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Datasheet for the decision of 15 December 2022

Case Number: T 2225/18 - 3.2.01

Application Number: 10710141.2

Publication Number: 2408493

IPC: A61M5/20, A61M5/30, A61K9/00

Language of the proceedings: EN

Title of invention:
HAZARDOUS AGENT INJECTION SYSTEM

Applicants:
Antares Pharma, Inc.
Hayes, John William

Headword:

Relevant legal provisions:
EPC Art. 84, 111
RPBA 2020 Art. 11

Keyword:
Claims - support in the description (yes) - clarity after amendment (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2225/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 15 December 2022

Appellant: (Applicant 1)	Antares Pharma, Inc. 13755 1st Avenue North Suite 100 Minneapolis, MN 55441 (US)
Appellant: (Applicant 2)	Hayes, John William 8835 Church Lake Road Boulevard Chaska, MN 55318 (US)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 26 March 2018 refusing European patent application No. 10710141.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	G. Pricolo
Members:	V. Vinci
	O. Loizou

Summary of Facts and Submissions

I. The appeal was filed by the appellant (applicants) against the decision of the examining division to refuse the European patent application N° 10 710 141.

II. In the decision under appeal the examining division came to the conclusion that the subject-matter of independent claim 1 of the main request and of the auxiliary requests 1 to 5 lacked clarity in the meaning of Article 84 EPC.

III. With the communication according to Article 15(1) RPBA dated 20 July 2022 the Board informed the appellant (applicants) of its preliminary assessment of the case.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 15 December 2022 by videoconference.

IV. The appellant requested that the decision under appeal be set aside and that an European patent be granted on the basis of the main request (previously filed as auxiliary request 3 on 25 January 2018 underlying the contested decision), in the alternative on the basis of one the auxiliary requests 4 and 5 also underlying the contested decision, further auxiliarily on the basis of auxiliary request 6 filed with the statement of grounds of appeal.

V. Claim 1 according to the main request reads as follows:

"A hazardous agent injection system, the hazardous agent injection system comprising:

methotrexate in an amount of from about 0.02 ml to about 4.0 ml and at a concentration of from about 7.5 mg/ml to about 150 mg/ml;

a powered injector (12), the powered injector (12) comprising:

a container (20, 22) configured to contain the methotrexate;

an injection outlet member (32, 204) associated with the container (20, 22), and configured to deliver methotrexate to a patient subcutaneously;

a firing mechanism associated with the container (20, 22) and configured to expel the methotrexate from the container (20, 22) through the injection outlet member (32, 204) for injecting the methotrexate;

an energy source associated with the firing mechanism and configured to power the firing mechanism and to inject the methotrexate from the injection outlet member (32, 204) in less than about 5 seconds;

and a trigger mechanism associated with the firing mechanism and configured to activate the firing mechanism,

wherein the powered injector (12) is configured to eject the methotrexate from the injection outlet member (32,204) such that one or more of confidence interval of (a) the maximum concentration of methotrexate in blood plasma of a patient following administration of a dose of the methotrexate to the patient ("Cmax") with the hazardous agent injection system, (b) the time to reach the maximum concentration of methotrexate in

blood plasma of a patient following administration of a dose of the methotrexate to the patient with the hazardous agent injection system ("T_{max}") and (c) area under the curve of the concentration-versus-time of methotrexate in blood plasma of a patient following administration of a dose of the methotrexate to the patient with the hazardous agent injection system ("AUC") falls between about 80% and about 125% of a measured confidence interval of the same dose of methotrexate delivered by a hand-powered hypodermic syringe;

wherein the energy source is configured for generating a pressure of at least about 80 p.s.i. in the container (20, 22);

wherein the injection outlet member (32, 204) includes an injection-assisting needle (24), the gauge of the injection-assisting needle (24) being selected from 26 to 28 gauge number; and

wherein the powered injector (12) is configured to inject the methotrexate such that the methotrexate is injected at a flow rate of at least about 0.5 ml/sec."

Reasons for the Decision

Lack of clarity: Article 84

1. The subject-matter of claim 1 of the main request meets the requirements of Article 84 EPC.

2. The examining division held that the feature of claim 1 of the main request underlying the contested decision

lacked clarity in the meaning of Article 84 EPC.

2.1 The examining division objected that in the feature reading:

"an energy source associated with the firing mechanism and configured to power the firing mechanism and to inject the methotrexate from the injection outlet member (32, 204) in less than about 5 seconds"

the energy source was defined only in terms of a result to be achieved, namely that the injection of the whole amount of methotrexate took less than 5 seconds, while the technical features of the energy source achieving this technical effect were not defined at all.

2.2 In the main request at stake, corresponding to the auxiliary request 3 underlying the contested decision, the appellant (applicants) introduced additional limitations for the minimum pressure to be generated by the energy source in the container, for the gauge range of the injection-assisting needle, and for the minimum flow rate which must be achieved by the injection device. In the Board's view this additional information has the consequence that the extension of the protection afforded by independent claim 1 is now on one side adequately supported by the description as also required by Article 84 EPC and, on the other side, imposes clear limitations to the energy source and to the powered injector in such a way to define them in term of the technical apparatus features which are required in order to achieved the claimed result. In view of the above, the Board considers that the feature above objected by the examining division under Article 84 EPC does not lack clarity in the present context of

the claim.

2.3 The examining division also objected that the powered injector was merely defined by a result to be achieved, namely that it should eject the methotrexate in such a way that one or more of the confidence intervals (a), (b) and (c) fell within 80% to 125% of those achieved by a hand-powered hypodermic syringe. The Board observes that this feature is still present unamended in claim 1 of the main request at stake.

2.4 However, the appellant convincingly explained at the oral proceedings that the formulation adopted and objected to under Article 84 EPC by the examining division reflected the standard set of data, in the present case "C_{max}", "T_{max}" and "*AUC*", normally used in the pertinent technical filed, for example by the European Medicines Agency (EMA), for defining the pharmacokinetic profile of a drogue. It was also pointed out that although the way how a drogue is absorbed and distributed in the human body may slight depend on the specific physiological characteristics of the patient, for example the body mass, the result of the measurements of these parameters was always interpreted by the person skilled in the art as a statistical distribution. Furthermore, the appellant (applicants) explained that hazardous agents as the methotrexate were manually injected by high qualified operators and according to standardized protocols, whereby the comparison between the confidence interval/ s achieved by the injection system according to the contested patent and by a manual delivery contained in claim 1 did not give rise to any ambiguity. Finally and most importantly, the appellant (applicants) pointed out that the technical features required to achieve the result stated in the last feature of claim 1 were only

(1) the amount of methotrexate to be injected, (2) its concentration and (3) the fact that this amount was injected in less that about 5 seconds, whereby all these features were already stated in claim 1. The appellant (applicants) also explained that the only purpose of the presence of the last feature of claim 1 contested by the examining division was to exclude from the scope of the protection non-working possibilities, i.e. devices that, in view of their technical features, fell within the wording of claim 1, but which failed, for some reasons, to meet the claimed pharmacokinetic profile. In this respect the appellant (applicants) mentioned as an example an injection device provided with a plurality of injection needles applied to different parts of the body of the patient providing all together an injection time of less than 5 seconds, but not resulting, due to the particular way to deliver the drogue, in the claimed pharmacokinetic profile.

2.5 The Board finds the explanations provided by the appellant (applicants) plausible and has no evidence of the contrary. Therefore the objection raised by the examining division under Article 84 in respect of this feature is not confirmed.

Remittal

3. The Board, in the exercise of the discretion provided by Article 111 EPC, considers it appropriate to remit the case to the first instance department for further prosecution, special reasons in the meaning of Article 11 RPBA 2020 being that patentability has not been assessed by the examining division. The appellant (applicants) did not object to the remittal of the case

to the examining division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chairman:

A. Voyé G. Pricolo

Decision electronically authenticated