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Datasheet for the decision of 13 September 2019

Case Number: T 2197/14 - 3.2.02

Application Number: 04716589.9

Publication Number: 1601396

IPC: A61M5/315

Language of the proceedings: EN

Title of invention:
IMPROVEMENTS IN AND RELATING TO DRIVE MECHANISMS SUITABLE FOR USE IN DRUG DELIVERY DEVICES

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
(withdrawn)

Headword:

Relevant legal provisions:
EPC Art. 83, 100(b), 111(1), 123(2)
EPC R. 42(1)(e), 43(1), 43(3)

Keyword:
Sufficiency of disclosure - main request (no)
sufficiency of disclosure - auxiliary request 5 - (yes)
Extension beyond the application as filed - auxiliary request 5 - (no)
Remittal to the department of first instance - (yes)

Decisions cited:
T 0409/91

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2197/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 September 2019

Appellant: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
Representative:	Keil & Schaafhausen Patent- und Rechtsanwälte PartGmbB Friedrichstraße 2-6 60323 Frankfurt am Main (DE)
Respondent: (Opponent)	withdrawn
Representative:	
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 November 2014 revoking European patent No. 1601396 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	D. Ceccarelli

Summary of Facts and Submissions

I. The appeal of the patent proprietor is against the decision of the Opposition Division dated 21 November 2014 to revoke the patent, in particular because of lack of sufficiency and added subject-matter.

II. Notice of appeal was filed on 7 November 2014 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 31 March 2015.

III. On 22 October 2015 the opponent withdrew its opposition.

IV. Oral proceedings were held on 13 September 2019.

The appellant/patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary requests 5, 1 to 4 and 6, filed by letter dated 24 July 2015, and auxiliary requests 7 to 15, filed by letter dated 13 August 2019, in that order.

V. Claim 1 according to the main request (of the patent as granted) reads as follows:

"A drive mechanism for use in a drug delivery device comprising:

a housing (2);

a dose dial sleeve (40) having a helical thread (41) of a first lead; and
a two-part piston rod (14);

characterised in that

the said two-part piston rod (14) comprises an outer part (18) having a helical thread (24) of a second lead and an inner part (16) having a helical thread (36) of a third lead, whereby the first lead of the thread (41) of the dose dial sleeve (40) is equal to the sum of the second lead of the thread (24) of the outer part (18) of the piston rod (14) and the third lead of the thread (24) of the inner part (16) of the piston rod."

VI. Claim 1 according to auxiliary request 5 reads as follows (amendments over claim 1 of the patent as granted underlined by the Board):

"A drive mechanism for use in a drug delivery device comprising:

a housing (2);

a dose dial sleeve (40) having a helical thread (41) of a first lead, which dose dial sleeve (40) is threadedly engaged with the housing (2) by a cylindrical spiral rib located on the internal surface of the housing (2) and a groove located on the external surface of the dose dial sleeve (40); and

a two-part piston rod (14);

characterised in that

the said two-part piston rod (14) comprises an outer part (18) having an external helical thread (24) of a second lead, which outer part (18) is adapted for longitudinal displacement only with respect to the housing (2), and an inner part (16) having an external

helical thread (22) of a third lead, whereby the first lead of the thread (41) of the dose dial sleeve (40) is equal to the sum of the second lead of the thread (24) of the outer part (18) of the piston rod (14) and the third lead of the thread (22) of the inner part (16) of the piston rod,

wherein the inner part (16) and the outer part (18) of the piston rod (14) are adapted for longitudinal displacement but restricted for rotation with respect to each other,

and wherein the drive mechanism further comprises a drive sleeve (30) wherein the thread (22) of the inner part (16) being designed to engage with the drive sleeve (30).”

VII. The arguments of the appellant/patent proprietor relevant for the decision and not endorsed by the Board in the reasons set out below can be summarised as follows.

Main request – sufficiency

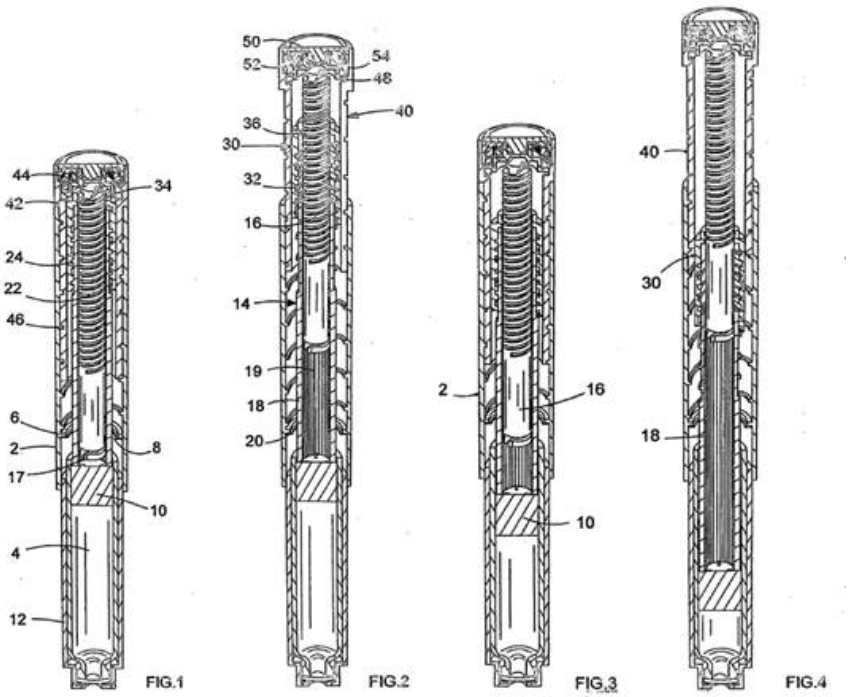
Claim 1 was limited to a drive mechanism for use in a drug delivery device so that the possible complexity of an injection pen, as in the specific embodiment disclosed, was not to be considered for the examination of sufficiency. A drive mechanism was much simpler and the number of alternatives much more reduced when compared to a multi-dose injection device. The introductory part of the description gave multiple pointers as to the way the mechanism could be designed. Moreover, the technical effect to be obtained was not an issue of sufficiency but of inventive step. The claim had only to contain the features giving the

person skilled in the art the opportunity to solve the problem, i.e. the basic idea. In addition, in the mechanical field, disclosing one functioning embodiment, as was the case here, was generally considered enough to satisfy the requirement of sufficiency.

Reasons for the Decision

1. The appeal is admissible.

2. The invention is a drive mechanism for use in a drug delivery device. The drive mechanism requires a lower dispensing force, since the displacement of the piston in the cartridge is only a part of the displacement of the dose dial sleeve on which the user presses, due to the fact that the lead on the dial sleeve is the sum of the leads on the two piston rod parts.



3. Main request – sufficiency

The appellant/patent proprietor submitted that claim 1 was limited to a drive mechanism for use in a drug delivery device so that the possible complexity of an injection pen, as in the specific embodiment disclosed, was not to be considered for the examination of sufficiency. A drive mechanism was much simpler and the number of alternatives much more reduced when compared to a multi-dose injection device. The introductory part of the description gave multiple pointers as to the way the mechanism could be designed. Moreover, the technical effect to be obtained was not an issue of sufficiency but of inventive step. The claim had only to contain the features giving the person skilled in the art the opportunity to solve the problem, i.e. the basic idea. In addition, in the mechanical field, disclosing one functioning embodiment, as was the case here, was generally considered enough to satisfy the requirement of sufficiency.

The Board does not share the view of the appellant/ patent proprietor.

In the present case, for the question of sufficiency, it is irrelevant whether only a drive mechanism or a multi-dose pen is claimed, since the only embodiment described in detail is a multi-dose injection pen. No specific embodiment in which the drive mechanism is used in a different way is disclosed in the patent in suit. General reference to medical devices for dispensing drugs in the introductory part of the description does not constitute, as such, a disclosure of other working embodiments.

As is well established, the requirement of sufficiency (Article 83 EPC) is one of the basic requirements of patent law. Applicants may only obtain a monopoly protection if they provide a disclosure of the invention (to enrich the state of the art) which is sufficient for the person skilled in the art to reproduce the invention. Said differently, no theoretical invention without the possibility to reduce it to practice should give rise to a (undue) monopoly. According to Rule 42(1)(e) EPC, at least one embodiment of the invention is to be described in detail. In this context the claims are supposed to comprise the essential technical features of the invention, since the protection conferred should be commensurate with the invention made. This can be derived, for instance, from the first sentence of Rule 43(1) EPC: "*The claims shall define the matter for which protection is sought in terms of the technical features of the invention*", or in Rule 43(3) EPC: "*Any claim stating the essential features of an invention may be followed by one or more claims concerning particular embodiments of that invention*" (emphasis added).

The decision of whether the requirements of sufficiency are satisfied is a decision on a case-by-case basis. While in some cases one embodiment presented in the description may be sufficient for allowing a fair generalisation in the claim, this is not a general rule. In any case, whether only one specific embodiment is described or not, the person skilled in the art must still be able to carry out the invention over the whole breadth of the claim without undue burden (e.g. T 0409/91, OJ 1994, 653). This requirement cannot depend on the technical field of the invention; the law cited above applies equally to all fields of invention.

Hence, when examining sufficiency, the complexity of the device and the difficulty for the skilled person to enhance the features of the claim, i.e. to easily find alternative designs to the one presented in the description and falling under the claim wording, must be taken into consideration.

It is undisputed that in the patent in suit one embodiment for carrying out the invention is disclosed, and that the person skilled in the art will eliminate non-working embodiments.

In the specific embodiment described, in order to obtain the desired effect of having a low dispensing force and to be able to easily set and correct a dose ([0003], [0007]), it is the specific interaction of several elements of the drive mechanism disclosed which is necessary.

Indeed, it is obtained by a fairly complicated mechanism comprising, among others things, a dose dial sleeve (40) threaded within a housing (2), a drive sleeve (30) splined to the dose dial sleeve and threaded on an inner part (16) of a piston rod (14) and on an outer part (18) of the piston rod (14), whereby the lead of the thread (41) of the dose dial sleeve (40) is equal to the sum of the lead of the thread (24) of the outer part (18) of the piston rod (14) and the lead of the thread (22) of the inner part (16) of the piston rod, and the leads of the threads on the inner and outer parts of the piston rod have opposite disposition.

Claim 1 only requires the lead of a thread of a dose dial sleeve to be the sum of the leads on an external piston rod part and on an internal piston rod part of a

two-part piston rod, and the presence of a housing. No interconnection between the different elements is mentioned. Whether the threads are internal or external ones, and if and how they may co-operate with each other or with the other elements, is not mentioned either. The present citation of features in claim 1 without any link between each other basically constitutes a juxtaposition of features without any technical interaction or effect. It also covers a great multiplicity of embodiments in which the proper arrangement of the different elements in order to obtain the desired technical effect of a low dispensing force and an easy setting and correcting of a dose is not deducible from the only detailed embodiment described, or more generally from the description and the common general knowledge, without undue burden.

The argument of the appellant/patent proprietor that the introductory part of the description would help the person skilled in the art in finding alternatives cannot be endorsed, because it is not by adding alternatives to the claim, which is already too broad, that the situation with regard to sufficiency will improve. In this context, in particular, the absence of the drive sleeve making a link between the different other elements is detrimental.

Hence, the Board considers that the person skilled in the art will not be able to design embodiments over the whole breadth of the claim without undue burden, on the basis of the patent specification and the common general knowledge.

Therefore, for the above reasons, Article 100(b) EPC prejudices the maintenance of the patent as granted.

4. Auxiliary request 5 – sufficiency

Additionally to the features of the drive mechanism present in claim 1 of the main request, in claim 1 of this auxiliary request it is indicated how the dose dial sleeve has to be connected to the housing (threading of a particular nature), that the outer part of the piston rod needs to have an external threading and needs to be adapted for longitudinal displacement only with respect to the housing, that the inner part of the piston rod needs to have an external helical thread, that the inner and outer parts of the piston rod have to be adapted for longitudinal displacement but restricted rotational displacement with respect to each other, and that a drive sleeve must be present and at least engaging with the thread of the inner part of the piston rod.

The Board considers that the person skilled in the art will be able without undue burden to enhance the interrelated features now present in claim 1 with different complementary design elements either belonging to their general knowledge or suggested by the description of the patent in order to arrive at different drive mechanisms falling under the whole scope of claim 1, and allowing the achievement of the desired technical effect of a low dispensing force and an easy setting and correcting of a dose. Indeed, the person skilled in the art can enhance the claimed features by trying several kinds of leads for the threads, several types of connections between the drive sleeve and the other elements, etc., testing the different options to arrive at alternative embodiments producing the desired technical effect, without undue burden.

For the above reasons, the Board is of the opinion that auxiliary request 5 fulfils the requirements of Article 83 EPC.

5. Auxiliary request 5 – extension beyond the content of the application as filed

The wording of claim 1 of the main request (patent as granted) corresponds to the wording of claim 1 of the application as filed.

The features added in claim 1 according to auxiliary request 5 are disclosed in the following passages of the application as filed:
- page 4, lines 15 to 19 (*In another preferred embodiment of instant invention, the dose dial sleeve is threadedly engaged with the housing,...*)
- page 4, lines 1 to 5 (*The term "helical thread" according to instant invention shall preferably mean a full or part thread, e.g., a cylindrical spiral rib/ groove, located on the internal and/or external surface of a component of the drug delivery device,...*)
- page 6, lines 4 to 6 (*In another preferred embodiment of the invention, the outer part of the said piston rod is adapted for longitudinal displacement only with respect to the housing, e.g., by a ratchet means.*)
- page 6, lines 1 to 3 (*In still another preferred embodiment of instant invention the inner and the outer part of the said piston rod are adapted for longitudinal displacement but are restricted for rotation with respect to each another.*)
- page 5, line 23 to page 6, line 1 (*The term "two-part piston rod" according to instant invention comprises an outer and an inner component ("outer part" and "inner part") and at least two helical threads, preferably an external helical thread on the outer part and an*

external helical thread on the inner part. - One of the said threads may be designed to engage with the drive sleeve.)

It is self-evident that these different passages in the general part of the description for the different features added in claim 1 are not mutually excluding each other but correspond to different options which can be combined.

The Board notes that claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 3 in the opposition proceedings. Thus, contrary to the finding of the Opposition Division in the impugned decision (point 7.2 of the decision), as can be inferred from the reasons above, in the Board's opinion, claim 1 does not include any non-allowable intermediate generalisation.

For the above reasons, the requirements of Article 123(2) EPC are satisfied.

6. Since the objections upon which the impugned decision is based have been overcome or considered as not well founded, and the other grounds for opposition have not yet been decided upon by the Opposition Division, remittal of the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant/ patent proprietor, is justified.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated