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**Datasheet for the decision
of 2 March 2023**

Case Number: T 1614/18 - 3.2.01

Application Number: 11726587.6

Publication Number: 2575935

IPC: A61M5/20, A61M5/142

Language of the proceedings: EN

Title of invention:
DRUG DELIVERY DEVICE

Patent Proprietor:
Amgen Inc.

Opponent:
Hoffmann Eitle

Headword:

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 84, 87, 123(2)
RPBA Art. 12(4)

Keyword:

Amendments - Main Request - allowable (no) - Auxiliary
Request - allowable (yes)
Claims - clarity (yes)
Priority - validity of priority date (yes)
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Late-filed facts - admitted (no) - lines of arguments could
have been filed in first instance proceedings (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1614/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 2 March 2023

Appellant: Amgen Inc.
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Appellant: Hoffmann Eitle
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Representative: Hoffmann Eitle
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
13 April 2018 concerning maintenance of the
European Patent No. 2575935 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor and the opponent against the interlocutory decision of the opposition division to maintain the European patent N° 2 575 935 in amended form.

II. The opposition division held that the ground for opposition under Article 100(c) in combination with Article 123(2) EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form according to the 1st auxiliary request filed at the oral proceedings. Novelty and inventive step in the meaning of Article 52(1) in combination with Articles 54 and 56 EPC respectively were assessed in view of the following state of the art:

D1: US 2004/0010207 A1

D2: Howard A. Burris III et al., "Pegfilgrastim on the Same Day Versus Next Day of Chemotherapy in Patients With Breast Cancer, Non-Small-Cell Lung Cancer, Ovarian Cancer, and Non-Hodgkin's Lymphoma: Results of Four Multicenter, Double-Blind, Randomized Phase II Studies", Journal of Oncology Practice, May 2010, vol. 6, p. 133-140.

D3: WO 2011 /046950 A1

D4: WO 2009/1 09344 A 1

D5: US 2008/0051738

D6: WO 98/34657

III. With a communication under Article 15(1) RPBA dated 9 June 2022, the Board informed the parties of its

preliminary assessment of the case according to which both appeals were most likely to be dismissed.

The appellant (opponent) announced with letter dated 19 July 2022 that they would not be attending the oral proceedings set for 27 February 2023 and withdrew their request for oral proceedings. They also informed the Board that no further written submissions will be filed.

The appellant (patent proprietor) with letter dated 22 February 2023 no longer requested oral proceedings if the Board were to dismiss the appeal of the opponent (eighth auxiliary request) and to allow one of the patent proprietor's main request, 1st auxiliary request, 7th auxiliary request or 8th auxiliary request, the latter corresponding to the patent as maintained by the opposition division, without the need for oral proceedings.

IV. The final request of the parties were thus the following:

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained according to any one of the 1st to 8th first auxiliary requests filed with the reply to the statement of the grounds of appeal, or according to the auxiliary request labelled 8a filed with letter dated 20 December 2019, as well as according to any one of the 9th to the 15th auxiliary requests filed with the reply to the statement of the grounds of appeal.

The appellant (opponent) requested that the decision

under appeal be set aside and the patent be revoked in its entirety.

In view of the final requests of the parties and of the assessment of the case by Board as set out below the appeal could be decided in writing and the oral proceedings scheduled on 27 February 2023 were cancelled.

V. Independent claim 1 as granted reads as follows:

"A drug delivery device (50) comprising:

a disposable housing (52) having an interior surface (80) defining an interior space (82), and an exterior surface (84);

a needle (54) having a retracted state wherein the needle (54) is withdrawn inside of the interior space (82) and a deployed state wherein a pointed end (58) of the needle (54) projects beyond the exterior surface (84) of the housing (52);

an injector (56) coupled to the needle (54) to move the needle (54) between the retracted and deployed states;

a reservoir (152) disposed within the interior space (82), the reservoir (152) configured to receive a volume of a drug and to be in fluid communication with the needle (54); and

a controller (60) coupled to the injector (56) and the reservoir (152), the controller (60) being configured to actuate the injector (56) to move the needle (54) from the retracted state to the deployed state only once, wherein the delivery device (50) is wearable and

disposable, characterized in that

the controller (60) is configured to actuate the reservoir (152) to deliver the volume of the drug to the patient as a single bolus after a preselected time period has elapsed after actuation of the device (50), the controller (60) being disposed within the interior space (82), wherein the delivery device (50) is single-use."

Independent claim 1 according to the 1st auxiliary request is based on claim 1 as granted, wherein the characterizing portion is amended as follows (amendments emphasized):

"the controller (60) is configured to actuate the reservoir (152) to deliver the volume of the drug to the patient as a single bolus after the controller has determined that a preselected time period has elapsed after actuation of the device (50), the controller (60) being disposed within the interior space (82), wherein the delivery device (50) is single-use."

Independent claim 1 according to the 7th auxiliary request is based on claim 1 as granted, wherein the characterizing portion is amended as follows (amendments emphasized):

"the controller (60) is configured to actuate the reservoir (152) to deliver the volume of the drug to the patient as a single bolus after a preselected time period has elapsed after actuation of the device (50), the controller (60) being disposed within the interior space (82), and configured prior to being disposed within the interior space, wherein the delivery device (50) is single-use."

Independent claim 1 according to the 8th auxiliary request correspond to claim 1 as allowed by the opposition division and is based on claim 1 as granted, wherein the characterizing portion is amended as follows (amendments emphasized):

"the controller (60) is configured to actuate the reservoir (152) to deliver the volume of the drug to the patient as a single bolus after the controller has determined that a preselected time period has elapsed after actuation of the device (50), the controller (60) being disposed within the interior space (82), and configured prior to being disposed within the interior space, wherein the delivery device (50) is single-use."

Reasons for the Decision

1. The parties did not submit any comment or further arguments in reaction to the preliminary assessment of the case provided with the communication under Article 15(1) RPBA dated 9 June 2022. The Board does not thus have any reason to deviate from the conclusions stated therein which are hereby confirmed and read as follows:

APPEAL OF THE PATENT PROPRIETOR

Main Request

Articles 100(c) in combination with Article 123 (2) EPC

2. The ground of opposition under Article 100(c) in combination with Article 123(2) EPC is prejudicial to the maintenance of the patent as granted as stated in the decision under appeal.

- 2.1 The appellant (patent proprietor) contested the conclusion of the opposition division according to which the following amendments introduced in claim 1 as granted, namely the deletion of the feature that

(i) "[the controller being] *configured prior to being disposed within the interior space*",

and the rewording of the expression "*after a selected time period has elapsed*"

which now reads

(ii) "*after a selected time period has elapsed after actuation of the device*",

resulted in unallowable intermediate generalisations infringing Article 123(2) EPC.

2.2 The Board does not agree and concurs with the view of the opposition division and of the appellant (opponent) for the following reasons:

Firstly it is worth reminding that according to established Case Law of the Boards of Appeal the relevant criterion to be applied for assessing whether an amendment complies with the provisions of Article 123(2) EPC is the so called "*gold standard*" requiring that it must be established whether the person skilled in the art would have directly and unambiguously derived the amendment from the original disclosure. In the Board's view this is not the case in the deletion of feature (i).

On this regard the Board shares the view of the opposition division and of the appellant (opponent) that the person skilled in the art cannot directly and unambiguously derive from the original disclosure that feature (i), which was originally presented in independent apparatus claim 1 as filed, is actually only optional and as such can be omitted from this claim 1 as granted without infringing Article 123(2) EPC. On the contrary, as observed by both the opposition division and the appellant (opponent), paragraphs [0065] and [0080] of the originally filed application clearly convey the impression that configuring the controller prior to dispose it within the interior space contributes to achieve an important technical effect aimed by the contested patent, namely to prevent deliberated or accidental reconfiguration of the controller by the health care provider or the

patient itself. Paragraphs [0065] and [0080] hence teach the person skilled in the art away from considering feature (i) as being merely optional.

- 2.3 The interpretation of the statement of paragraph [0049] provided by the appellant (patent proprietor) in support of their view that feature (i) was merely presented as optional in the application as originally filed is not convincing because, also in this respect, the Board shares the view of the opposition division and of the appellant (opponent) that the term "may" is used to stress only the directly following expression "only once" of this sentence, rather than the teaching recited thereafter that *"the controller 60 being configured to determine the preselected time before the controller 60 is disposed in the space"*.
- 2.4 The appellant (patent proprietor) further expressed the view that the feature that the controller is configured before being disposed in the interior space was specified only in dependent method claim 30 as filed, but was omitted in original independent method claim 22. In their view this represented a clear indication that feature (i) was not originally disclosed as mandatory and, as such, could be omitted.
- 2.5 However, also in this respect, the Board shares the view of the opposition division and the appellant (opponent) that independent method claim 22 is "de facto" a claim directed to the use of an obviously already assembled device whereby, in its technical context, it stands to reason that feature (i) is redundant and thus not explicitly mentioned. The same does not necessarily apply to the claim for the apparatus itself. Therefore, the Board concurs with the appellant (opponent) that, at least in the case at

stake, borrowing information from an independent method/use claim, i.e. the omission of feature (i), to justify the omission of a feature in an independent apparatus claim goes beyond the content of the application as originally filed at least in absence of any clear hint in the original disclosure supporting the omission as it is the case here.

2.6 The appellant (patent proprietor) further argued that the wording of feature (i) merely defines a manufacturing step which, as such, was not distinguishable on the assembled injection device and did not thus impose any limitation on the scope of the protection afforded by the claim. Consequently it was asserted that the omission of the non-limiting feature (i) did not alter the scope of the protection covered by the claim and hence did not infringe Article 123(2) EPC.

2.7 However, the Board agrees with the opposition division and the appellant (opponent) that the feature that the controller is *"configured prior to being disposed within the interior space"* involves indeed some inherent structural and/or functional limitation in that it requires at least that the controller is configurable prior to being disposed in the interior space. This may however not be always the case. Furthermore, removing the feature at stake would mean that the controller of claim 1 may also be configurable only after mounting it in the interior space. However, there is no such disclosure in the application as originally filed.

2.8 Regarding feature (ii) the Board supports the view of the opposition division and the appellant (opponent) that the wording *"after actuation of the device"* is

only originally disclosed in combination with the *"controller being configured to determine that the predetermined time period has elapsed"*, whereby there is no support for a determination that the predetermined time period has elapsed which is not carried out by controller itself.

In particular the Board agrees with the opposition division that the functionality expressed in paragraph [0067] that the controller may be programmed to determine that a predetermined time period has elapsed by accessing a timer or clockwork mechanism merely indicates how the controller obtains timing information, whereas it does not imply, contrary to the view of the appellant (patent proprietor), that the actual determination step is not done by the controller itself.

- 2.9 For the reasons above the conclusions of the opposition division regarding compliance with Article 123(2) EPC are confirmed and the main request is dismissed.

1st and 7th Auxiliary Requests

3. The 1st and 7th auxiliary requests suffer of the issues (i) and (ii) respectively raised above in respect of the main request and are thus not allowable for the same reasons.

APPEAL OF THE OPPONENT: PATENT AS MAINTAINED

4. The appeal of the appellant (opponent) is directed against the decision of the opposition division to maintain the patent in amended form according to the 1st auxiliary request filed during the opposition oral proceedings. This request corresponds to the 8th auxiliary filed in appeal by the appellant (patent

proprietor).

Amendments: Article 123(2) EPC

5. The subject-matter of claim 1 as maintained meets the requirements of Article 123(2) EPC as stated in the decision under appeal.
- 5.1 The appellant (opponent) disagreed with the conclusions of the opposition division and essentially argued that the amendment to claim 1 that the *"controller is configured to actuate the reservoir to deliver the volume of the drug to the patient as a single bolus after the controller has determined that a preselected time period has elapsed after actuation of the device"* (amendment underlined) implied in their view that the actuation of the reservoir could take place at any time after activation of the reservoir. This resulted in an open-ended time interval not supported by the application as originally filed, in particular paragraphs [0070], [0074], [0075], [0080] and [0081] from which, in the appellant's (opponent's) view, it could only be derived that the actuation of the reservoir by the controller took place immediately after that the controller had determined that a preselected time period had elapsed and not at any time thereafter.
- 5.2 The appellant (patent proprietor) objected that this line of argument was not submitted during the opposition proceedings where the objections raised against claim 1 by the appellant (opponent) under Article 123(2) EPC were based on different issues. They thus requested to disregard this allegedly new line of argument.

- 5.3 Irrespective of the assessment of the above admissibility issue, the objection is unjustified in substance. The Board shares the view of the appellant (patent proprietor) that while in practice it should be expected that the actuation of the reservoir in order to deliver the volume of the drug to the patient takes place after that a relatively short time interval has elapsed from the determination of the controller, the person skilled in the art cannot derive from the cited paragraphs that according to the contested patent this actuation must take place immediately thereafter. Furthermore, the objected open-ended interval is already fully supported by claim 1 as filed irrespective of the introduction of the wording "*after the controller has determined*", namely by the original formulation that "*the controller is configured to actuate the reservoir to deliver the volume of the drug to the patient as a single bolus after that a preselected time period has elapsed after actuation of the device*". This wording covers the possibility that delivery of the drug may begin at any time after actuation of the device and not mandatorily immediately thereafter.
- 5.4 The assessment of the opposition division of compliance with Article 123(2) EPC of claim 1 as maintained is thus confirmed.

Clarity: Article 84 EPC

6. The appellant (opponent) objected that the formulation "*after the controller has determined that*" defines an undefined point of time and thus result in unclear subject-matter infringing the requirements of Article 84 EPC.

- 6.1 The appellant (patent proprietor) convincingly argued that the lack of clarity alleged by the appellant (opponent) is not subject to examination for compliance with Article 84 EPC since the question whether the objected formulation defines an undefined point of time and thus unclear subject-matter does not arise from the amendments (see G 3/14). In fact the Board concurs with the appellant (patent proprietor) that the alleged lack of clarity is possibly only caused by the term "after". However, this term was already present in claim 1 as granted in the statement *"after that a preselected time period has elapsed after actuation of the device"*. Furthermore, the Board preliminarily follows the view of the appellant (patent proprietor) that the general teaching arising from the introduction of the expression *"the controller has determined that"* in claim 1 as maintained essentially results from the combination of claims 1 and 3 as granted.
- 6.2 The Board thus confirms the finding of the opposition division that claim 1 as maintained is not subject to examination for compliance with the requirements of Article 84 EPC.

Validity of the Priority

7. The validity of the priority claim was objected by the appellant (opponent). The appellant (patent proprietor) requested to dismiss this objection arguing that it was an abandoned position that was not fought for at the oral proceedings before the opposition division.
- 7.1 Irrespective of the admissibility issue raised by the appellant (patent proprietor), the objection of the appellant (opponent) is not justified in substance for

the following reasons:

- 7.2 As correctly stressed by the opposition division, it is not necessary for the priority to be valid that the objected subject-matter of claim 1 is literally expressed in the priority document, but it is enough that it can be directly and unambiguously derived from the disclosure of the invention in the priority document taken as a whole. The appellant's (opponent's) first issue was that claim 1 of the priority document referred to *"a sealed space"* whereas claim 1 as maintained referred to *"an interior space"*. However, the Board's agrees with the appellant (patent proprietor) that from paragraph [0056] describing an aperture (130) in the housing which *"may be unobstructed"*, the person skilled in the art directly and unambiguously derives the information that the housing does not delimit a mandatorily sealed space. Furthermore, although a *"sealed space"* is indeed disclosed in paragraph [0052] and recited in claim 1 of the priority document as pointed out by the appellant (opponent), the appellant (patent proprietor) correctly observed that paragraph [0051] states that the *"dome (72) is attached to the plate (70), preferably by a seal at an interface between a peripheral edge (74) of the plate (70) and a peripheral edge (76) of the dome (72) "*, thereby implying that a sealed space is not disclosed in the priority document as a mandatory feature.
- 7.3 Regarding the further allegation of the appellant (opponent) that the priority document failed to disclose the open-ended time interval allegedly resulting from the wording *"after the controller has determined that ..."*, the same considerations and conclusions expressed in paragraph 5.3 above apply to

the disclosure of the priority document.

7.4 Regarding the further objection of the appellant (opponent) that no support could be found in the priority document directly and unambiguously supporting the omission of the expression "*only once*" in the feature of claim 1 at stake that the controller is "*programmed to determine that a preselected time period has elapsed*", the Board follows the view of the opposition division that this omission is supported by the first 2 lines of paragraph [0067] of the priority document.

7.5 The priority claimed by the contested patent is thus valid as correctly stated in the decision under appeal. This has the consequence that document D3 represents a prior art according to Article 54(3) EPC which, as such, is relevant for the question of novelty only.

Admittance of document D6

8. The appellant (patent proprietor) contested the decision of the opposition division to admit the late filed document D6.

8.1 In this regard the Board finds that the opposition division exercised the discretion foreseen by Article 114(1) EPC according to the correct criterion of the "*prima facie*" relevance in particular for the assessment of inventive step. As stated in the EPO "Guidelines" VI, 2.1" also cited by the appellant (patent proprietor), the competent department has in fact to take such a late filed and "*prima facie*" relevant evidence into consideration no matter what stage the procedure has reached and whatever the reasons for the belated submission. The fact that after

discussion at the oral proceedings the suspected relevance was not confirmed does not imply that the discretion was applied incorrectly. Furthermore, as noted by the opposition division, procedural expediency was not an issue since D6 was filed two months before the oral proceedings, and therefore no undue burden affecting negatively the position of the appellant (patent proprietor) in the opposition proceedings can be reasonably invoked. Therefore, the Board does not see any reason to interfere with the discretionary decision of the opposition division to admit document D6. In any case, regardless of the conclusion above and as it will be explained below, document D6 is not prejudicial to novelty or inventive step of the subject-matter of claim 1 of the patent in the version maintained by the opposition division.

Novelty: Articles 52(1) and 54 EPC

9. The appellant (opponent) contested the view of the opposition division that the technical features labelled (i) and (ii) in the decision under appeal were not disclosed in document D6 in combination with the remaining features of claim 1. The Board does not agree for following reasons:

Feature (i): Delivery of the drug *"as a single bolus"* in combination with delivery *"after a preselected time period has elapsed after actuation of the device"*

- 9.1 The appellant (opponent) read this feature in the light of the description of the preferred embodiment starting from page 10, line 5 of D6. However, while the Board agrees with the appellant (opponent) that the person skilled in the art understands the passages on lines 18-27 as meaning that delivery of the drug shall

begin after a certain time started from a previous and triggering event has elapsed, there is no unambiguous and direct disclosure that this event coincides with the actuation of the device as specified in claim 1.

Feature (ii) : *"the controller being disposed within an interior space of the disposable housing and configured prior to being disposed within the interior space"*

9.2 The appellant (opponent) referred to the passage on page 9, lines 30 to 35 of D6 which envisaged the possibility to embody the control pad (10) and the delivery module (20) shown in figure 1 of D6 in a single device, and implied therefrom that this teaching corresponded to dispose the control pad (10) within the interior space in which the delivery module (20) was located, thus according to feature (ii). However, the Board follows the view of the opposition division that the cited passage of D6 does not rule out other possibilities like for example an embodiment where the control pad (10) is mounted on or attached to the exterior of the housing containing the module (20). This possibility implicitly encompassed in D6 does not correspond to feature (ii) . It follows that D6 does not directly and unambiguously disclose the teaching of disposing the controller within the interior space of the disposable housing.

9.3 Therefore, at least for the reasons above and irrespective of the disputed question of whether the statement that *"the controller is configured before being disposed within the interior space"* imposes a clear limitation in terms of technical apparatus features, the Board confirms the conclusion of the opposition division that document D6 is not prejudicial

to novelty of claim 1 as maintained.

- 9.4 As no further novelty attacks have been submitted by the appellant (opponent) the positive novelty assessment of the opposition division is hereby confirmed.

Inventive Step: Articles 52(1) and 56 EPC

10. The subject-matter of claim 1 of the patent as maintained also involves an inventive step over the prior art in the meaning of Articles 52(1) and 56 EPC as stated in the decision under appeal.

- 10.1 Following inventive step attacks have been submitted by the appellant (opponent):

D6 + D3, D6 + D2 + D3 or D4 + D3

- 10.2 In view of the fact that document D3 represents a state of art according to Art 54(3) EPC (see point 7.5 above) hence relevant for novelty only, these lines of inventive step attack involving the teaching of D3 are moot.

D6 + D2

- 10.3 The reasoning provided by the appellant (opponent) with the statement of grounds of appeal is based on the assumption that feature (ii) of claim 1 is disclosed in document D6. However, as for the reasons given under point 9.2 this assumption cannot be followed, the arguments of the appellant (opponent) in support of this inventive step attack do not convince.

D4 + D6 and D1 + D6

- 10.4 The appellant (patent proprietor) correctly objected arguing that these lines of inventive step attack were submitted for the first time with the statement of grounds of appeal. No reasons as to why these lines of attack were not submitted during the first instance proceedings were presented by the appellant (opponent) nor such reasons are immediately apparent to the Board. Under these circumstances the Board decides to exercise the discretion provided by Article 12(4) in the version 2007, which in view of Article 25(2) RPBA in version 2020 applies to the present appeal, to hold these new arguments inadmissible because they could and should have been presented in the first instance proceedings and were not.
- 10.5 In conclusion the Boards confirms the assessment of the opposition division that the subject-matter of claim 1 as maintained is not rendered obvious by the cited prior art.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated