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Datasheet for the decision of 9 July 2026

Case Number: T 1253/24 - 3.3.07

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Patent Proprietor:
Novartis AG

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EPC Art. 76(1)

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Case Number: T 1253/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 9 July 2026

Appellant: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 13 August 2024 revoking European patent No. 3536310 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	L. Basterreix

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent.

The decision was based on a main request and 75 auxiliary requests filed with letter dated 2 May 2024.

II. Claim 1 of the main request read as follows:

"A terminally sterilized, prefilled syringe for ophthalmic injections, the syringe comprising a body (2), a stopper (10) and a plunger (4), the body comprising an outlet (12) at an outlet end (14) and the stopper (10) being arranged within the body (2) such that a front surface (16) of the stopper (10) and the body (2) define a variable volume chamber (18) from which a fluid can be expelled though the outlet (12), the plunger (4) comprising a plunger contact surface (22) at a first end (24) and a rod (26) extending between the plunger contact surface (22) and a rear portion (25),
characterized in that
- the syringe is filled with an injectable medicament solution with a dosage volume of (i) 0.03 ml or 0.05 ml of 10 mg/ml ranibizumab, or (ii) 0.05 ml of 40mg/ml aflibercept.
- the plunger contact surface (22) is arranged to contact the stopper (10) but not couple thereto, such that the plunger (4) can be used to force the stopper (10) towards the outlet end (14) of the body (2), reducing the volume of the variable volume chamber (18), but not to move the stopper (10) away from the outlet end (14), and

- the rod comprises at least one rod shoulder directed away from the outlet end and the syringe (1) includes a backstop (6) arranged at a rear portion of the body (2), the backstop (6) including a backstop shoulder (34) directed towards the outlet end (14) to cooperate with the rod shoulder (32) to substantially prevent movement of the plunger rod (26) away from the outlet end (14) when the backstop shoulder (34) and rod shoulder (32) are in contact, and
- when the plunger contact surface (22) is in contact with the stopper (10) and the variable volume chamber (18) is at its intended maximum volume there is a clearance of no more than 2mm between the rod shoulder (32) and the backstop shoulder (34)."

Claim 1 of auxiliary request 4 differed from claim 1 of the main request in that the syringe was "filled with an injectable medicament solution with a dosage volume of (i) 0.03 ml or 0.05 ml of 10 mg/ml ranibizumab as aqueous solution with 10 mM histidine HCl, 10% α,α-trehalose dihydrate, 0.01% polysorbate 20, pH 5.5, or (ii) 0.05 ml of 40mg/ml aflibercept as an aqueous solution with 10 mM sodium phosphate, 40 mM sodium chloride, 0.03% polysorbate 20, and 5% sucrose, pH 6.2." (additions emphasised by the Board)

III. The opposition division decided that the main request and auxiliary requests 1-16, 17-19, 21-24, 26, 28, 30, 33-67 and 69-71 did not meet the requirements of Article 76(1) EPC as regards the specification of the "dosage volume" in a device having an "intended maximum volume", as regards the absence of sealing and of mention of the manner of terminal sterilisation and/or as regards the active ingredients. Furthermore auxiliary requests 17-32 and 65-75 were unclear contrary to Article 84 EPC.

IV. With their statement setting out the grounds of appeal, the appellant defended their case on the basis of the same main request and 75 auxiliary requests.

V. Two of the opponents had withdrawn their oppositions during the proceedings before the opposition division, by letters dated 19 December 2023 and 5 March 2024, respectively. The third and last opponent (former respondent) withdrew their opposition by letter dated 14 April 2025. The appellant is the sole remaining party.

VI. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

VII. With their letter dated 1 May 2026, the appellant made auxiliary request 4 their new main request, while maintaining all other auxiliary requests.

VIII. Oral proceedings were held before the Board.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division to examine the remaining grounds of opposition (Articles 100(a) and 100(b) EPC) based on the main request, filed as the 4th auxiliary request, and 75 auxiliary requests, all filed by letter dated 2 May 2024.

X. The appellant's arguments may be summarised as follows:

Claim 1 found basis in the parent application as filed, essentially in the combination of claims 1, 3 and 8 of the parent application. Page 10, lines 18-21, provided basis for the claimed medicaments and dosage volumes.

The medicaments were not inextricably linked to any other feature(s) in this passage.

In this respect, the patent referred to several different volumes, including:
- the fill volume, which was the volume of medicament within the syringe (page 10, lines 6 to 9); and
- the dosage volume, which quantified the volume of liquid intended for delivery to a patient in an injection (page 10, lines 14-15).

The fill volume had, in practice, to be more than the dosage volume to take into account wastage due to dead space within the syringe and the needle (page 10, lines 9 to 12).

Page 10, lines 6-21 did not define a fill volume. The mention of a dosage volume in this passage meant that there implicitly was a fill volume which was necessarily greater than the dosage volume. Furthermore, the passage providing basis on page 10 was not in lines 12-17, but in lines 18-21. This sentence did not use the word "fill", but simply stated the dosage volume, exactly as claimed.

Reasons for the Decision

1. Article 76(1) EPC, main request

1.1 The present patent was filed as a divisional application.

Claim 1 of the main request differs from a combination of claims 1, 3 and 8 of the parent application as filed in that:

"the syringe is filled with an injectable medicament solution with a dosage volume of (i) 0.03 ml or 0.05 ml of 10 mg/ml ranibizumab as aqueous solution with 10 mM histidine HCl, 10% α,α-trehalose dihydrate, 0.01% polysorbate 20, pH 5.5, or (ii) 0.05 ml of 40mg/ml aflibercept as an aqueous solution with 10 mM sodium phosphate, 40 mM sodium chloride, 0.03% polysorbate 20, and 5% sucrose, pH 6.2".

1.2 Regarding the syringe contents, the appellant referred to page 10, lines 6-21 of the parent application as filed as basis. This paragraph reads:

"In one embodiment, the syringe is filled with between about 0.01ml and about 2ml [...] of an injectable medicament. Of course, typically a syringe is filled with more than the desired dose to be administered to the patient, to take into account wastage due to "dead space" within the syringe and needle. Thus, in one embodiment, the syringe is filled with a dosage volume (i.e. the volume of medicament intended for delivery to the patent) of between about 0.01ml and about 2ml [...] of an injectable medicament. For example, for Lucentis, the dosage volume is 0.05ml or 0.03ml (0.5mg or 0.3mg) of a 10mg⁄ml injectable medicament solution; for Eylea, the dosage volume is 0.05ml of a 40mg⁄ml injectable medicament solution."

1.3 In the Board's view, this passage generally discloses the fill volume, i.e. the volume of medicament within the syringe. This is clearly expressed by both the first and the third sentences, using the term "fill" and defining a range for the volume ("the syringe is filled with between about 0.01ml and about 2ml [...] of an injectable medicament", "the syringe is filled with

a dosage volume [...] of between about 0.01ml and about 2ml [...] of an injectable medicament").

The passage also gives a definition for a dosage volume, namely "the volume of medicament intended for delivery to the patent", and defines the dosage volume for both Lucentis ("0.05ml or 0.03ml (0.5mg or 0.3mg) of a 10mg⁄ml injectable medicament solution") and for Eylea ("0.05ml of a 40mg⁄ml injectable medicament solution"). However, the dosage volumes for Lucentis and Eylea are only mentioned on lines 18-21 in the context of an embodiment wherein the syringe is filled with that dosage volume. This follows from the reference, on line 18 ("For example, for Lucentis, the dosage volume") to the dosage volume mentioned immediately before, namely in "the syringe is filled with a dosage volume".

Accordingly, and contrary to the appellant's view, the Board concludes that the passage on page 10, lines 6-21 defines a fill volume, and that the mention of a dosage volume in this passage is only made in the context of a fill volume being equal to that dosage volume.

1.4 The appellant pointed out the sentence "Of course, typically a syringe is filled with more than the desired dose to be administered to the patient, to take into account wastage due to "dead space" within the syringe and needle". According to the appellant, this would mean that the passage discloses that the fill volume is higher than the desired dose to be administered, i.e. the dosage volume. The Board concurs in that a contradiction is apparent in the paragraph between stating that the syringe is filled with more than the desired dose and stating that "Thus", the syringe is filled with the dosage volume. However, in

the Board's view, the first statement is not worded as mandatory, considering the expression "typically", and it is limited to the fill volume being higher than the desired dose "to take into account wastage due to "dead space" within the syringe and needle". Thus, even if a contradiction can be seen in the two sentences, it cannot be directly and unambiguously derived from this contradiction that, for a medicament with a given dosage volume, the fill volume may be left undefined.

The Board does not share either the appellant's non-limiting interpretation of "the syringe is filled with a dosage volume". Considering that the sentence specifies a volume, and even specifies an upper limit, this sentence cannot be construed as allowing for the syringe being filled with any volume higher than the dosage volume.

1.5 In contrast, claim 1 of the main request does not define the fill volume.

The appellant expressed the view that the wording of claim 1 ("the syringe is filled with an injectable medicament solution with a dosage volume of [...]") means that the claim is not limited to syringes containing only the dosage volume, and instead that a greater fill volume may be present (see §3.13 of the statement setting out the grounds of appeal).

The Board agrees that the wording of claim 1 does not define the fill volume, but only requires that the syringe is filled with (an undefined amount of) an injectable medicament solution, and that the dosage volume is only a feature of the injectable medicament solution, i.e. it is the volume of medicament intended

for delivery to the patient (as explained on page 10) and not the fill volume.

This means that the wording of claim 1 does not find a basis on page 10, which requires that the syringe is filled with a defined dosage volume of the injectable medicament ("the syringe is filled with a dosage volume [...]"). In other words, page 10 defines the fill volume, whereas claim 1 of the main request does not. The parent application as filed does not provide a basis for defining the dosage volume without defining the fill volume of the syringe.

During the oral proceedings, the appellant expressed the view that claim 1 implicitly required that the fill volume be higher than the dosage volume. However, the appellant did not identify which wording in claim 1 made this limitation implicit, in the sense of being a mandatory feature of claim 1. In the Board's view, the appellant's argument is essentially that, starting from a defined (intended) dosage volume, it would be obvious to fill the syringe with a fill volume higher than this dosage volume so that the desired volume can be injected in one injection, and that it would also be obvious to depart from the literal wording of page 10 equating the fill volume with the dosage volume and to fill the syringe with more than the specified 0.05ml or 0.03ml Lucentis or 0.05ml Eylea. This, however, falls short of a direct and unambiguous disclosure of the features of claim 1.

1.6 Accordingly, the main request does not meet the requirement of Article 76(1) EPC.

2. Auxiliary requests

2.1 In each of the auxiliary requests 1-75, claim 1 contains the same wording "the syringe is filled with an injectable medicament solution with a dosage volume of (i) 0.03 ml or 0.05 ml of [...]" as in claim 1 of the main request.

2.2 Accordingly, none of the auxiliary requests meet the requirement of Article 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated