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Datasheet for the decision of 15 January 2009

Case Number: T 0156/06 - 3.3.02

Application Number: 97909449.7

Publication Number: 0939622

IPC: A61K 9/16

Language of the proceedings: EN

Title of invention:
Porous microcapsules and their use as therapeutic and diagnostic vehicles

Patentee:
Quadrant Drug Delivery Limited

Opponents:
BOEHRINGER INGELHEIM PHARMA GmbH & CO.KG
Nektar Therapeutics

Headword:
Porous microcapsules/QUADRANT DRUG DELIVERY LIMITED

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"None of the requests is allowable since they extend beyond the content of the application as filed"

Decisions cited:
-

Catchword:
-

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Case Number: T 0156/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 15 January 2009

Appellant: (Opponent I)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 6 December 2005 concerning maintenance of European patent No. 0939622 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 939 622, which was filed as application number 97 909 449.7, based on international application WO 98/017257, was granted on the basis of eight claims.

Claim 1 as granted read as follows:

"1. Microcapsules each consisting of a wall defining a hollow, empty core, characterised in that the wall is porous."

Independent claim 3 as granted read as follows:

"3. Microcapsules each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically or diagnostically-active component, linked to the pores in the walls of the microcapsules**." (*emphasis added*)

II. The following documents cited during the proceedings are relevant for the present decision:

(5) G. Crotts, T. G. Park, Journal of Controlled Release 35, 91-105, 1995
(10) WO 96/09814
(11) WO 96/18388
(22) WO 96/26746
(23) WO 92/18164
(25) EP-A-0 466 986
(27) US 4 777 154
(33) P. Giunchedi, U. Conte, S.T.P. Pharma Sciences 5(4), 276-290, 1995

III. Oppositions were filed and revocation of the patent in its entirety was requested pursuant to Articles 100(c) (the subject-matter of the patent extends beyond the content of the application as filed), 100(b) (insufficiency of disclosure) and 100(a) EPC (lack of novelty and inventive step).

IV. The appeals lie from a decision of the opposition division maintaining the patent in amended form on the basis of the fifth auxiliary request (Articles 102(3) and 106(3) EPC, version 1973).

Claim 1 of the fifth auxiliary request serving as basis for the opposition division's decision to maintain the patent in amended form read as follows:

"1. Process for producing microcapsules for use in therapy each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules**, comprising co-spray-drying a wall-forming material and a material that can be removed from the capsule walls and removing said material." (*emphasis added*)

V. The opposition division did not admit the main request and the third auxiliary request into the procedure since they were clearly not allowable.

The opposition division considered that auxiliary request 1 met the requirements of Articles 123(2) and 83 EPC.

In the opposition division's view, the subject-matter of claim 1 of the first, second and fourth auxiliary requests lacked novelty vis-à-vis documents (22), (23) and (25).

As regards auxiliary request 5, the opposition division considered the amendments to be allowable. Moreover, in the opposition division's opinion the requirements of Articles 84 and 83 EPC were met.

Additionally, the opposition division considered that the subject-matter claimed in the fifth auxiliary request was novel over the content of document (25) since it had not been shown that the beads prepared according to the method disclosed in document (25) were inevitably microcapsules having a hollow core.

As regards the issue of inventive step, the opposition division considered document (10) as the closest prior art. In the opposition division's view the problem to be solved was "modification of the spray-drying process of document (10) such that porous hollow microspheres were obtained". The opposition division considered that the problem was solved by "co-spray-drying the wall-forming material together with a pore-forming agent". Additionally, according to the opposition division's findings, the solution was not obvious in the light of the cited prior art.

VI. The patent proprietor and opponent I filed appeals against said interlocutory decision.

The appellant-patentee filed a main request and eleven auxiliary requests with its grounds of appeal.

VII. Appellant-opponent I filed counter-arguments to the patentee's grounds of appeal. The appellant-patentee filed counter-arguments to the appeal of opponent I.

VIII. The board sent a communication as an annex to the summons for oral proceedings in which the board's preliminary opinion was expressed. In particular, there were strong doubts as to whether the requirements of Article 123(2) and (3) EPC (including objections pursuant to the ground of opposition under Article 100(c) EPC) and of Articles 84 and 83 EPC were met.

The board also sent a copy of the review article document (33) with the communication.

IX. The appellant-patentee filed a response to the board's communication with letter of 13 October 2008. It also filed a claim set B consisting of a main request and eleven auxiliary requests.

X. Appellant-opponent I filed a response with letter of 14 November 2008 requesting the appellant-patentee to clarify the ranking of its requests.

XI. Opponent II, which is respondent to the patentee's appeal, filed as a response to the board's communication a letter dated 17 December 2008 with further arguments against both sets of requests A and B, in which it requested that the patentee's appeal be dismissed.

XII. Oral proceedings took place on 15 January 2009.

XIII. At the beginning of the proceedings the appellant-patentee withdrew auxiliary requests 1, 3, 5, 7, 10 and 11 from both sets A and B.

The appellant-patentee renumbered all remaining requests in order to clarify their ranking and filed them in a new order to avoid confusion when discussing the different sets of claims.

Claim 1 of the main request read as follows:

"1. Microcapsules each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** for use in therapy, wherein the microcapsules are 0.1 to 50 µm in size." (*emphasis added*)

Claim 1 of the first auxiliary request read as follows:

"1. Microcapsules for use in therapy each comprising **a** porous wall defining a hollow core, and which additionally have an associated physiologically active component, **linked to the pores in the walls of the microcapsules**, wherein the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls and removing said material." (*emphasis added*)

Claim 1 of the second auxiliary request read as follows:

"1. Microcapsules for use in the delivery of a physiologically active component by means of a powder

inhaler to the alveoli, each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules**, wherein the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material and the loading of the active component is a factor of at least two times that obtainable for the same size of non-porous microcapsules." (*emphasis added*)

Claim 1 of the third auxiliary request was identical to claim 1 of the fifth auxiliary request before the opposition division.

Claim 1 of the fourth auxiliary request read as follows:

"1. Process for producing microcapsules for use in the delivery of a physiologically active component by means of a powder inhaler to the alveoli, each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** comprising co-spray-drying a wall-forming material and an additional material that can subsequently be removed from the capsule walls, and removing said material." (*emphasis added*)

Claim 1 of the fifth auxiliary request read as follows:

"1. Use of microcapsules each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** wherein

the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material, for increasing the loading of the physiologically active agent."(*emphasis added*)

Claim 1 of the sixth auxiliary request read as follows:

"1. Hollow microcapsules each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** for use in therapy, wherein the microcapsules are 0.1 to 50 µm in size." (*emphasis added*)

Claim 1 of the seventh auxiliary request read as follows:

"1. Hollow microcapsules for use in therapy each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** wherein the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material." (emphasis added)

Claim 1 of the eight auxiliary request read as follows:

"1. Hollow microcapsules for use in the delivery of a physiologically active component by means of a powder inhaler to the alveoli, each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked**

to the pores in the walls of the microcapsules, wherein the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material and the loading of the active component is a factor of at least two times that obtainable for the same size of non-porous microcapsules." (*emphasis added*)

Claim 1 of the ninth auxiliary request read as follows:

"1. Process for producing hollow microcapsules for use in therapy each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules**, comprising co-spray-drying a wall-forming material and a material that can be removed from the capsule walls and removing said material." (*emphasis added*)

Claim 1 of the tenth auxiliary request read as follows:

"1. Process for producing hollow microcapsules for use in the delivery of a physiologically active component by means of a powder inhaler to the alveoli, each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** comprising co-spray-drying a wall-forming material and an additional material that can subsequently be removed from the capsule walls, and removing said material." (*emphasis added*)

Claim 1 of the eleventh auxiliary request read as follows:

"1. Use of hollow microcapsules each comprising **a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules,** wherein the microcapsules are obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material, for increasing the loading of the physiologically active agent." (*emphasis added*)

XIV. The appellant-patentee's arguments, as far as relevant for the present decision, are the following.

Auxiliary requests 6 to 11 should be admitted into the proceedings since they were initially filed with the letter of 13 October 2008 as a response to the board's communication sent as an annex to the summons.

Claim 1 of the main request did not contravene the requirements of Article 123(2) EPC since the application as filed disclosed the technical features of the claim. In particular, the feature that the associated physiologically active component was linked to the pores in the walls appeared in claim 5 as originally filed. Moreover, the morphology of the microcapsules was also disclosed in the application as filed. The term "hollow microcapsules" appeared on page 2, lines 16 to 18.

Additionally, the appellant-patentee submitted that the specification as originally filed disclosed microcapsules like those depicted in Fig 4(a) on page 278 of document (33), i.e. microcapsules wherein a

wall or shell surrounded a central core. The appellant-patentee added that the term microparticles was a generic term which covered the term microcapsules. The passage on page 2 of the originally filed description specified the microcapsules as having a discrete wall and a hollow core. Additionally, it cited page 3, line 28 of the application as filed to provide support for the wall being porous. The appellant-patentee also submitted that the description specified at least that the microcapsules had a central cavity and cited page 4, lines 22 and 23. Thus, in the appellant-patentee's view, there was support in the application as filed for the feature of a wall defining a hollow core.

As a further argument, the appellant-patentee submitted that the terms "porous microparticles" and "hollow microcapsules" were used interchangeably. In this context it pointed to the prior-art documents (namely, (23), (10) and (11)) which were cited in the first full paragraph on page 3 of the application as filed, and argued that these documents defined what kind of microparticles were obtained by spray-drying techniques. The appellant-patentee stressed that the only intended structure was microcapsules such as those obtained by spray-drying, i.e. hollow microparticles, which were made porous in order to increase the surface area. Therefore, claim 1 did not relate to a new combination of features. The appellant-patentee cited again document (23) (in particular, it pointed to page 10, lines 10-14) and stated that the microparticles of the patent in suit were obtained by means of the materials and techniques disclosed in said document. Hence, their structure was that defined in document (23).

The appellant-patentee stressed that the question to be answered was how would the skilled person consider the term at the time of the effective date of filing of the application in suit.

The appellant-patentee added that microspheres were microcapsules with a hollow core and it cited document (5) (page 99, Fig 6 (B)) in order to show that multi-core particles were possible, but were not the same as hollow microparticles which necessarily had a single cavity (document (5), page 101, Fig 9).

Asked by the board whether, in order to have a complete disclosure, it was required to invoke the common general knowledge of the skilled person, the appellant-patentee answered in the affirmative, and added that the skilled person would give a technical content to the terms employed in the specification, in the light of the prior-art documents referred to. The skilled person would read the application in that context and conclude that microcapsules with a single cavity surrounded by a wall were meant.

The appellant-patentee also stated that document (33) defined microcapsules as having a hollow core surrounded by a membrane which is formed by the wall-building material (it cited page 278, left-hand column, under the heading microparticle classification). Furthermore, document (33) stated that "When the spray-drying technique is applied, the microparticles obtained are microspheres or microcapsules" (it cited page 278, right-hand column, under the heading spray-drying as a preparation method for microparticles). The

microparticles disclosed in the application as filed were those obtainable by spray-drying. The physiologically active agent could be introduced into the hollow spaces.

The appellant-patentee further argued that if a microcapsule was prepared by spray-drying then it would have the structure defined in the claims, a wall defining a hollow core or a central cavity. This was the natural reading of the claims' wording.

The appellant-patentee also cited document (27) which showed hollow microspheres, i.e. microparticles with a central cavity and a spherical geometry.

The appellant-patentee stated that his argumentation applied *mutatis mutandis* to all requests.

The appellant-patentee stressed that the product-by-process features delimited the structure of the microcapsule. The product-by-process features were explicitly defined in claim 1 of the first auxiliary request. Moreover, the claim was narrower than the granted product claims since the microcapsules were more specifically defined owing to the presence of the product-by-process features.

As regards the sixth auxiliary request (and this was also applicable to auxiliary requests 7 to 11) the appellant-patentee explained that the replacement of the definition "microcapsules each comprising a porous wall defining a hollow core" by the definition "hollow microcapsules each comprising a porous wall defining a central cavity" was undertaken in order to overcome the

objections in relation to Article 100(c) and Article 123(2) EPC for the main request (and auxiliary requests 1 to 5). This amendment was based on page 2 (hollow microcapsules) and page 4 (central cavity) of the application as filed. The appellant-patentee argued that the central cavity was a common feature of all microparticles. Moreover, the scope of protection had been narrowed in comparison to the granted version since the cavity had to be "central".

XV. The appellant-opponent's arguments can be summarised as follows:

The combination of features concerning the morphology of the microparticles and the locus to which the physiologically active component was linked was not disclosed in the application as filed. In fact, the word "core" appeared nowhere in the application as filed. Hence, there was no basis in the application as filed for the term "porous wall defining a hollow core" appearing in the claims. As regards the text quoted by the appellant-patentee on page 2, lines 16-18, it was modified in the patent document.

The appellant-opponent stated that it shared the opinion of the board expressed in the communication sent as an annex to the oral proceedings. In this respect the appellant-opponent added that document (33) clearly defined several morphologies for microparticles obtained by spray-drying, but the application as filed did not define which of them were addressed. Document (33) showed that multi-nuclear microcapsules were also obtainable.

The appellant-opponent mentioned that the expression "obtainable" did not restrict the microparticles of the claims to those specifically obtained by a certain process.

Additionally, the specification of the application as filed disclosed several embodiments, concerning different microparticles. The disclosure on page 4 taught that the porosity could be increased, making porous microparticles from microparticles which were not initially porous. Furthermore, in the case of microparticles with a central cavity the active component was inside the microparticles and thus it was not linked to the pores in the wall.

XVI. Opponent II endorsed the appellant-opponent's submissions and also put forward the following:

It would appear that the specification on page 2 of the application as filed mentioned "hollow microcapsules" as encompassed by the term "porous microparticles". However, there was no technical link between porosity of particles and the presence of a hollow core.

Document (33) was a review article prior to the effective date of filing of the patent in suit and hence was more relevant for defining the common general knowledge of the skilled person than some specific patent or non-patent literature. Document (33) did not disclose microcapsules with an empty, hollow core but disclosed that microcapsules could be defined as "particles in which a solid or liquid core constituted by the drug is surrounded by a membrane" (page 278). Furthermore, the specification on page 4 of the

application as filed in which a central cavity was mentioned, indicated that the drug entered into the central cavity through the pores, which is substantially different from the drug being linked to the pores in the wall. Indeed, this specification on page 4 related to another embodiment, namely that concerning microparticles for ultrasound diagnostic agents. This was a different option to that selected from originally filed claim 5. The application as filed clearly related to different and separate options.

Opponent II also stated that there was a general principle that a patent application was its own dictionary; this must be kept in mind if one referred to patent applications as a basis for disclosure. In fact, if one referred to secondary documents as the appellant-patentee had done, then one had to know that the meaning of the terms microspheres and microcapsules varied from one document to another.

Document (33) related to a review and showed that microcapsules containing hollow spaces like the multinuclear microcapsules shown in Fig 4(c) were obtainable by spray-drying. Hence, to employ a spray-drying technique did not inevitably yield microcapsules with a single hollow core, or central cavity, such as those depicted in Fig 4(a) of document (33). This argumentation directly applied to the first auxiliary request which contained product-by-process features.

Opponent II also submitted that the amendment replacing the expression "hollow core" by "central cavity" did not change anything as regards the argumentation previously brought. The combination of features

"central cavity" and physiologically active component linked to the pores in the wall was not disclosed in the application as filed. The embodiment on page 4 clearly corresponded to the option of ultrasound diagnostic agents appearing in original claim 5, and could not be generalised to other kinds of microcapsules without contravening Article 123(2) EPC.

Opponent II also questioned whether the sets of claims of auxiliary requests 6 to 11 met the requirements of Article 123(3) EPC, but it did not advance any arguments in this respect.

XVII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of any of the auxiliary requests 1 to 11 filed at the oral proceedings.

The appellant (opponent I) and opponent II requested that the decision under appeal be set aside and that the European patent No. 0 939 622 be revoked.

Reasons for the Decision

1. *Admissibility*

1.1 The appeals are admissible.

1.2 The sets of claims filed at the oral proceedings are admissible since they concern sets of claims already on file, i.e. filed either with the grounds of appeal or with the letter of 13 October 2008 (as a direct

response to the board's communication sent as an annex to the summons for oral proceedings).

At the oral proceedings none of the opponents disputed their admissibility.

2. *Article 100(c) and Article 123(2) EPC*

2.1 Article 100(c) EPC was a ground for opposition in the present case. Therefore, the investigation of the amended claims in relation to the requirements of Article 123(2) EPC also addresses those amendments introduced during the examination procedure, which are present in the granted claims.

2.2 Claim 1 of the main request and each claim 1 of auxiliary requests 1 to 5 contains the following definition for the microcapsules:

"Microcapsules each comprising **a porous wall defining a hollow core, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules".** (*emphasis added*)

Said definition was introduced during the examination procedure, in the form of granted product claim 3 (with the only difference that the option concerning a diagnostically-active component has been deleted in the sets of claims serving as basis for the present decision). Therefore, it has to be investigated whether or not the above-mentioned definition is directly and unambiguously derivable from the application as originally filed.

On a natural reading, said definition must be understood to relate to microcapsules in which a porous wall surrounds a hollow core, i.e. a single domain (or area) not containing wall material. This appears to have been confirmed by the appellant-patentee's argumentation.

Moreover, it is an indisputable fact that the term "hollow **core**" does not appear *verbatim* in the application as filed.

Starting from the originally filed claims it becomes evident that the microparticles were defined in a very broad and vague manner in the application as filed. Thus, claim 1 as originally filed related to "porous microcapsules". The natural reading of this expression is microparticles which are suitable for encapsulation of (or for loading with) some agent, and which contain pores (i.e. hollow domains or areas). However, nothing in the definition "porous microcapsules" implies that the microparticles must have "**a hollow core**", surrounded by a porous wall.

Claim 2 as originally filed is dependent on claim 1 and relates to microcapsules "obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls, and removing said material". This product-by-process definition does not necessarily imply that the microcapsules obtained have "a hollow core".

The reason is that several microcapsule morphologies are possible, for instance mononuclear or multinuclear microcapsules, comprising a core surrounded by a wall,

or multiple cores or cavities (i.e. multiple core domains or areas) embedded in the wall material, but without a single central core or cavity.

The "product-by-process" feature "obtainable by co-spray-drying a wall-forming material and a material that can be removed from the capsule walls" appearing in claim 2 as originally filed does not delimit the structure of the microcapsules exclusively to those having **a single hollow core surrounded** by a (porous) wall. Moreover, the product-by-process feature "removing said material" relates to the formation of pores, or hollow domains or areas, in the microparticle structure by elimination of one of the components building the wall, but does not imply that the pores remain exclusively in the wall, surrounding a central hollow core.

The broad definition, given in the application as filed (claim 2 and page 2), of the process for preparing the "porous microcapsules" does not suffice for delimiting the structure of the microcapsules, since the morphology of the microcapsules is also dictated by the nature and proportions of the components employed in the co-spray-drying process, as well as by the process parameters. None of these technical features has been specified either in the claims as originally filed or in the generic disclosure of the specification as originally filed. Hence, the structure of the microcapsules (apart from the presence of pores or hollow domains or areas) remains undetermined in the application as filed.

Additionally, claim 5 as originally filed, which is a dependent claim "according to any preceding claim", relates to microcapsules "which have an associated physiologically or diagnostically-active component, wherein **at least a proportion** of said component is present within the microcapsules **and/or** linked to the pores in the walls of the microcapsules". (*emphasis added*)

Therefore, the amendment relating to the physiologically active component as linked to the pores in the walls of the microcapsules was not a mandatory feature of the porous microcapsules disclosed in the application as originally filed.

Furthermore, the definition of the structure of the microcapsules appearing in each claim 1 of the main request and auxiliary requests 1 to 5 cannot be derived directly and unambiguously from the description as originally filed.

The passage under the heading "Summary of the invention" which has been repeatedly cited by the appellant-patentee reads as follows: "The present invention is based on the utility of porous microparticles, but specifically hollow microcapsules, and for a purpose different from controlled release" (page 2, lines 16 to 19).

This passage merely states that the "porous microparticles" are suitable for loading an agent (microcapsules) and that they have hollow domains or areas (pores). There is no definition of the morphology "a porous wall defining a hollow core", and there is no

hint to the further structural feature that the associated physiologically active component has to be "linked to the pores in the walls of the microcapsules".

Page 2 further states: "In particular, it has been discovered that the loading of drugs on microcapsules, of the type that can be obtained by spray-drying, can be generally enhanced" (lines 19 to 21). There is no more information here about the microcapsule structure than that given in claim 2 as originally filed, which has been already commented on.

Page 2 further states: "This and other desirable effects are achieved by rendering the walls of suitable microcapsules porous. The pores provide **additional** surface area, to which a physiologically or diagnostically-active agent can be chemically or physically linked, **in addition to surface binding**. The porosity may also be used as a means to introduce the agent into the microparticles. It may also enhance biodegradability". (page 2, lines 26 to 33) (*emphasis added*)

This passage clearly shows that, according to the content of the description, the porous microcapsules do not have to have a physiologically active agent linked to the pores in the wall, since it may also be linked to the rest of the surface or in the interior of the microcapsule (this is a clear counterpart of claim 5 as originally filed).

Page 3, lines 2 to 3 confirms that "The agent may be chemically or physically linked to, trapped in, or otherwise associated with, the microparticles", i.e. it

is not mandatory that it is linked to the pores in the wall.

Reading the passages of the specification dedicated on pages 3 and 4 to the description of the "invention" immediately shows that there are several options for obtaining porous microparticles with increased surface area. The disclosure on the third full paragraph on page 4 (which has been repeatedly cited by the appellant-patentee) clearly relates to **one** of the possible options and reads: "Porosity may also be introduced by chemical or physical treatment of intact microparticles, fixed or unfixed. A suitable physical process comprises high energy ultrasound exposure of microcapsules suspended in a concentrated drug solution. This results in **passage of the drug into the central cavity**. Subsequent removal of the water by, for example, lyophilisation should leave the drug within the microcapsule". (*emphasis added*)

This is the only passage in the whole application as originally filed in which the central cavity is mentioned. However, the disclosure on page 4 is very specific as regards the presence of the drug inside the central cavity. Hence, this passage cannot serve as a basis for the definition of the structure of the microcapsule as having a single hollow core surrounded by a porous wall with the physiologically active material linked to the pores in the wall.

Therefore, the definition of the microcapsules appearing in claim 1 of the main request and each claim 1 of auxiliary requests 1 to 5 extends beyond the

content of the application as filed (Article 100(c) and Article 123(2) EPC).

2.3 The appellant-patentee invoked the common general knowledge of the skilled person in order to supplement the brief information given in the application as filed. However, it cited for this purpose the international patent applications mentioned on page 3 of the application as originally filed, as well as US patent document (27) and non-patent literature document (5).

It is however very unusual that patent literature may serve to define the common general knowledge of the skilled person. Normally, the common general knowledge should be shown by means of handbooks, technical dictionaries or even review articles. The reasons are that each patent document reflects basically its own nomenclature and it is rather seldom that patent literature contains an appropriately neutral and comprehensive analysis of background art. Naturally, it may always be possible that a certain term becomes standard in a specific technical field before it is reflected in general books. In such a case it may be useful to cite a group of patent documents in which the same term is repeatedly used in an analogous way. However, this is not the case of the terms used in the present claims.

Documents (23), (10) and (11) were cited in the application as filed (page 3) as references for the materials and techniques to be used in preparing microparticles; the word "microcapsules" is not even mentioned in this context. Moreover, a brief overview of the cited documents immediately shows that there is

no common definition of the term "microcapsules" shared by all of them. Each of the documents addresses the definition of microparticles differently, depending on the particular material used and the different process parameters. Indeed, only document (23) explicitly contains a definition for the term "microcapsules", namely: "The term "microcapsules" means hollow particles enclosing a space, which space is filled with gas or vapour but not with any solid materials". This definition is very specific since it clearly states that the space is **filled with a gas**. Moreover such definition cannot be directly and unambiguously applied to **porous** microcapsules.

Moreover, even if this definition were considered applicable in general to all microcapsules obtainable by spray-drying (although this appears to be rather doubtful), it has to be considered that the microcapsules disclosed in the application as filed require an additional (chemical or physical) treatment for increasing or creating pores in the wall material. This additional treatment may take place in fixed or unfixed microcapsules as mentioned in the description (see passage at the end of page 2). Therefore, the final porous microcapsules may have varied their initial structure as a consequence of the treatment for creating hollow domains (areas) or pores. In other words, even if an initial structure of the type depicted in Fig 4(a) of the review article (33) were obtained by co-spray-drying, it is not disclosed in the application as filed whether such initial structure remains stable after the treatments which it has necessarily to undergo in order to create or increase the hollow domains (or areas).

As regards the other documents cited by the appellant-patentee, which are not cited in the application as filed, the following has to be said. Documents (5) and (27) do not employ the term "microcapsules" but the term "microspheres". Therefore, this opens a door for speculation about their possible equivalence or analogousness and, hence, these two prior-art citations cannot be invoked to provide clear support for the contested definition.

2.4 As regards claim 1 of auxiliary request 6 and each claim 1 of auxiliary requests 7 to 11, the following has to be said.

The microcapsules are defined as "hollow microcapsules each comprising a porous wall defining a central cavity, and which additionally have an associated physiologically active component, linked to the pores in the walls of the microcapsules".

The analysis made above for claim 1 of the main request and auxiliary requests 1 to 5 applies mutatis mutandis to the amended term underlined above which appears in each claim 1 of auxiliary requests 6 to 11. As already mentioned, the only passage of the description in which the term "central cavity" appears (see page 4) is too specific for allowing a generalisation to all hollow microcapsules, together with the combination with the feature that the physiologically active component is linked to the pores in the wall. In contrast to the definition appearing in the claims, the active component must be inside the central cavity, as disclosed on page 4.

Therefore, claim 1 of the sets of claims of auxiliary requests 6 to 11 contravenes the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald