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D E C I S I O N
of 24 March 2004

Case Number: T 1096/02 - 3.2.2

Application Number: 97918077.5

Publication Number: 0895481

IPC: A61M 5/32

Language of the proceedings: EN

Title of invention:
Injection Needle

Patentee:
NOVO NORDISK A/S

Opponent:
Disetronic Licensing AG

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1096/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 March 2004

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 20 August 2002 rejecting the opposition filed against European patent No. 0895481 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (opponent) appealed against the decision of the opposition division to reject the opposition.

II. The opposition was based on the grounds of lack of novelty against document

D1 = US-5 462 535

and lack of inventive step on the basis of a combination of document D1 with document

D2 = ISO 9626, 1991 or with four further documents cited.

III. Following a request from both parties, oral proceedings were held on 24 March 2004.

IV. At the end of the oral proceedings, the appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained as granted (main request) or on the basis of either the amended description and claims 1 to 5 submitted as first auxiliary request or the amended description and claims 1 to 3 submitted as second auxiliary request, both filed at the oral proceedings.

V. Claim 1 as granted reads as follows:

"An injection needle mounted in a needle hub fitting onto an injection device from which preset doses of a medicine from a cartridge accommodated in the device may be administered through the needle being mounted on the device and exposing a back needle for penetrating a closure membrane of the cartridge and a free injection part, characterized in that the length of the injection part is shorter than 9 mm and that the outer diameter and the diameter of the bore of the needle complies with one of the conditions:
a) the outer diameter is smaller that 0,320 mm and the diameter of the bore is larger than 0,165 mm,
b) the outer diameter is smaller that 0,298 mm and the diameter of the bore is larger than 0,133 mm."

Claim 1 according to the first auxiliary request reads as follows:

"An injection needle mounted in a needle hub fitting onto an injection device from which preset doses of a medicine from a cartridge accommodated in the device may be administered through the needle being mounted on the device and exposing a back needle for penetrating a closure membrane of the cartridge and a free injection part, characterized in that the free injection part of the needle has a length in the interval 4 - 8 mm and that the outer diameter and the diameter of the bore of the needle complies with the condition: the outer diameter is smaller that 0,298 mm and the diameter of the bore is larger than 0,133 mm."

Claim 1 according to the second auxiliary request reads as follows:

"An injection needle mounted in a needle hub fitting onto an injection device from which preset doses of the crystalline insulin from a cartridge accommodated in the device may be administered through the needle being mounted on the device and exposing a back needle for penetrating a closure membrane of the cartridge and a free injection part, characterized in that the length of the injection part is shorter than 9 mm and that the outer diameter and the diameter of the bore of the needle complies with the condition: the outer diameter is smaller that 0,320 mm and the diameter of the bore is larger than 0,165 mm."

VI. The appellant argued as follows:

The appeal was admissible because it was directed to reverse the decision of the first instance on the basis of a line of arguments which had been already introduced in the first instance proceedings but not been thoroughly considered. The main request did not involve an inventive step having regard to the teaching of document D1 and the general knowledge of the person skilled in the art. The person skilled in the art knew, starting from the teaching of document D1, that the problems to be solved were, from one side, to relieve pain, and on the other side to improve flow. Thinner and shorter needles caused less pain, whereas the flow was improved either by using fluids with low viscosity and having suspension particles with smaller diameter or by widening the diameter of the bore. In general there was a trade-off between the relieve of pain

attained by lowering the diameter of the needle and the improvement of flow attained by broadening of the diameter of the bore. Claim 1 of the main request reflected merely the teaching of document D1 combined with the general knowledge as described above. The fact that claim 1 claimed values for the diameter of the bore and of the needle which went against the standard of document D2 was irrelevant because the standard in this case was only a recommendation and did not prove that there was a prejudice against the teaching of the patent in suit. It was in particular obvious, starting from document D1, to improve flow by raising the diameter of the bore, when the possibilities of improvement by choosing a fluid with lower viscosity were exhausted.

For the first auxiliary request the arguments brought forward for the main request remained valid. Document D1 contained furthermore a hint to reduce pain by shortening the needle, see column 2, lines 40 to 44 and line 57. At column 6, line 62 of document D1 it made clear that the length of the needle depended on whether was necessary an intramuscular or subcutaneous injection. The claimed invention, on the other hand, did not exclude subcutaneous injections. Furthermore claim 6 of document D1 contained the valued of 0,8 cm for the length of the needle. On the other hand, claim 1 of the first auxiliary request claimed also the value 0,8 cm, as it became clear, when the claim was read on the light of the description, column 3, line 22.

The second auxiliary request contained claim 1 which was the same as claim 1 of the main request, first alternative.

VII. The respondent submitted the following arguments:

The appeal was not admissible. The appellant had failed to show why the finding of the first instance regarding the combinations of certain documents (D1, D2, D3 and D5) was incorrect. Furthermore, during the oral proceedings the respondent referred to the decision T 846/01, according to which, for an appeal to be admissible, at least one of the grounds for appeal must relate to a point which could have been decided in the appellant's favour by the first instance and such favourable decision on this point would have produced a different outcome. He argues that this was not the case here, because the argument now presented against inventive step had been already presented during the opposition proceedings and been held unfounded.

Regarding inventive step, the object of the invention was stated at point 6 of the description as to provide a needle by which the advantages of the G30 needle was enhanced and/or its drawbacks minimized. The advantage to be enhanced was the reduction of pain, the problem to be overcome was to avoid excessively high injection pressure. Having in mind that document D2, the ISO standard defining the needle G30, was antecedent to document D1, and that document D1 adopted the ISO standard for the G30 needle, it became clear that a combination of D1 and D2 could not render the claimed invention obvious. The invention went against the teaching of document D1 because such document clearly

delivered as solution for the problem of clogging, to change the type of fluid, namely to choose a fluid containing smaller crystals. Nowhere in document D2 had been suggested to modify (increase) the diameter of the bore in order to improve the flow. On the other hand, the invention went against the standards defined by document D2 for the G30 needle. The decision T 300/92, point 2.3.5 dealt with the same issue. The further development of the standard (G31 and G32) went in the direction of reducing the external diameter and the diameter of the bore. In contrast there to, the invention claimed to reduce the diameter of the needle and to increase the diameter of the bore.

The first auxiliary request addressed in particular the problem of reduction of pain. To this purpose a reduction of the length of the needle was claimed. The claim did not cover the extreme values (8 and 4) of the range of values for the needle length.

The second auxiliary request contained the functional limitation regarding the use of crystalline insulin.

Reasons for the Decision

1. *Admissibility*

Contrary to what the respondent apparently contended, grounds of appeal, in order to be sufficiently substantiated, do not need to show (at least) why the specific considerations, on which the contested decision was based, are incorrect. Rather, an appeal is admissible, even if it is exclusively based on fresh

grounds unconnected with those in the decision under appeal, but which are still within the same opposition ground (one for many decisions: T 611/90). The notice of appeal in question clearly met that requirement, in that it set out extensive arguments against inventive step concerning the subject-matter of claim 1 (these arguments, in addition, being based *inter alia* on documents D1 and D2 which had been discussed in the decision under appeal as to their bearing on inventive step). As regards decision T 846/01 it suffices to point out that in the present case inventive step is a point, to which the grounds of appeal (extensively and exclusively) relate and which could have been decided in the appellant's (opponent's) favour by the first instance and such decision had produced a different outcome, namely the revocation of the patent or its maintenance in amended form. That point was not, contrary to the situation underlying decision T 846/01, a matter that had been finally decided before the present appeal and thus would have been excluded from further review.

All relevant legal requirements being met, the appeal is admissible.

2. *Main request*

2.1 Starting from document D1 which represents, according o the submissions of the parties, the closest state of the art, the following features of claim 1, first alternative, are known:

An injection needle (30) mounted in a needle hub (31-33) fitting onto an injection device from which preset

doses of a medicine from a cartridge (113, 22) accommodated in the device may be administered through the needle being mounted on the device and exposing a back needle for penetrating a closure membrane of the cartridge and a free injection part, the length of the injection part being shorter than 9 mm (8 mm, claim 8) the needle (a G30 needle, claim 1) having an outer diameter smaller than 0,320 mm (column 1, line 46: 0,300 mm).

The subject—matter of claim 1 differs from this state of the art that either

(a) in a first option the bore diameter d is equal or larger than 0,165 mm, or

(b) in a second option the bore diameter d is equal or larger than 0.133 mm and the outer diameter D is equal or smaller than O,298 mm.

It is, therefore, unchallenged that the subject—matter of claim 1 is novel.

2.2 This means, see patent in suit (column 2, lines 24 to 46), that according to the main request, one of the following two conditions is complied with.

(a) the outer diameter corresponds to the outer diameter of a G30 needle according to 1SO9626 and the bore diameter is larger than the bore diameter of an ordinary G30 needle, or

(b) the outer diameter is smaller than the outer diameter of a G30 needle and the diameter of the

bore is larger than the minimum diameter or the bore in an ordinary G30 needle.

In principle the essence of these two options is that the wall thickness of the needle is reduced with respect to the ISO9626 standard either by

(a) reducing the outer diameter of the needle with respect to the standard, or by

(b) enlarging the bore diameter of the needle with respect to the standard.

According to document D1 ("Background of the invention"), in the treatment of diabetes it is aspired to make the injections as painless as possible to the patient and to reduce the physical malaise many people feel when they have to pass a needle into their own body. As the malaise seems to grow with the length and the thickness of the needle and the sensation of pain seems to be reduced when the needle is made thinner and shorter. Therefore according to document D1, the use of G30 needles was suggested instead of prior used G27, G28 or G29 needles.

Still according to document D1, the use of standard G30 needles, although bringing about a certain pain relief, suffered from the drawback that certain qualities of insulin containing suspended crystals of considerable size could no longer be administered because the crystals tended to align themselves across the inside of the needle resulting in its clogging. Consequently, document D1 (cf claims 1 and 2) suggests that only a type of insulin be administered which may freely flow

through a G30 needle, in particular an insuline with a maximal crystal size of 15 µm.

The patent in suit claims that a patient using the device according to Dl, or its family member WO93/00948, is confronted with the first drawback of an excessively high injection pressure and of the restriction with respect to the type of insuline which has to be used in connection with a standard G30 needle.

A second drawback, independent of the first one mentioned before, may be seen in a still unbearably high pain sensation when using the device with the standard G30 needle disclosed in D1.

Being aware that a relief to the first drawback does not remedy the second one, the options a) or b) in the alternative feature in claim 1 solve either the problem based on the first drawback by increasing the diameter of the bore or the one based on the second one by reducing the outer diameter.

2.3 From the law of Hagen-Poiseuille, originally developed for hemodynamics and being common ground in this field, it is obvious that the increased bore diameter according to option (a) of claim 1 will result in a massive reduction of the injection pressure. Moreover, the practitioner understood from document Dl that the larger bore will permit him to return to the use of insulin types with larger crystal sizes.

2.4 Option (b) of claim 1 is obvious in the light of document Dl alone which, departing from larger diameter

needles, chose the G30 standard needle for the purpose to relieve the pain sensation.

2.5 Contrary to the arguments put forward in the oral proceedings, in the description of the patent itself, see paragraph [0010], it is acknowledged in principle the above described technical effects brought about by the reduced wall thickness of a G30 needle, are obvious. It is asserted, however, that the skilled world, suspecting an increased risk of breaking, was hesitant to use such thin-walled needles in connection with devices not for use by professionals but designed for self administration of medicine.

Such negative attitude against deviating from an official standard may be applicable for the marketing division which sees the risk of a lengthy procedure to obtain the authorisation by a governmental health administration. It is, however, not typical for the R&D division of the same company which is accustomed to leave the limits of old standards und create new ones.

The assertion of such a prejudice is even less valid for the subject-matter of the present claim 1. The wall thicknesses of the needle system defined in standard ISO 9626, document D2, are based on the mechanical (in particular the bending) properties of certain standardised stainless steels. The granted claims of the patent in suit, however, do not refer to any official standard nor do they contain any restriction with respect to the material from wich the needle is to be made.

In consequence of the considerations above, the subject-matter of claim 1 of the main request does not involve an inventive step.

3. *First auxiliary request*

Claim 1 according to the first auxiliary request corresponds to option (b) in claim 1 of the main request with the proviso that the free injection part has a length in the interval 4 - 8 mm.

This measure, however, does not reverse the considerations in paragraphs 2.4 and 2.5 above resulting in lack of inventive step of option (b), because it is already hinted at in document D1, column 1, lines 25 to 32, that malaise seems to grow with the length and the thickness of the needle and the sensation of pain seems to be reduced when the needle is made thinner and shorter. The needle must, however, still have a length permitting the subcutaneous injection of insulin.

Therefore, also the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step.

4. *Second auxiliary request*

Claim 1 according to the second auxiliary request corresponds to the option (a) in claim 1 of the main request with the proviso that the claim now specifies that the injection device is adapted to administer preset doses of crystalline insulin.

Since the considerations in paragraph 2.3 and 2.5 above resulting in lack of inventive step of option (a) have already included the administration of crystalline insuline, they apply for claim 1 of the second auxiliary request as well.

Therefore, also the subject-matter of claim 1 of the second auxiliary request lacks an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

V. Commare W. D. Weiß