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D E C I S I O N
of 24 January 1995

Case Number: T 1031/92 - 3.2.2

Application Number: 83900114.6

Publication Number: 0097670

IPC: B23P 11/02

Language of the proceedings: EN

Title of invention:
Injection site

Patentee:
BAXTER INTERNATIONAL INC.

Opponent:
Fresenius AG

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no) - obvious combination of known features"

Decisions cited:

Catchword:



Case Number: T 1031/92 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 January 1995

Appellant: Fresenius AG
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office dated 17 September
1992 concerning maintenance of European patent
No. 0 097 670 in amended form.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noel
J. Van Moer

Summary of Facts and Submissions

I. In consequence of an opposition filed by the Appellant against the European patent No. 0 097 670, the Opposition Division decided in an interlocutory decision dated 17 September 1992 to maintain the European patent in amended form, having regard to the state of the art illustrated by documents:

- (1) FR-A-1 325 077
- (2) DE-A-2805 354.

II. Claim 1 reads as follows:

"A medical needle-pierceable injection site comprising:
a generally tubular port (20) including a base end (19) and a top end (26); a needle-pierceable membrane (24) extending across and closing said base end; said generally tubular port and needle-pierceable membrane defining a volume (28), said top end defining a substantially circular opening (30) to said defined volume, said defined volume (28) between said top end (26) and said base end (19) being substantially cylindrical; a needle-pierceable situs (22) of self-sealing material forcibly engaged in said generally tubular port and retained in sealing relation thereto, characterised in that the situs (22) is in the form of a sphere in its unstressed state before engagement with the port and is sufficiently oversized with respect to said defined volume (28) so as to be under diametral compression such that the said sealing relationship is provided and such that the situs conforms substantially

in shape to the defined volume and is held in place thereby and is not readily withdrawn from the port when a needle is introduced into the situs and then withdrawn."

III. The reasoning given by the Opposition Division in support of the maintenance of the patent was that starting from the injection site disclosed in document (1) in which a needle-pierceable situs is cylindrical in shape and forcibly engaged in a cylindrical port, the skilled person would not arrive at the subject-matter of Claim 1 by combining this state of the art with the teaching of document (2). Document (2) describes a spherical situs having a diameter smaller than that of the housing, the thus undersized situs being clamped in position by means of a two-part clamping system and sealing being obtained by deforming the situs into tight engagement with part-spherical seats in the cylindrical housing. Therefore, there is no suggestion in document (2) that an oversized spherical situs should be engaged with a cylindrical port so that the situs is forced to conform to the shape of the port.

IV. The Appellant (Opponent) lodged an appeal against this decision on 14 November 1992 paying the fee on the same date and filed a Statement of Grounds within the prescribed time limit.

In a response dated 5 October 1993, the Respondent (Proprietor of the patent) submitted, a main and an auxiliary request, Claim 1 according to the main request being based on Claim 1 as maintained by the Opposition Division.

V. Oral proceedings were held on 24 January 1995.

(i) The Appellant argued substantially as follows:

Document (2) with reference to the embodiment of Figure 3 is regarded as the closest prior art since it discloses a spherical situs compressed into a cylindrical housing having, in addition, an upper opening. By replacing the snap-in ring used in document (2) by the membrane provided at the base end of the tubular port of the injection site described in document (1) and by forcing the spherical situs through the narrower upper opening, the skilled person would certainly arrive at the subject-matter of Claim 1 according to the main request without any difficulty.

Claim 1 according to the auxiliary request only differs from the main request by a minor detail without inventive significance since an upper opening for engaging the situs is already present in either embodiments of documents (1) or (2).

(ii) The Respondent replied as follows:

Document (1) represents the closest prior art since it describes a situs force-fitted into a cylindrical port. However, it is difficult to insert a cylindrical situs into a port of similar shape and the resistance to withdrawal of the situs is poor, so that attempted withdrawal of a needle may cause the situs to come out of the port. Contrary to that, the spherical situs according to the invention is oversized relative to the volume of its cylindrical housing so as to be under diametral compression, which facilitates insertion

of the situs and provides a much higher resistive force to withdrawal and a better target to needle insertion.

The skilled person would not find in document (2) any hint to the claimed solution since the spherical situs used there is undersized, i.e. loosely fitted in the port, and the seat is spherically preformed to conform to the shape of the situs. Document (2), therefore, teaches a totally different approach for mounting the situs, requiring axial clamping, so that a combination of documents (1) and (2) appears to be unlikely and would result in an ex-post facto analysis.

Claim 1 according to the auxiliary request provides additional particulars about the mounting of the situs.

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 according to either the main or auxiliary request filed on 5 October 1993.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The subject-matter of Claim 1 in the version according to either the main or auxiliary request is based on the content of Claim 1 as originally filed, supplemented by

features drawn up from the description of the application as filed, in particular page 5. Therefore, the current versions of Claim 1 are not open to formal objection under Article 123 EPC.

In the following items up to point 6, reference is made to Claim 1 according to the main request.

3. *Novelty*

- 3.1 In the Board's judgment, document (1) represents the state of the art closest to the invention since it discloses all the features recited in the precharacterising portion of Claim 1, whereas the injection site described in document (2) has no membrane at the base end of the tubular port and the situs is not force-fitted in its housing as will be further detailed hereinafter.

Document (1) describes with reference to Figure 1 a medical needle-pierceable injection site comprising a port 2 including a base end in the form of a membrane 4 extending across and closing the volume defined by the port and a top end 3 defining an opening to said volume. Since the injection site is designed for the neck of a bottle, the moulded wall 2 of the central port has a form generated by revolution. In other words, said volume like said port are substantially cylindrical in shape and said opening substantially circular, in accordance with the wordings of Claim 1.

Further, a needle-pierceable situs 5 is said to be forcibly engaged ("enfoncé à force") in the tubular port. The situs is made of elastomeric material to ensure a sealing contact ("contact parfait") with the wall of the port and it is compressed within the port after assembly (cf. page 1, right column, second

paragraph and abstract, page 2, point d). Therefore, it is directly and unambiguously derivable from what is expressly mentioned in document (1) (see Guidelines for examination, C-IV, 7.2 and 7.4) that the elastomeric situs must be oversized with respect to the port when still in its unstressed state before engagement and, after introduction, in a state under diametral compression, in conformity with the second characterising feature of Claim 1.

3.2 The characterising features of Claim 1 introduced by the terms "such that" impose limitations by way of achieving certain results. Even if technical effects can be regarded as functional features, which is generally admissible in a device claim, in particular when the claimed subject-matter cannot be otherwise defined, in the present case, however, these features represent, with other words, no more than the logical consequence of the structural features previously defined in Claim 1, all known from document (1). The fact that the situs used in this document is forcibly engaged so as to be under compression automatically implies that a sealing relationship is provided with the contacting surface of the tubular port, that the situs conforms substantially in shape to the defined volume and that it is held in place and not readily withdrawn from the port when a needle is introduced into the situs and then withdrawn. The fact that an additional inwardly tapered end 3 is also present in the injection site described in document (1) - as compared with the top end 26 of the injection site according to the patent in suit - for enhancing maintenance of the compressed situs in its housing, does not lower the retaining effect provided in other respects by the very compression of the situs alone.

3.3 With respect to the injection site described in document (1), the subject-matter of Claim 1 only differs by the remaining feature according to which the situs is in the form of a sphere in its unstressed state before engagement with the port.

Since in none of the documents revealed in the proceedings are all the features of Claim 1 disclosed in combination, its subject-matter must be regarded as novel over the prior art.

4. *Problem and solution*

Document (1) teaches the frictional fitting of a rubber-like cylindrical situs in and about a cylindrical port. Therefore, the risk occurs of the situs being accidentally removed out of the port by a needle after repeated injections.

The technical problem underlying the present patent was, therefore, to prevent inadvertent removal of the situs and enhance the sealing characteristics.

This problem is solved by the remaining feature of Claim 1 mentioned above (point 3.3) with the additional effects of presenting an easy target for injection and permitting automated assembly.

5. *Inventive step*

5.1 The skilled person faced with the problem of how to retain efficiently a force-fitted situs in a port will turn necessarily to document (2) which refers to the same narrow field of providing a needle-pierceable injection site permitting effective self-sealing after removal of the needle (cf. page 3, third paragraph).

In the embodiment according to Figure 3 of document (2), the injection site comprises a spherical situs 7a made of elastomeric material, which is compressed ("durch Zusammenpressen des Propfens", page 3, last paragraph) in a tubular housing 2a by means of a snap-in ring 4a. The situs has a diameter smaller than the diameter of the port, so that it is loosely engaged in the port before compression and deformation by the fastening ring (cf. Claim 2) as a result of a volume reduction of the housing. As explained on page 6 of document (2) the spherical situs is confined between two spherical seats 8a and 9a provided in the bottom of the port and in the ring, respectively. However, the straight section of the housing is principally tubular ("Rohrstutzen"), i.e. cylindrical in form, as clearly shown in Figure 3. Therefore, any compression force exercised axially by the snap-in ring on the spherical situs will result, in view of its deformation, in an increased radial contacting force on the tubular wall of the port, with the inevitable consequence of reinforcing the retaining force and thus the sealing effect of the situs, as is also the case with the situs according to the patent in suit (cf. Figure 4).

It is still to be noticed that for the sealing and retaining functions of the situs, it matters little whether the situs is deformed axially or radially with respect to the axis of the tubular port. The direction of the deformation depends only on the diameter ratio between the spherical situs and the cylindrical port. In the case of document (2) where the diameter of the situs before engagement is smaller than that of its housing, the deformation is radial because this is the only direction in which the situs can expand. Inversely, and for the same reasons, the deformation is axial in the embodiment according to the patent. But an unquestionable fact remains that in document (2) "the

situs is in the form of a sphere in its unstressed state before engagement with the port", in strict conformity with the wording of the remaining feature of Claim 1 as set out in point 3.3 above.

- 5.2 Thus the determinative question to consider is whether the skilled person having regard to the prior art would have got the idea of replacing the oversized cylindrical situs used in the embodiment of document (1) by the spherical situs disclosed by document (2) so as to arrive at the solution as defined in Claim 1 in suit.

In the Board's view, the skilled person is given a direct indication to do so, since document (2) discloses with reference to Figure 3 the co-operation of a spherical situs with a generally cylindrical housing, in particular in the straight section of the cylindrical wall where the pressing force resulting from the situs deformation is maximum. It is therefore obvious that the spherical situs used in document (2) would be also suitable for engagement in force into the cylindrical port of the injection site of document (1), in view of its beneficial effect. Once it has been decided to forcibly engage a spherical situs in the cylindrical port, other additional advantages such as easy target for injection and automated assembly possibility are also obtained by the arrangement.

Moreover, document (2) proposes as an alternative (cf. Figure 4 and page 6, last paragraph) a functionally equivalent embodiment, according to which the resilient spherical situs 7a used in Figure 3 can be replaced by a cylindrical situs 7b, the remaining structure being

unchanged and working in the same way. Therefore, the skilled person would also be led to contemplate the reciprocal substitution of a cylindrical situs by a spherical one, all other factors being equal.

5.3 Any other constructional differences relied on in the Respondent's argumentation regarding the embodiment disclosed in document (2) are irrelevant. For example, it is of no consequence whether the resilient spherical situs is undersized with respect to the port and not forcibly engaged, but compressed only after engagement by means of an additional fastening element, since all the features which refer to oversizing of the situs, force-fitting in the port and the resulting compression state are all known from document (1) taken as starting point for the assessment of the inventive step of Claim 1.

5.4 For the foregoing reasons, the subject-matter of Claim 1 according to the main request lacks any inventive step in the sense that it is obvious to a person skilled in the art, having regard to the combination of documents (1) and (2) (Art. 56 EPC).

6. *Auxiliary request*

The subject-matter of Claim 1 according to the auxiliary request only differs from Claim 1 of the main request by the incorporation of the terms "through said opening 30" behind the word "engaged" in the precharacterising portion of Claim 1 for specifying the location of engagement of the situs. In the Board's view, this additional feature is not only superfluous, since Claim 1 already states that an opening is present in the port to give access to the situs, but also known from document (1) as explained above in point 3.1.

Consequently, the same conclusion as before concerning lack of inventive step also applies to Claim 1 according to the auxiliary request.

Order

For these reasons it is decided that:

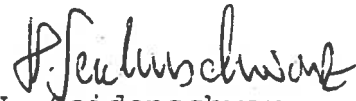
1. The decision under appeal is set aside.
2. The European patent is revoked.

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz

