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**Datasheet for the decision
of 3 April 2012**

Case Number: T 1741/10 - 3.2.08

Application Number: 03797325.2

Publication Number: 1539063

IPC: A61F 6/14, A61K 9/00

Language of the proceedings: EN

Title of invention:

A delivery system and a manufacturing process of a delivery system

Patent Proprietor:

Bayer Schering Pharma Oy

Opponent:

N.V. Organon

Headword:

-

Relevant legal provisions:

RPBA Art. 12(4)

Relevant legal provisions (EPC 1973):

EPC Art. 100(a)

Keyword:

"Novelty (main request, no)"

"Inventive step (auxiliary request 1 and 2, no)"

"Request filed with statement of grounds (admitted)"

Decisions cited:

-

Catchword:

-



Case Number: T 1741/10 - 3.2.08

DECISION
of the Technical Board of Appeal 3.2.08
of 3 April 2012

Appellant:
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
17 June 2010 concerning maintenance of European
patent No. 1539063 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
U. Tronser

Summary of Facts and Submissions

I. By decision posted on 17 June 2010 the opposition division decided that European Patent No. 1 539 063, amended according to auxiliary request 4 then on file, and the invention to which it related met the requirements of the EPC.

II. The appellant (patent proprietor) lodged an appeal against this decision on 17 August 2010, paying the appeal fee on the same day. The statement setting out the grounds for appeal was filed on 15 October 2010.

III. The appellant requested that the appealed decision be set aside and the opposition be rejected or the patent be maintained on the basis of one of the auxiliary requests 1 to 3 filed by letter dated 15 October 2010.

The respondent (opponent) requested that the appeal be dismissed.

IV. Independent claim 1 of the main request (patent as granted) reads as follows:

"A delivery system comprising a body construction and at least one capsule containing a pharmaceutical composition, said capsule having at least a first end and a second end, characterized in that the body construction (7, 12, 34) has at least two locking parts (9, 10), each locking part (9, 10) having at least a first end and a second end, said first end of each locking part (9, 10) having a surface adapted to face and cover one of the at least first and second ends of the capsule (8), the diameter of at least one of the

locking parts varying along its length between said first end and said second end, and in that the capsule (8) is mounted between said at least two locking parts (9, 10)."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request by the addition of the feature according to which

"... said locking parts (9, 10) have the shape of a truncated cone and in that the end of the truncated cone having a larger diameter is the end having the said surface facing said end of the capsule (8)."

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 by the addition of the feature according to which the delivery system is an

"intrauterine" delivery system.

Auxiliary request 3 is identical to auxiliary request 4 underlying the appealed decision, i.e. the request on which the decision of the opposition division to maintain the patent in amended form was based.

V. The following document is relevant for the present decision:

D2: US -A- 5 443 461.

VI. The arguments of the appellant relevant to the present decision can be summarised as follows:

Main request

The capsule shown in D2 could not be regarded as a body construction in the sense of the patent in suit. It was well known to a person skilled in the art that the body construction of a delivery system did not influence the release of the pharmaceutical composition. By contrast the caps of the system disclosed in D2 had an influence on said release. Hence, said caps could not be regarded as locking parts of a body construction, as required by present claim 1. Accordingly, the subject-matter of claim 1 was novel.

Auxiliary request 1

The object underlying claim 1 of this request could be seen as an easier manufacture of a delivery system. This object was achieved by means of the shape of the locking parts, which was a truncated cone. Moreover, this feature reduced the incidence of shifting the capsule in respect of the body construction, as demonstrated by the embodiments shown in the drawings.

The prior art neither disclosed nor suggested the claimed invention. The caps of the device shown in D2 did not have the shape of a truncated cone but rather that of a hemisphere. Moreover, this document did not serve as a starting point for a consideration of the problem of the shifting of the capsule, since the device shown therein did not have a body construction.

Accordingly, the subject-matter of claim 1 of auxiliary request 1 was novel and involved an inventive step.

Auxiliary request 2

Auxiliary request 2 was to be admitted into the proceedings since it had been filed with the grounds of opposition. Moreover, its claim 1 resulted from a combination of the claims as granted. Additionally, all the embodiments whose use was explicitly disclosed in the patent related to intrauterine systems.

The feature according to which the claimed delivery system was an intrauterine system also distinguished it from the system disclosed in D2. This document did not disclose that the depicted device was to be used in the uterus. Moreover, said device was not suitable for this use either. Although it was true that IUS (intrauterine systems) could have different shapes, none of the shapes proposed in the patent corresponded to that of the device known from D2. Moreover, an IUS had to anchor itself somehow in the uterus without damaging it. In view of the shape of the device shown in D2, an anchoring effect could not be expected while at the same time excluding damage to the uterus. Also for this reason the subject-matter of claim 1 of auxiliary request 2 involved an inventive step.

- VII. The arguments of the respondent relevant to the present decision can be summarised as follows:

Main request

D2 disclosed all the features of claim 1. In particular, there was no reason why the cylindrical section and the caps shown in D2 could not be considered as a body construction and the locking parts

of this body construction. First of all, it could not be excluded that the body construction according to claim 1 influenced the release of the pharmaceutical composition. Moreover, D2 did not disclose that the caps influenced said release. Therefore, the subject-matter of claim 1 lacked novelty.

Auxiliary request 1

In the embodiments disclosed in the patent in suit the locking parts as a whole did not exhibit the shape of a truncated cone. Said shape could only be obtained by cutting a section of the locking parts. Since also in the case of D2 it was possible to cut out of the hemispherical caps a section in the shape of a truncated cone, no distinguishing feature was introduced in claim 1 of auxiliary request 1. Accordingly, also the subject-matter of said claim lacked novelty.

In addition, even if the feature relating to the shape of the locking parts were to be seen as novel, it could not justify an inventive step since it was not associated with any effect.

Auxiliary request 2

Since auxiliary request 2 could have been filed during the first instance proceedings, it was late-filed. Moreover, it raised the issue of what was an intrauterine delivery system, which had not been considered in the decision under appeal. Hence, it should not be admitted into the appeal proceedings.

Moreover, in the event that the board decided to admit it into the proceedings it should at least reject it as not allowable. The system described in D2 was an intravaginal system which could, in view of its shape and dimensions, also be inserted into the uterus of an unspecified animal. Since the patent in suit did not state any limitation in respect of the animal to be treated, of the time of residence in the uterus of the system and of the shape of the system, the system shown in D2 could be considered as an intrauterine delivery system. Therefore, auxiliary request 2 was not allowable for the same reasons given for auxiliary request 1.

Reasons for the Decision

1. The appeal is admissible.
2. Main request- Novelty
 - 2.1 D2 undisputedly discloses a delivery system (column 1, line 6-9) comprising two cylindrical sections and at least one capsule (13, 14, 36) containing a pharmaceutical composition (see column 6, lines 34-39), said capsule having a first end and a second end, wherein the system comprises two caps (15, 16), each cap having a first end and a second end, said first end of each cap having a surface adapted to face and cover one of the at least first and second ends of the capsule, the diameter of the cap varying along their length between said first end and said second end, wherein the capsule is mounted between said at least two caps (see Figures 1 and 2).

2.2 According to the appellant, the cylindrical sections could not be regarded as a body construction and the caps shown in D2 could not be regarded as locking parts of this body construction because they had an influence on the release of the pharmaceutical composition.

However, present claim 1 does not specify what is to be considered as a "body construction". Moreover, neither has this term a well-recognised meaning in the technical field of the patent nor does the description of the patent in suit define it. Accordingly, the cylindrical section of the delivery system according to D2 can be considered as forming a body construction and the caps of the system can be considered to be locking parts of this body construction. This would apply even if they had an influence on the release of the pharmaceutical composition, which has not been shown, since said influence is not excluded by the patent in suit. Therefore, the subject-matter of claim 1 of the main request lacks novelty.

3. Auxiliary request 1- Novelty

In the delivery system disclosed in D2 the diameters of the locking parts vary along their length so that the end having a larger diameter is that having the surface facing the end of the capsule. However, the locking parts have the shape of a hemisphere. Hence, it is not possible to obtain the shape of a truncated cone (which is by definition obtained by cutting a cone) by cutting out a section from them. Therefore, contrary to the respondent's view, the subject-matter of claim 1 of auxiliary request 1 is novel over D2 by virtue of the

feature according to which the locking parts have the shape of a truncated cone.

4. Auxiliary request 1 - inventive step

The shape of a truncated cone in accordance with claim 1 is very similar to the shape of a hemisphere of the caps of D2. Since in both cases the end of the locking part with the larger diameter is that having the surface facing the end of the capsule, none of these two shapes results in a significantly easier insertion or extraction of the delivery system. Nor is a truncated cone easier to manufacture than a hemisphere, which can be produced by standard processes such as injection-moulding (see D2, column 8, lines 58-67). The appellant submitted that some of the arrangements shown in the embodiments of the patent in suit reduced the incidence of the problem of shifting the capsule in respect of the body construction. However, this effect cannot be attributed to the truncated cone shape of the locking parts but is rather provided by some of the specific features of said embodiments which are not comprised in the claim, like, for example, the fact that the capsule is arranged around the body construction.

Therefore, no effect is provided by the distinguishing feature of claim 1 vis-à-vis D2. Accordingly, the object underlying the claimed invention cannot be seen as an easier manufacture of the device but merely as the provision of an alternative shape of the delivery system.

In view of this object it was obvious to consider shapes slightly differing from the known one and exhibiting similar properties to it, such as for instance caps in the shape of truncated cones instead of the known hemispherical ones. Hence, it was obvious to arrive at the claimed delivery system.

Therefore, the subject-matter of claim 1 lacks inventive step.

5. Auxiliary request 2 - Admissibility

According to Article 12(4) of the Rules of Procedure of the Boards of Appeal (OJ EPO 11/2007, page 536), the board has the power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings.

In the present case, auxiliary request 2 was introduced for the first time with the statement of grounds of appeal. However, the feature added by this request, according to which the delivery system is an intrauterine one, was already present in claim 9 as granted. Moreover, this use of the claimed delivery system was presented in the description as a preferred use of the delivery system (see paragraph [0003]) and was the sole application disclosed for the systems according to the preferred embodiments. Furthermore, auxiliary request 2 was submitted at the earliest possible stage of the appeal proceedings. Hence, the respondent could not have been taken by surprise by this request and had sufficient time to react to it.

Under these circumstances auxiliary request 2 is admitted into the proceedings.

6. Auxiliary request 2 - Inventive step

An intrauterine delivery system is a delivery system which is capable of being inserted into the uterus of a human or an animal. In the present case its shape is not defined. Although the most frequently adopted shape for intrauterine systems is a T-shape, several other shapes are possible according to the patent in suit. The last two sentences of paragraph [0003] list in a non-limiting way a ring, a "7" shape or an "S" shape, and further state that similar constructions are used inter alia for intravaginal systems. Moreover, the claim does not define how long said system must be capable of remaining in the uterus. Hence, an anchoring effect of this system is not implicit.

D2 explicitly states that the delivery system may be applied vaginally (see column 8, lines 46-49). In view of its dimensions (see column 9, lines 50-53) it can also be inserted into the uterus of an animal. Moreover, there is no reason why this system, which has no exposed edges, would damage the uterus more easily than the systems according to the embodiments of the patent in suit.

Under these circumstances there is no reason why the system disclosed in D2 cannot be regarded as an intrauterine delivery system.

Hence, the sole distinguishing feature of the subject-matter of claim 1 of auxiliary request 2 is the same as

for claim 1 of auxiliary request 1. Since, as explained above, it was obvious to provide said distinguishing feature, the subject-matter of claim 1 of auxiliary request 2 does also not involve an inventive step.

7. Auxiliary request 3

Auxiliary request 3 corresponds to the request on which the decision of the opposition division to maintain the patent in amended form was based. Therefore, it does not involve setting aside the decision under appeal and is de facto a request to dismiss the appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner