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Datasheet for the decision of 1 October 2025

Case Number: T 0765/23 - 3.2.01

Application Number: 17155371.2

Publication Number: 3187219

IPC: A61M5/34, A61M5/32

Language of the proceedings: EN

Title of invention:
INJECTION DEVICE

Patent Proprietor:
ALLERGAN, INC.

Opponent:
Merz Pharma GmbH & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 83, 76, 123(2), 52(1), 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:
Sufficiency of disclosure - (yes)
Divisional application - added subject-matter (no)
Amendments - extension beyond the content of the application as filed (no)
Inventive step - (yes)
Late-filed objection - should have been submitted in first-instance proceedings (yes)
Late-filed evidence - should have been submitted in first-instance proceedings (yes)

Decisions cited:
T 0184/17

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0765/23 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 1 October 2025

Respondent: (Patent Proprietor)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92612 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant: (Opponent)	Merz Pharma GmbH & Co. KGaA Eckenheimer Landstrasse 100 60318 Frankfurt (DE)
Representative:	Wallinger, Michael Wallinger Ricker Schlotter Tostmann Patent- und Rechtsanwälte Partnerschaft mbB Zweibrückenstrasse 5-7 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 February 2023 concerning maintenance of the European Patent No. 3187219 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	V. Vinci
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. Appeals were filed by the patent proprietor and the opponent against the interlocutory decision of the Opposition Division maintaining the European patent No. EP 3 187 219 in amended form.

In its decision, the Opposition Division found that the ground for opposition raised by the opponent under Article 100(b) in association with Article 83 EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form based on the auxiliary request 1 filed at the oral proceedings. Novelty and inventive step were positively assessed in view of the following prior-art documents which are relevant for the present decision:

D1: EP 1 051 988 A2
D2: WO 2008/019265 A2
D5: US 2002/0010433 Al
D9: US-A-5 792 099
D10: SUMMARY OF SAFETY AND EFFECTIVENES DATA (FDA approval information about JUVÉDERM 30, JUVÉDERM 24HV and JUVÉDERM 30HV)
D11: DIN EN 20594-1: 1995-01
D12: SMITH, K.C.: Practical Use of JUVÉDERM: Early Experience Plastic and Reconstructive Surgery, November Supplement 2007, Volume 120, Number 6S, p67S-73S
D15: J. & A. Carruthers: Soft Tissue Augmentation, 2nd edition, 2008, Saunders Elsevier
D16: DIN EN 1707: 1997-01
D17: DIN EN ISO 7864: 1996-01
D18: DIN EN ISO 7886-1: 1997-10
D20: EP 0 838 229 A2

In addition, document

D28: US 2004/0122377 A1

filed after expiring of the opposition period, was not admitted into the opposition proceedings by the Opposition Division under Article 114(2) EPC.

With their statement of the grounds of appeal, the appellant (opponent) submitted the further evidence

D29: The Use of Restylane in Cosmetic Facial Surgery Joseph Niamtu, III, DMD

and requested its admittance into the appeal proceedings.

The further evidence labelled D30 to D33 also filed by the appellant (opponent) during the appeal proceedings are not relevant for this decision.

II. With a communication in accordance with Article 15(1) RPBA dated 31 March 2025, the Board informed the parties of its preliminary assessment of the case.

Oral proceedings took place before the Board on 1 October 2025.

At the end of the oral proceedings and before the decision of the Board was announced, the patent proprietor withdrew their appeal, thereby acquiring the status of respondent in the appeal proceedings.

III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the patent be maintained in amended form according to one of the auxiliary requests 2 to 11 filed on 17 November 2023 with the reply to statement of grounds of appeal of the appellant (opponent).

IV. Independent claim 1 of the patent as maintained according to the auxiliary request 1 filed during the oral proceedings before the department of first instance reads as follows (labelling of the features according to the contested decision):

[1] "*An injection device (10) comprising:*

[1A] *a syringe (12) having a body (14) suitable for containing fluid (62), the body (14) having a piston (18) disposed therein and an open distal end (22);*

[2A] *a needle assembly (26) comprising a cannula (30) and a luer connector (38) engageable with the syringe distal end (22),*

[2B] *said luer connector (38) comprising a hub (42) with a distal end (46) supporting said cannula (30) and a proximal end (50) mateable with the syringe distal end (22);*

[3] *a hub retention cavity (80), disposed in said hub (42), for preventing detachment of said hub (42) from the syringe distal end (22) during injection of fluid (62); and*

[4A] *internal threads (52, 54) disposed in the syringe distal end (22) and*

[4B] *external threads (56, 58) disposed on said hub (42) enabling mating engagement and ejection of fluid (62) through said cannula (30) upon operation of said piston (18),*

characterized in that

[5] *the cannula (30) has a gauge of about 18 or greater,*

[6] *said internal threads (52, 54) have a pitch (P) of between about 2 mm and about 5 mm, sufficient to further prevent separation of the hub (42) and syringe distal end (22) during injection of fluid (62), and*

[7'] *the injection device is for dispensing high viscosity hyaluronic acid-based dermal fillers comprising a viscosity of between about 50,000 cps and about 500,000 cps, measured at about 25 °C with a controlled stress rheometer (RS600) and a cone plate geometry (40 mm, 2 °).*

Reasons for the Decision

1. The appeal of the appellant (opponent) is directed against the interlocutory decision of the opposition division maintaining the contested patent in amended form according to the auxiliary request 1 (thereafter *"the patent as maintained"*) filed during the first instance oral proceedings.

Sufficiency of Disclosure: Article 83 EPC

2. The patent as maintained complies with the requirements of Article 83 EPC as correctly found by the Opposition Division.

2.1 The appellant (opponent) held that - contrary to the findings of the Opposition Division - the patent as maintained did not comply with the requirements of Article 83 EPC. The parties at the oral proceedings referred in this respect to the arguments presented in writing and did not make any further submission. The Board has thus no reasons to deviate from its preliminary assessment of this objection as set out in the communication according to Article 15(1) RPBA dated 31 March 2025 which is herewith confirmed and reads as follow:

2.2 The appellant (opponent) maintained that the modifications introduced in the feature [7'] of claim 1 of the patent as maintained were not suitable for restoring compliance with the requirements of Article 83 EPC which was denied by the Opposition Division in respect of the patent as granted. It was pointed out that the amended claim 1 still failed to indicate the frequency at which the viscosity was measured which was a parameter very much influencing the result of the

measurement. Furthermore, feature [5] of claim 1 failed to set an upper limit for the gauge of the cannula. This circumstance resulted in the possibility encompassed by the claim that the detachment forces generated during the injecting the high viscosity fluid were almost arbitrarily high. In the appellant's (opponent's) view, this had the consequence that the claimed technical effect to prevent detachment of the hub from the syringe distal end could not be achieved over the whole scope of the claim. Since the patent did not contain any information as to how design a hub retention cavity and a luer connector that prevented detachment of the hub from the syringe when indefinitely high detaching forces were generated, the invention could not be carried out by a person skilled in the art over the entire breath of the claim without undue burden.

2.3 The Board is not convinced:

According to the wording of feature [7'] of the amended independent claim 1 of the patent as maintained, the use of the claimed injection device has be restricted to the injection of high viscosity hyaluronic acid-based dermal fillers comprising a viscosity of between about 50,000 cps and about 500,000 cps. Furthermore, some parameters and conditions of the measurement method applied to determine the viscosity of the dermal filler have been introduced in the claim. These limitations clearly restrict the magnitude of the detachment forces which can be generated in the connection between the hub and the syringe distal end to an extent that the claim does not longer cover the possibility that undefined and arbitrarily high detachment forces can occur as alleged by the appellant (opponent) and as it was the case - in the Opposition

Division's view - of the injection device of claim 1 as granted. The Board follows the view of the Opposition Division and the respondent (patent proprietor) that in the specific case of the injection of hyaluronic acid-based dermal fillers now specified in claim 1, the person skilled in the art assumes - based on common general knowledge supported for example by document D13 (see Table II) - that the measurement of the viscosity is carried out at low frequency, i.e. at 0.68rad/sec= 0.1Hz. This is thus also inherently the case of the measurement of the viscosity of the HA-based dermal fillers of the "*Juvederm*™" family mentioned in paragraph [0037] of the contested patent describing a way to carry out the invention. Therefore, the person skilled in the art understands that the value of the the viscosity recited in claim 1 and suggested in the patent is the result of a measurement carried out at low frequency, i.e. at 0.1 Hz. Furthermore, as convincingly explained by the respondent (patent proprietor), this choice is reasonable and consistent with the range of physiologic stresses to which dermal fillers are subjected when injected into facial tissue. Moreover, as mentioned above, the patent discloses in paragraph [0037] at least a way to carry out the invention. It is true as objected by the appellant (opponent) that the fact that no upper limit for the gauge of the cannula is indicated in the patent may potentially result in a injection device with a cannula with an extremely small diameter and hence in the occurrence of extremely high detachment forces. However, the Board agrees with the argument of the respondent (patent proprietor) that the person skilled in the art in view of common general knowledge implicitly reads in the claim an upper limitation for the gauge cannula which is inherently imposed by the particular application of the injection device to the

injection of HA based dermal fillers. Therefore, when carrying out the invention, the person skilled in the art certainly rules out the hypothetical possibility to use an extremely small needle below a certain diameter that would be not in line with a reasonable interpretation of the scope of claim 1 as amended which has instead to be correctly construed in the light of its actual technical context, namely the injection of high viscosity hyaluronic acid-based dermal filler into the human or animal body. This specific application inherently imposes a limitation to the upper limit of the gauge of the cannula.

Amendments: Articles 76 and 123(2) EPC

3. The patent as maintained complies with the requirements of Articles 76(1) and 123(2) EPC as correctly found by the Opposition Division.

3.1 Feature [7] of independent claim 1 as granted reading:

"the injection device is for dispensing high viscosity fluids comprising a viscosity of between about 50.000 cps and about 500.000 cps."

was amended in independent claim 1 of the patent as maintained to read (amendments emphasized):

[7'] *"the injection device is for dispensing high viscosity hyaluronic acid based dermal fillers comprising a viscosity of between about 50.000 cps and about 500.000 cps, measured at about 25 °C with a controlled stress rheometer (RS600) and a cone plate geometry (40 mm, 2°)."*

3.2 With their appeal the appellant (opponent) contested the findings of the Opposition Division that the amendments comply with the requirements of Articles 76(1) and 123(2) EPC. Following objections were raised:

Amendments to feature [7']

3.3 The appellant (opponent) objected that there was no clear and unambiguous basis in the originally filed parent application WO 2010/065649 (thereafter *"earlier application"*) for a hyaluronic acid-based dermal filler having a viscosity between about 50.000 cps to about 500.00 cps measured at about 25 °C with a controlled stress rheometer (RS600) and a cone plate geometry (40 mm, 2°). They pointed out that in the cited passage on page 4, lines 21-25 of the earlier application a viscosity range between about 50,000 cps and about 500,000 cps was not disclosed for hyaluronic acid-based dermal fillers as now recited in claim 1, but more generally only in association with hyaluronic acid-based fluids. For hyaluronic acid-based dermal fillers, a lower viscosity limit of 130,000 cps was disclosed instead both in the cited passage of the description and in claim 10 of the earlier application which could thus support the amendments introduced in claim 1. It was also pointed out that neither an evident error nor an unambiguous correction could be directly and unambiguously identified in the cited passage of the earlier application which could support the disputed amendment to feature [7'] of claim 1.

3.4 The Board does not agree:

As convincingly argued by the Opposition Division and the respondent (patent proprietor), the skilled reader promptly realizes that the whole earlier application

actually deals with the injection of high viscosity dermal fillers, whereby all the viscosity values and/or ranges disclosed throughout the original disclosure are meant to be (also) applicable to dermal fillers. Therefore, the Board - in agreement with the Opposition Division - does not see any reason why the person skilled in the art should not associate the viscosity range and measurement parameters wordly presented in association with hyaluronic acid-based fluids on page 4 , lines 21-25 of the earlier application also to the hyaluronic acid-based dermal fillers now recited in claim 1. In support of this conclusion, it is emphasised that the earlier application does not even mention any specific hyaluronic acid-based fluids other than hyaluronic acid-based dermal fillers.

Allegedly undisclosed combination of features

3.5 The appellant (opponent) criticized that the Opposition Division did not deal in the contested decision with their key objection pointing to an alleged lack of direct and unambiguous support in the earlier application for the whole combination of the features of claim 1, but rather discussed the disclosure of these features taken individually. It was argued that claim 10 of the earlier application related to a specific embodiment and therefore, could not form the basis for the different embodiment resulting from the combination of features recited in independent claim 1 of the patent as maintained. In this respect, the appellant (opponent) put forward that starting from claim 10 of the earlier application and in order to arrive to the combination of features recited in claim 1 of the patent as maintained it was necessary:

(1) to replace the originally claimed value of the

gauge of the cannula greater than about 25 and of the viscosity greater than about 130.000 by a gauge greater than about 18 and a viscosity ranging between about about 50.000 and about 500.000 cps;

(2) to select from the description and introduce the pitch of the internal thread according to feature [6];

(3) to remove the limitations contained in original claim 10 that the syringe comprised the viscous fluid and that this fluid had to be injected into a peripheral location of a human or animal body.

The appellant (opponent) thus concluded that the subject-matter of claim 1 of the patent as maintained was the result of an arbitrary and undisclosed selection of information individually presented in the earlier application in the context of different embodiments rather than in combination.

3.6 The Board does not agree:

It is correct that starting from independent claim 10 of the earlier application as basis for claim 1 of the patent as maintained replacements, additions and deletions of features are required to arrive to the injection device recited in claim 1 of the patent as maintained. However, the Board takes the view that a person skilled in the art directly and unambiguously derives from the technical context of the earlier application as a whole that the added and replaced feature/s mentioned by the appellant (opponent) are not specific of a single specific embodiment, i.e. of the embodiments of original claims 1 or 10, but rather can be adopted in each of them, i.e. also in the embodiment covered by the original independent claim 10. In

support of this conclusion the respondent (patent proprietor) convincingly drew the attention to the general description of the invention ("*Summary of the Invention*"), page 2, lines 5-9 of the earlier application disclosing a gauge of about 18 or greater in combination with further structural features recited both in original claim 10 and in claim 1 of the patent as maintained. The same applies to the claimed pitch between about 2 mm and about 5 mm introduced in claim 1 which is disclosed in the same section of the original description, page 2, lines 23 to 24. Regarding the claimed range of viscosity reference is made to the cited passage on page 4, lines 21-25 of the earlier application and to the reasons given under point 3.4 above.

3.7 Regarding the objection of the appellant (opponent) that the injection device of claim 1 of the patent as maintained was only suitable for injecting a high viscosity while claim 10 of the earlier application required that the injection device comprised a viscous fluid disposed in its body, wherein this fluid was to be injected into a peripheral location of a human or animal body through the cannula, the parties at the oral proceedings referred to the arguments provided in writing and did not make any further submission. The Board has thus no reason to deviate from its preliminary assessment of this objection as set out in the communication according to Article 15(1) RPBA dated 31 March 2025 which is herewith confirmed and reads as follow:

3.8 The Board concurs with the respondent (patent proprietor) that the earlier application contains several passages describing the injection device "*per se*", namely an injection device merely suitable for

dispensing high viscosity fluids (see for example original claim 18 and the description, page 2, first 2 lines). Furthermore, structural limitations to the injection device implied by the characteristics of the high viscosity fluid to be injected are inherently imposed by feature [7'] of claim 1 . The fact that claim 1 of the patent as maintained is directed to an injection device merely suitable for injecting a high viscosity fluid and not to an injection device in combination with such a high viscosity fluid does not thus result in any undisclosed information. The same applies to the omission of the feature that the fluid is to be injected into a peripheral location of a human or animal body through the cannula. This limitation can be considered inherent in view of the technical context of claim 1 and in particular of feature [7'] referring to a hyaluronic acid-based dermal filler.

Dependent claim 4

3.9 The appellant (opponent) observed that the feature *"stepped interior surface"* recited in dependent claim 4 of the patent as maintained could be found in claim 17 of the earlier application as filed, which depended on independent claim 10. However, since in their opinion claim 10 could form a direct and unambiguous basis for the amendments in claim 1 of the patent as maintained, also its combination with the additional features of original claim 17 could not form a direct and unambiguous basis for the combination of features implied by dependent claim 4 of the patent as maintained.

3.10 The Board does not agree:

For the reasons given under point 3.6 above claim 10 of

the earlier application in combination with the description forms a sufficient basis for the subject-matter of claim 1 of the patent as maintained. It follows that the arguments of the appellant (opponent) in support of their objection raised under Articles 76(1) and 123(2) EPC against independent claim 4 of the patent as maintained are moot. For the sake of completeness, the Board observes that the stepped interior surface of the cavity is also disclosed in the general part of the description of the earlier application, page 3, line 6 onwards. Therefore, it can be assumed that this cavity geometry directly and unambiguously applies to all the embodiments as also confirmed by the Figures of the earlier application.

Dependent Claim 5

3.11 Regarding dependent claim 5, the appellant (opponent) objected that the feature *"stepped dead space reducing cavity"* is recited in original independent claim 1 and hence in the context of a different embodiment disclosed in the earlier application. Furthermore, they put forward that the passage cited by the Opposition Division and the respondent (patent proprietor) on page 3, lines 4-8 of the earlier application was restricted to a stepped dead space reducing cavity that reduced (1) dead space in the syringe and (not in the needle assembly) and (2) the possibility of detachment of the hub from the syringe distal end during injection of the viscous fluid. The appellant (opponent) objected that since these features presented in combination with the stepped dead space reducing cavity in the cited passage of the earlier application were omitted in claim 5 an unallowable intermediate generalisation arose.

3.12 The Board is not convinced:

Firstly - as correctly pointed out by the Opposition Division - the feature of claim 5 of the patent as maintained reading *"the hub retention cavity is a stepped dead space reducing cavity"* is wordly disclosed in the general part of the description, page 3, lines 4-8 of the earlier application. Therefore, for the same reason presented under point 3.6 above, it can be directly and unambiguously applied to any embodiment. Having said that, the Board shares the view of the respondent (patent proprietor) that the term *"dead space"* in the technical context of the application is clearly understood by the person skilled in the art to designate the space remaining between the syringe tip and the needle hub. There are no other/different dead spaces in an injection device of the kind of the contested patent. The above interpretation is supported by the location of the *"dead space (92)"* in Figure 6 of the earlier application. The omission of the expression *"of the syringe"* is thus justified by the above technical considerations and interpretation and therefore does not lead to any unallowable intermediate generalisation. Furthermore, the Board concurs with the Opposition Division and the respondent (patent proprietor) that the functionality that the *"stepped dead space reducing cavity"* recited in dependent claim 5 has also the functionality to significantly reduce the risk of detachment of the hub from the syringe distal end is already implied, and hence not unallowably omitted, by the wording of the claim, see in particular feature [3].

Discretionary decision of the Opposition Division not to admit document D28

4. Document D28 filed by the appellant (opponent) after the expiring of the opposition period was not admitted by the Opposition Division in the opposition proceedings under Article 114(2) EPC. This discretionary decision of the department of first instance and in particular its negative assessment of the *prima facie* relevance of this evidence was contested by appellant (opponent). At the oral proceedings before the Board, the appellant (opponent) also alleged that the late filing of D28 was due to the fact that it was *"hard to find"*. The appellant (opponent) requested to overturn the discretionary decision of the Opposition Division disregarding document D28 which in their opinion was highly relevant in combination with other pieces of prior art for the assessment of inventive step. The respondent (patent proprietor) requested to confirm the discretionary decision of the Opposition Division and thus to disregard document D28.

4.1 The Board confirms the discretionary decision of the Opposition Division not admitting document D28 into the opposition proceedings.

According to established Case Law of the Boards of Appeal, the review of a discretionary decision of the department of first instance by the Board should be generally restricted to the question whether the department has exercised its discretion power properly, according to the correct criteria and in a logic and reasonable way. The Board emphasises that its role here is not to review all the facts and circumstances of the case as if it were in the Opposition Division’s place

and decide whether or not it would have exercised discretion in the same way. Instead, a board of appeal should only overrule a discretionary decision of the department of first instance if it is concluded that it applied the wrong principles, did not take the right principles into account, or behaved in an arbitrary or unreasonable way, thereby exceeding the proper limits of its discretion. However, in the Board's view, this is not the case here.

4.2 It is undisputed that the Opposition Division when deciding to disregard the late filed document D28 has exercised its discretion under Article 114(2) EPC by applying the correct criterion of the *prima facie* relevance (see decision page 19, point (d)) and this - in the Board's view - also in an appropriate and reasonable way. In particular, the Opposition Division stated that the technical content of D28 was *prima facie* not more relevant than the prior art already part of the opposition procedure because this document failed to discuss the aspect of the hub cavity design as a solution to the problem of preventing hub-syringe detachment. The Board takes the view that the motivated conclusion of the Opposition Division is also prima facie reasonable in the context of a *prima facie* assessment.

4.3 In view of the above, the lines of arguments questioning the inventiveness of the subject-matter of claim 1 of the patent as maintained implying document D28 will thus be disregarded in this decision.

Inventive Step: Articles 52(1) and 56 EPC

5. The patent as maintained meets the requirements of Articles 52(1) and 56 EPC as correctly found by the

Opposition Division.

5.1 With their appeal the appellant (opponent) held that - contrary to the assessment of the Opposition Division - the subject-matter of claim 1 of the patent as maintained was rendered obvious by the prior art. Following lines of inventive step attack raised during the first instance proceedings were maintained with the statement of grounds of appeal:

D14 as closest prior art in view of the *"Luer standard"* allegedly embodied by D11 and D16-D18 or of any one of documents D1, D5 and D20

5.2 The Opposition Division found that the subject-matter of claim 1 of the patent as maintained differed from the technical content of document D14 in the features [2B], [3], [4A], [4B] and [6] which also involved an inventive contribution over the cited prior art. These findings were contested by the appellant (opponent). They referred to paragraph XIV of D14, sections *"How supplied"* and *"Directions of Use"*, step *"B1"* disclosing a syringe used to inject a dermal filler according to feature [7'] of claim 1 available on the market under the trade name of *"Restylane ®"*, wherein a 30 gauge needle according to feature [5] of claim 1 of the patent as maintained was attached onto the *"luer-lock"* of the syringe by screwing. This assessment of the features disclosed in D14 was not contested by the respondent (patent proprietor). The appellant (opponent) argued that since screwing the needle was only possible if internal threads were provided at the syringe distal end also feature [4A] of claim 1 of the patent as maintained was at least implicitly disclosed in D14. The appellant (opponent) alleged that the Opposition Division came to its positive assessment of

inventive step by erroneously disregarding the applicable common general knowledge of a skilled person in the technical field of the design and manufacture of injection devices, what allegedly led to a unjustified broader interpretation of the term *"luer-lock"* of D14. In support of this allegation they referred to documents D11 and D16 to D18 representing luer-lock standards well known to the person skilled in the art. In particular, the information contained in D16 confirmed that a standard luer-lock connector of the kind mentioned in D14 presupposed internal threads provided in the syringe distal end (see Figures 1, 7 and 8 of D16), said threads having a standard pitch falling within the range recited in feature [6] of claim 1 of the patent as maintained (see Figures 7 and 8 of D16). The appellant (opponent) put forward that if the applicable common general knowledge demonstrated by D11 and D16 to D18 was properly considered, features 2B, 4A and 6 were implicitly disclosed in D14 or at leats obvious. Regarding feature [3], the appellant (opponent) argued that - as also acknowledged by the Opposition Division - the design of a luer-lock according to the cited standards inherently implied a cavity in the hub according to the first part of feature [3]. It was alleged that - depending on the fluid viscosity - the design of the cavity did not necessarily play a role in preventing detachment of the hub from the syringe distal end. This was only the case for fluids with a viscosity laying in the upper part of the very broad range recited in claim 1, but certainly not for fluids with a viscosity laying in the lower portion of the claimed range. The appellant (opponent) further argued that - in any event - the conical cavity of any standard luer-lock as disclosed in D11, D16 to D18 also contributed at least to some extent to oppose the detaching forces generated during injection of the

fluid as required by feature [3]. Since neither a particular shape of the cavity nor the extent of its contribution to the achievement of the claimed affect was defined in claim 1 of the patent as maintained, also feature [3] had to be considered inherently disclosed in D14 or at least to be obvious in view of the standards D11 and D16 to D18. The appellant (opponent) concluded that it was obvious for the person skilled starting from D14 and aiming to further increase the resistance of the connection against detaching forces generated by the injection of high viscosity fluids to adopt a luer-lock according to the *"luer standard"* available in D11 and D16-D18, in particular a luer-lock with an internal thread disposed on the distal end of the syringe and and external thread disposed on the hub according to features 4A and 4B respectively, thereby arriving without inventive skill to the subject-matter of independent claim 1 of the patent as maintained. The same reasoning and conclusions applied when starting from D14 in view of documents D1, D5 and D20 which disclosed luer-locks solutions with the features recited in claim 1 of the patent as maintained.

5.3 The arguments of the appellant (opponent) are not convincing:

The Board observes that D14 relates to a study concerning the implantation into the human body of a hyaluronic acid-based dermal filler marketed under the trade name of *"Restylane®"*. This fluid indisputably meets the characteristics recited in feature [7'] of claim 1 of the patent as maintained. Specifically, D14 focuses on the safety and effectiveness data resulting from the injection of this specific dermal filler into the human body rather than on the structural details of

the injection device used therefor. As a matter of fact, this D14 provides only few explicit information regarding the design of the syringe used for the injection, namely that the needle has a gauge of 30, i.e. falling within the range recited in feature [5], and that a no further defined *"luer-lock"* is used to connect the needle to the syringe. Regarding the disputed interpretation of the term *"luer-lock"*, the Board takes the view that this expression is commonly understood by the person skilled in the art as generally meaning a connection involving a male and a female connecting elements shaped in such a way to be fittingly inserted and engaged one within the other and secured to each other by means of cooperating protrusions and recesses respectively. As also acknowledged by the respondent (patent proprietor) during the oral proceedings, it can be assumed that any luer connection, be a luer-slip or a luer-lock as that mentioned in D14, presupposes a cavity associated with the female element of the connection, in the case of the contested patent formed within the hub supporting the cannula. Therefore, the Board is of the opinion that features [2A], [2B] and at least the first part of feature [3], namely that a cavity is provided in the hub, can be considered inherently implied by the term *"luer-lock"* used in D14. Having said that, the Board concurs with the Opposition Division and the respondent (patent proprietor) that this term does not imply or provide a hint to any univocal and specific standardized constructive design of the connection, let alone to a luer connector according to features [2A] [2B] and [4A] in combination with features [4B] and [6] of claim 1 as maintained. Turning now to the Standards D11 and D16 to D18 cited by the appellant (opponent) in combination with D14, the Board observes that the only document explicitly suggesting a constructive variant

of a luer lock having internal threads disposed in the syringe distal end according to features [4A] and [6] of claim 1 in combination with a externals threads or an outwardly extending flange cooperating with the internal threads of the syringe distal end is document D16. Reference is made in this respect to Figures 1, 7 and 8 of D14. Documents D11, D17 and D18 are directed to so called *"luer slip"* connectors, i.e. luer connectors deprived of inter-engaging threads. Having said that, the Board takes the view that the person skilled aiming to reliably prevent detachment of the hub from the syringe when high viscosity fluids are injected cannot find in any of the evidence D11 and D16 to D18 a clear hint to select from all possible designs of a luer connector a solution including the provision of an external threads on the hub according to feature [4B] of claim 1 of the patent as maintained. In this respect it is pointed out that none of constructional solution presented in D11 and D16 to D18 is disclosed as being suitable for the injection of high viscosity fluids according to feature [7'] trough a cannula with a gauge of about 18 or greater. Therefore, documents D11 and D16 to D18 do not present the person skilled in the art with an obvious hint to the claimed solution of the technical problem addressed by the contested patent. The same conclusions apply for the same reasons when considering the combination of D14 with D1, D5 or D20. Also in this case there is no indication in this prior art documents that the luer connectors disclosed therein are suitable to prevent separation of the syringe from the hub when a high viscosity fluid with the characteristics of feature [7'] is injected into the human or animal body through a cannula with a gauge of about 18 or greater. Furthermore, none of these documents suggests a pitch according to feature [6] of

claim 1 of the patent as maintained.

5.4 In view of the above conclusions, it is not necessary to decide on the disputed availability to the public of the information contained in D14 before the priority date of the contested patent.

D2 as closest prior art in view of the *"Luer standard"* as embodied by D11 and D16-D18 or any of documents D1, D5 and D20.

5.5 In their statement of grounds of appeal, the appellant (opponent) did not dispute the conclusion of the Opposition Division that D2 failed to explicitly disclose features 2A, 3, 4A and 4B, 6 of claim 1 of the patent as maintained in combination. However, they contested the findings of the Opposition Division that the syringe of D2 was not suitable to inject a fluid in the viscosity range recited in feature [7'] without occurrence of separation of the hub from the syringe distal end. In this respect, the appellant (opponent) pointed to the passage on page 40, lines 7-15 of this prior art document disclosing a *"carrier medium"* with a viscosity up to 300,000 cps hence falling within the range recited in claim 1. Furthermore they argued that although D2 did not explicitly disclose a luer connector according to features [2A], [2B], [4A],[4B] and [6] in combination, a clear hint to a threaded connection was made available in the passage on page 27, line 26 onwards read in combination with Figure 3. The appellant (opponent) concluded that the person skilled in the art in view of the information contained in the standards D11, D16 to D18 or in any of documents D1, D5 and D20 did not need any inventive skill to arrive to the design of the syringe recited in claim 1 of the patent as maintained, and this

essentially for the same reasons presented in support of the lines of inventive step attack starting from D14 as closest prior art.

5.6 These arguments are not convincing:

The Board concurs with the appellant (opponent) that a person skilled in the art starting from the embodiment in Figure 3 and aiming to provide a more secure and reliable connection between syringe and the hub finds indeed on page 27 of D2 a hint to provide a threaded connection between the hub and the distal end of the syringe. However, since the hub (48) of the know syringe is designed to surround its distal end, the first choice would be to provide an internal thread in the hub cavity and an external thread on the syringe distal end. This does not correspond to the threaded luer connector according to features [2A], [2B], [4A], [4B] and [6]. Furthermore, the Board follows the view of the Opposition Division and the respondent (patent proprietor) that the person skilled in the art aiming to provide an injection device enabling a secure connection between syringe and needle hub also when injecting highly viscous fluids cannot find in the standards D11 and D16 to D18 or in documents D1, D5 any obvious hint to adopt a luer connection according to claim 1 in the syringe of D2 and this for the same reasons presented regarding the lines of inventive step attack starting from D14.

D10 or D9 as closest prior art

5.7 With their statement of grounds of appeal the appellant (opponent) contested the conclusion of the Opposition Division that the subject-matter of claim 1 of the patent as maintained was not obvious starting from

these prior art documents as closest prior art.

5.8 The parties at the oral proceedings referred in this respect to the arguments provided in writing and did not make any further submission. The Board has thus no reason to deviate from its preliminary assessment of these inventive step objections as set out in the communication according to Article 15(1) RPBA preliminarily confirming the assessment of the Opposition Division.

5.9 With their written submissions, the appellant (opponent) did not dispute that document D10 failed to disclose features 2A and 2B, 4B, 6 and 7' of claim 1 of the patent as maintained. However, regarding the disputed presence of the cavity according to feature [3], the same arguments raised in this respect in the context of the inventive step attack starting from D14 were maintained. The appellant (opponent) essentially argued that due to the hint in D10 to use a *"luer lock"* connection to secure the syringe to the hub, the person skilled in the art would obviously be directed to the standards presented in D11 and D16 to D18 or to the design of the luer connection suggested in D20, D5 or D1, thereby arriving without inventive skill at a syringe according to claim 1 of the patent as maintained.

5.9.1 However, irrespective of the assessment of the disputed disclosure and/or inventive contribution of features [3] and [7'] of claim 1 of the patent as maintained, the Board takes the view that it would not be obvious to introduce in the syringe mentioned in D10 a luer connector according to features [2A, [2B], [4A], [4B] [6] in combination for the same reasons presented in the context of the discussion of the lines of inventive

step attack starting from D14.

5.10 Regarding the lines of inventive step attack starting from D9 the appellant (opponent) maintained the same arguments regarding feature [3] and [7'] of claim 1 and held that it would be obvious - in case of the injection of high viscosity fluids - to adopt a threaded luer connector with internal and external thread according to features [4A], [4B] and [6] in combination in view of D11, D16 to D18 of the solutions disclosed in D1, D5 and D20. The same line of arguments applied when starting from D1, D5 or D20.

5.11 However, irrespective of the inventive contribution of the other features recited in claim 1, the introduction of a luer connection according to features [4A], [4B] and [6] is not obvious for the same reasons presented in the context of the discussion of the lines of inventive step attack starting from D14.

D1, D5 or D20 as closest prior art

5.12 Also regarding the lines of inventive step attack the appellant (opponent) at the oral proceedings referred to their written submissions and did not submit any comments in reaction to the preliminary opinion issued pursuant to Article 15(1) RPBA according to which the Board was inclined to confirm the assessment of the Opposition Division. The Board see thus no reasons to deviate from its preliminary conclusions. In this respect, it is emphasised that - as already pointed out by the Opposition Division and the respondent (patent proprietor) - documents D1, D5 and D20 are completely silent regarding the possibility to use the injections device disclosed therein for the injection of the specific class of high viscosity fluid as specified in

feature [7'] of claim 1 of the patent as maintained.

Disputed admittance of the lines of inventive step attack based on D12 and D15

6. These lines of inventive step attack have been submitted for the first time with the statement of grounds of appeal of the appellant (opponent). Their admissibility is questioned by the respondent (patent proprietor) who also alleged a lack of substantiation.

6.1 The appellant (opponent) argued in writing that these lines of inventive step attack were submitted in appeal as a direct and timely reaction to the new arguments presented by the respondent (patent proprietor) for the first time at the oral proceedings that D14 did not qualify as prior art pursuant to Article 54(2) EPC. At the oral proceedings before the Board the appellant (opponent) drew the attention to the fact that document D12 had been used in the context of the novelty attack raised in view of the *"Dermal Filler Kit Restylane"* during the first instance proceeding. They referred to the decision T0184/17 in which the deciding Board held that the inventive step attack raised for the first time in appeal remained within the factual and evidentiary framework relied upon by the opponent in the notice of opposition under the ground of Article 100(a) EPC in association with Article 54 EPC (lack of novelty) and decided that for this reasons this attack had to be admitted.

6.2 The Board cannot follow the arguments of the appellant (opponent):

Firstly the Board cannot see why the appellant (opponent) did not develop these inventive step attacks

during the first instance proceedings once they were aware of the objection of the respondent (patent proprietor) that D14 did not allegedly qualify as prior art pursuant to Article 54(2) EPC, but decided to postpone the submission of this fall back position to the appeal proceedings. Nor convincing reasons have been provided by the appellant (opponent). At least a statement at the oral proceedings that the same arguments in support of the objection of lack of inventive step raised starting from D14 analogously applied starting from D12 or D15 would have been possible and sufficient. Regarding the conclusions of the decision T0184/17, the Board emphasises on the one hand that the decision is antecedent to the entry into force of the RPBA 2000. On the other hand, it is evident that the conclusions of the deciding Board were based on the assumption that the specific factual and evidentiary framework of the novelty assessment did not change when discussing inventive step. However, this is not the case here because D14 on one side and D12 and D15 on the other side are different documents, whereby a fresh assessment of the possible inventive contribution of the distinguishing features should be carried out for the first time during the appeal proceedings.

6.3 For the reasons above, the Board in exercise of the discretion pursuant to Articles 12(4) and (6) RPBA decided not to admit the lines of inventive step attacks based on D12 and D15 as closest prior art into the appeal proceedings.

Admissibility of document D29 and of the line of inventive step attack based on this document

7. Document D29 was submitted by the appellant (opponent) for the first time with the statement of grounds of appeal (1) to prove the public availability of D14 questioned by the appellant (opponent) during the opposition oral proceedings and (2) as an alternative starting point for the assessment of inventive step. The respondent (patent proprietor) questioned the admittance of this document and of the inventive step attack based thereon under Articles 12(4) and (6) RPBA.

7.1 However, as explained above, the question of the public availability of document D14 is not relevant for the assessment of inventive step. Furthermore, regarding the new inventive step attack starting from this piece of prior art, the Board does not see any convincing reason why this document and the relative line of arguments could not have been presented at the first instance proceedings. Furthermore, this document is silent regarding the provision of a luer connection with an internal and an external thread and therefore is not more relevant of the other pieces of prior art cited for the assessment of inventive step. Finally the allegation of the appellant (opponent) that this document was hard to find is not a valid reason speaking for its admittance.

7.2 For the reasons above, the Board in exercise of the discretion pursuant to Articles 12(4) and (6) RPBA decided not to admit document D29 and the lines of inventive step attacks based thereon into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

H. Jenney G. Pricolo

Decision electronically authenticated