs such as indomethacin or ketazolam or diazepam absorbed in Sipernat 50 as the silica material to give a 60% liquid inclusion level, the Board is satisfied that the problem has indeed been solved in a plausible manner.

6. It remains therefore to consider whether or not the said solution satisfies the requirements of Article 56 EPC in respect of inventive step.

6.1 Although the closest prior art according to document (6) makes reference to high dispersed silica and silica gel, respectively, as the adsorbent material, having regard to the clear statement in this document "Dabei läßt man die flüssigen oder gelösten Wirkstoffe durch das Adsorbens aufsaugen" (see column 1, last two lines), there is no doubt that this prior art relates to the same effect of absorption within the meaning of the patent in suit. Document (6) clearly teaches the use of a mean particle size of the adsorbent material within the range presently claimed and gives preference to the use of porous silica as the adsorbent material.

The Board agrees with the Respondent that document (6) discloses several difficulties in relation to the preparation of pharmaceutical compositions in tablet form containing high amounts of absorbed liquid drug and that this document itself does not contain the slightest hint how to increase the amount of liquid drug to be absorbed into the silica gel material used according to the worked examples. It is, however, to be noted that document (6) in the same way does not contain a prejudice against the use of porous silica as the adsorbent material for liquid pharmaceutical compositions. Moreover, taking into account the disclosure of this prior art as a whole, it is clear that those skilled in the art continuously made efforts to investigate adsorbent materials having higher absorption capacity and suitable for putting pharmaceutical active compounds in unit dosage forms such as tablets or capsules. In the Board's opinion, the teaching of document (6) creates a

"straightforward" situation for the skilled person to take a view on which silica material appear to be more effective in absorbing liquid active compounds.

6.2 As far as a selection of the silica material is alleged, the Board generally considers it as forming part of the normal activities of the person skilled in the art first of all to have a look at materials available on the market. In view of the Respondent's own argument that there was no high absorption material available in the field of pharmaceuticals, it is all the more likely that the skilled person would have inevitably turned to the best silica material already available in the broader general field of the absorption of liquids (cf. T 176/84 OJ EPO 1986, 50). In this respect the skilled person's attention is clearly drawn to document (3a) disclosing a palette of silica materials specified for a variety of uses. On page 2, second paragraph, last two sentences, it is indicated that silicas and silicates prepared by a precipitation process contain an exceptionally low content of impurities. Having regard to the content of heavy metals, these materials are described as also fulfilling the very restrictive requirements of the WHO and Pharmacopoeia. Out of the large group of silicas described and specified in document (3a) only Sipernat 50, a silica prepared by a precipitation process, appears to be the most promising material for absorbing high amounts of liquids. Sipernat 50 is described as a spray-dried carrier silica having an exceptionally high absorbency (capacity to soak up liquids) ("Saugfähigkeit") (see page 5, left column, last paragraph). It is then stated that this silica product allows the transfer of liquid active components or solutions into a freely flowable powder. By using

Sipernat 50 it is possible to achieve a grade of concentration of up to 75% in most cases. Typical fields of applications are rubber and plastic additives, pesticides, plant protecting agents and food-stuff additives.

The Respondent did not contest that the Sipernat 50 product according to document (3a) was available before the priority date of the patent in suit and that this silica product fulfils each of the requirements of claim 1 of the main request.

Once the skilled person recognized in the light of the disclosure of document (6) that the Sipernat 50 product may increase the amount of absorbed liquid drug in a tablet, there was clearly no need for document (3a), which already indicated an exceptional low content of impurities fulfilling the Pharmacopoeia requirements, to make expressly reference to possible applications in the field of pharmaceuticals. The Board is convinced that the skilled person in any case would try to use Sipernat 50 in a general method for preparing a pharmaceutical composition in unit dosage form.

- 6.3 The Board cannot follow the Respondents argumentation that in view of the disclosure of document (2), in particular pages 235 and 251, the skilled person would come to the conclusion that high absorbing silica materials are in general unsuitable for pharmaceutical compositions because of unacceptable drug release properties and therefore, the skilled person would be discouraged from testing the high absorption silica product known from document (3a) in the preparation of pharmaceutical compositions. Document (2) is a well known handbook in the field of pharmaceuticals referring in a separate chapter on more than thirty pages to product specifications and possible applications of silicas and silicates in the field of pharmaceuticals.

Document (2) clearly indicates in conformity with the teaching of document (6) the preferred use of porous silica as a carrier material for liquid substances to form inter alia tablets, dragees and capsules (cf. page 232 under the heading "Kieselgur"; page 235 under the heading "Kieselgur-Adsorbentien", on page 248, second paragraph under the heading "Die mikronisierten Kieselsäuren als Trägerstoff" and on page 248, paragraph beginning "Die Anwendungen.."; on page 251, first paragraph, under the heading "Gefällte Kieselsäuren" - "Anwendung" and on page 265, paragraphs "(e) Kapseln" and "(g) Pillen" under the heading "Pyrolytisch hergestellte Kieselsäure (Gasphasenkieselsäure)"). The reference on page 265 particularly emphasizes the advantageous use of silica material in a process for the preparation of tablets. In the Board's opinion, it is not meaningful to take the said passages on pages 235 and 251, referring to the release of adsorbed material, out of its context. Taking into account the whole content of the chapter "Kieselsäuren und Silicate" according to document (2), it is clear that pages 235 and 251 contain not more than a hint for a person skilled in the art to pay attention to the fact that excellent adsorption properties of silicas could cause drug release problems (page 235, "... muß aber auch..gerechnet werden.."; page 251, "..ist jedoch..zu achten"). This is confirmed by the statement on page 248, second paragraph, that even in a case in which a quantitative desorption may be expected, a determination of the drug release rate has to be carried out.

For the same reasons the proposed use of Sipernat 50 in plant protecting agents and pesticides according to document (3a) would not discourage the skilled person from using Sipernat 50 in absorption tests with liquid pharmaceutically active compounds.

6.4 Furthermore, it is to be noted that claim 1 of the main request relates to a pharmaceutical composition *per se* and does not relate to subject-matter in the form of a second medical use.

6.5 It follows from the preceding paragraphs that the subject-matter of claim 1 of the main request lacks inventive step.

7. Each of the claims 1 of the auxiliary claim sets 1 to 6 relate to a pharmaceutical composition defined by the same product parameters as set out in claim 1 of the main request (see paragraph V above).

7.1 The mere indication of an effect relating to a more rapid and complete release than conventional drug containing formulations, without specifying additional concrete product parameters, according to claim 1 of auxiliary claim set 1, cannot support inventiveness of a product *per se* which provision is regarded as obvious in the light of the prior art.

7.2 The inclusion of disclaimers according to auxiliary claim sets 2 to 4 could only have had an effect on the question of novelty under Article 54 EPC.

7.3 The Board notes that the provision of tablets or capsules as unit dosage formulations was well known when preparing pharmaceutical compositions comprising a liquid pharmaceutically active compound absorbed in silica (see paragraphs 6.1 and 6.3 above). The restriction to these formulations is the only difference between claim 1 of the main request and the respective claims 1 of the auxiliary requests 5 and 6.

Such a restriction leaves the reasoning above set out in relation to claim 1 of the main request equally applicable to the claims 1 of auxiliary claim sets 5 and 6, which claims thus also lack the required inventive step.

8. As each of the requests put forward by the Respondent contains a claim which fails to comply with the patentability requirements of the EPC, the patent must be revoked.

9. Finally, it is to be noted that the Board considered "*ex officio*" whether or not to remit the present case to the first instance. However, in view of the very clear situation in the present case that each of the amendments according to the auxiliary requests were foreseeable in the light of the prior art and the description of the patent in suit and that no change of category of claims took place, the Board has decided on each of the subject-matter according to the auxiliary sets of claims 1 to 6.

Order

For these reasons it is decided that:

1. The appealed decision is set aside.
2. The patent is revoked.

The Registrar:



P. Martorana

The Chairman:



P. A. M. Lançon

rio 24.2.16

mm.

