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**Datasheet for the decision
of 22 April 2021**

Case Number: T 0233/18 - 3.2.02

Application Number: 08728022.8

Publication Number: 2125075

IPC: A61M5/14

Language of the proceedings: EN

Title of invention:

MEDICAL INJECTOR WITH COMPLIANCE TRACKING AND MONITORING

Applicant:

Kaleo, Inc.

Headword:

Relevant legal provisions:

EPC Art. 113(1)
EPC R. 103(1) (a)
RPBA 2020 Art. 11

Keyword:

Right to be heard - opportunity to comment (no) - substantial procedural violation (yes) - reimbursement of the appeal fee (yes)

Decisions cited:

T 0951/92, T 0556/15

Catchword:



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Case Number: T 0233/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 April 2021

Appellant: Kaleo, Inc.
(Applicant) 111 Virginia Street, Suite 300
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Representative: Gill Jennings & Every LLP
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 17 May 2017
refusing European patent application No.
08728022.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: M. Stern
N. Obrovski

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division refusing European patent application No. 08 728 022.8 on the grounds that claim 1 then on file contravened Article 123(2) EPC.

II. During the examination proceedings, a single communication under Article 94(3) EPC (dated 20 January 2016) was issued in which objections of extended subject-matter under Article 123(2) EPC were raised against the claims filed with letter dated 8 October 2009. Concerning claim 1, the following reasoning was given:

"Claim 1: there is no obvious basis for the replacement of the terms "(first/second) position" by the terms "(first/second) configuration"."

III. With letter dated 24 May 2016 received on 25 May 2016, the applicant filed a replacement set of amended claims. Based on these claims, the Examining Division refused the application for lack of compliance with Article 123(2) EPC holding, inter alia, that:

"Amendments to said claims [i.e. claims 1-14 received on 25 May 2016] are considered as being intermediate generalisations. Specific features of the description are picked from various different embodiments in order to limit a product in the claim that has not been originally disclosed comprising said feature." (page 2, last paragraph of the appealed decision).

The Examining Division further stated that:

"In particular claim 1 relates to an apparatus comprising a container including a retainer configured to matingly receive a proximal end portion of a delivery device. The only embodiment in the description and the figures comprising a container with a retainer that is configured to matingly receive a proximal end portion of a delivery device, is the embodiment disclosed in fig. 29-31 and par. (1151)-(1159). So to say, the independent claim 1 is limited to the said embodiment. The wording "first medicament delivery device" in claim 1 is not within the ambit of the said embodiment." (page 3, first paragraph of the appealed decision)

and that:

"... the amended claim 1 relates to an electronic circuit system. This is a broadening not only of the original subject-matter of claim 1, but is also not disclosed within the subject-matter of fig. 29-31. Both, the original claim 1 and the respectively claimed embodiment, relate to the cooperation of two electronic circuit systems (13530 on the container and 13920 on the delivery device). The embodiment concerned produces 3 electronic signals S2', S3' and S4' within the two electronic circuit systems. Independent claim 1 on file relates to only one electronic circuit system, namely the one on the container (13530)." (page 3, second paragraph of the appealed decision).

- IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the auxiliary request, both filed with the statement setting out the grounds of appeal dated 20 September 2017. As a further auxiliary request, oral proceedings were requested.
- V. In a communication under Rule 100(2) EPC dated 16 February 2021, the Board informed the appellant that it considered the impugned decision to be tainted by a substantial procedural violation and that it intended to remit the case to the Examining Division ordering the reimbursement of the appeal fee.
- VI. By letter dated 16 April 2021, the appellant confirmed their acceptance of the proposed remittal of the case to the Examining Division for further consideration.

Reasons for the Decision

1. Under Article 113(1) EPC the decisions of the EPO may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. This important procedural right is intended to ensure that no party affected by a decision is caught unaware by reasons on which it did not have an opportunity to comment (T 951/92, OJ EPO 1996, 53, point 3 of the Reasons). The right to be heard under Article 113(1) EPC is not just a right to present comments but also to have those comments duly considered (Case Law of the Boards of Appeal, 9th Edition, 2019, III.K.3.4.2).
2. During the examination proceedings, a single communication under Article 94(3) EPC (dated

20 January 2016) was issued. Therein, claim 1 (filed on 8 October 2009) was objected under Article 123(2) EPC with the following brief reasoning:

"Claim 1: there is no obvious basis for the replacement of the terms "(first/second) position" by the terms "(first/second) configuration"."

3. The applicant responded by filing amended replacement claims (received on 25 May 2016). Without further ado, the Examining Division refused the application for lack of compliance with Article 123(2) EPC based, however, on an entirely different reasoning (see point III above). It was held that the amendments of the claims were intermediate generalisations and that features of the description were picked from various different embodiments (page 2, last paragraph of the appealed decision). The Examining Division considered that claim 1, the sole claim for which reasons were provided, related to an apparatus comprising a container and that the only embodiment in the description and the figures comprising such a container was the embodiment disclosed in Figures 29-31 and paragraphs [1151]-[1159]. However, the wording "first medicament delivery device" in claim 1 was not within the ambit of the said embodiment (page 3, first paragraph of the appealed decision). Furthermore, it was held that while original claim 1 related to the cooperation of two electronic circuit systems (13530 on the container and 13920 on the delivery device), claim 1 on file related to only one electronic circuit system, namely the one on the container (13530) (page 3, second paragraph of the appealed decision).

None of these reasons were mentioned in the brief reasoning given in the sole communication issued by the Examining Division (see point 2 above).

4. Hence, the applicant has not been given an opportunity to present its comments against the grounds on which the decision is based. A fortiori, the Examining Division could not duly consider the merit of such comments in the decision.
5. It is noteworthy that the Examining Division explicitly remarked in the decision (page 2, penultimate paragraph) that:

"In the office communication of 20-01-2016 under item 3, applicant's attention had been drawn to the fact that failure to meet the requirements of Art. 123(2) EPC will lead to the refusal of the Application."

It thus appears that the Examining Division felt entitled to refuse the application under Article 123(2) EPC for the sole reason that it had previously raised an objection under that same legal provision.

However, according to the established jurisprudence, the term "grounds or evidence" in Article 113(1) EPC should not be narrowly interpreted and has to be understood as referring to the legal and **factual** reasons leading to the refusal of the application, and not in the narrow sense of a (legal) requirement of the EPC (Case Law of the Boards of Appeal, 9th Edition, 2019, III.B.2.3.2; see in particular T 556/15, point 1.3.1 of the Reasons).

6. The infringement of the right to be heard is a substantial procedural violation justifying the reimbursement of the appeal fee under Rule 103(1)(a) EPC.

In accordance with Article 11 RPBA 2020, it is therefore appropriate to remit the case to the Examining Division for further prosecution.

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.
3. The appeal fee is reimbursed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated