Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC_CFI_480/2025

Decision

of the Court of First Instance of the Unified Patent Court

Central Division Milan

issued on 10 April 2026

concerning EP4185356

HEADNOTE:

When assessing novelty, the Court will examine the disclosure of the prior art document overall and will compare this disclosure to the scope of the patent in suit. If one way of “mapping” leads to the assessment that a piece of prior art is novelty destroying, this leads to the result that the patent must be revoked.

KEYWORDS:

Claim interpretation. Admissibility of auxiliary requests. Lack of clarity.

CLAIMANT:

Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland, 2013, New Zealand,

Representatives: Thorsten Haslinde, Marc Wachenhausen and Vladimir Traykov, European Patent Attorneys and registered representatives before the Unified Patent Court, WBH Wachenhausen Patentanwälte PartG mbB, Müllerstraße 40, 80469 Munich, Germany

Further represented by: Dr. Arno Rißе and Dr. Felix Beck, German Attorneys at Law (Rechtsanwälte), Arnold Ruess Rechtsanwälte Partnerschaft mbB, Königsallee 59 a, 40215 Düsseldorf, Germany

DEFENDANT:

Flexicare (Group) Limited, Cynon Valley Business Park, Mountain Ash, Mid Glamorgan, CF45 4ER / UK,

Representatives: Matthew Naylor and Isobel Stone, European Patent Attorneys and registered representatives before the Unified Patent Court, Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX United Kingdom

PATENT AT ISSUE: European Patent no. 4185356

DECIDING JUDGES:

This decision is taken by Presiding judge Andrea Postiglione, Legally qualified judge and judge rapporteur Anna-Lena Klein and Technically qualified judge Kerstin Roselinger.

LANGUAGE OF THE PROCEEDINGS:

English

SUBJECT MATTER OF THE PROCEEDINGS:

Revocation action. Here: Final decision.

A. Summary of the facts and requests

I. Procedural background and proceedings before the Central Division

1 On 29 May 2025, Fisher & Paykel Healthcare Limited (“the claimant”) brought the present revocation action in the Central Division (section Milan) against Flexicare (Group) Limited (“the defendant”), concerning nullity of the European Patent 4 185 356 with respect to all contracting member states of the Agreement on a Unified Patent Court.

2 The defendant filed an application to amend the patent.

3 An online interim conference was held on 18 December 2025. The outcome of the interim conference is laid down in the procedural order issued on 23 December 2025.

4 The oral hearing was held in person in Milan on 27 February 2026, with some persons participating remotely. During the oral hearing, the parties agreed that the decision may be lodged on the CMS without being announced in open Court.

5 The parties agreed on a value of the case of EUR 250.000,00 and on recoverable costs being limited to EUR 38.000,00 corresponding to the applicable UPC ceiling for a case value of EUR 250.000,00. The parties further agreed that, for the purpose of substantiating recoverable costs up to this amount, it shall be sufficient for the respective party to submit an attorney's confirmation that such costs have been incurred, without the need for further supporting documentation (submission of 12 February 2026).

II. The patent in suit

6 European patent 4 185 356 entitled “Nasal Cannula” (“the patent” or “the patent in suit”) was filed on 23 July 2021 and claims priority of 24 July 2020 (GB 202011539). The claimant did not challenge the validity of the priority date.

7 The mention of the grant of the patent was published on 28 August 2024. No opposition was filed against the patent. The patent is registered with unitary effect (exhibit RA2). The defendant is the registered proprietor of the patent (exhibit RA3).

8 The patent relates to a nasal cannula and a system including a nasal cannula, [0001]. Its independent claim 1 reads as follows:

A nasal cannula (1) configured to deliver airflow to a user, comprising:

a manifold (2);

a connector for attaching a gas tube (7) to the manifold;

a pair of non-sealing nasal prongs (3) extending from the manifold for delivering a supply of gas to a user via the gas tube;

wherein the connector is configured to form a swivel connection with the manifold so as to provide relative rotation between the manifold and the gas tube, characterised in that:

the swivel connection has an axis of rotation configured to be substantially normal to a face of the user; and

the nasal cannula further comprising a selective retainer means configured to selectively hold the connector in a plurality of rotary positions relative to the manifold.

III. Requests of the parties

9 The claimant argues that the patent is invalid because it is not novel and at least lacks inventive step. According to the claimant, the subject matter of claims 1 and 4 extends beyond the content of the application as filed. Furthermore, the claimant submits that the subject matter of claim 4 is not sufficiently clear and complete for it to be carried out by the skilled person.

10 The **claimant requests**:

"1. The European patent EP 4 185 356 is revoked in its entirety with effect on the territory of all Contracting Member States to the Agreement on a Unified Patent Court.

2. The defendant bears the costs of the proceedings."

11 On 1 August 2025, the defendant lodged a defence to the statement for revocation and an application to amend the patent.

12 The **defendant requests**:

"1.1. The Defendant's Main Request is that the revocation action is dismissed, with the effect that the patent is maintained in the form as granted by the European Patent Office with respect to all contracting member states of the Agreement on a Unified Patent Court.

1.2. In the event that the Defendant's Main Request cannot be granted, we request maintenance of the patent based on any of the Auxiliary Requests (ARs) filed with the accompanying Application to amend, or according to any Auxiliary Request which may be filed later in these proceedings.

1.3. In the event that either of the Defendant's requests under 1.1 or 1.2 cannot be granted, we request that the patent is maintained in a form based on one or more

valid claims of the patent as granted or of any Auxiliary Request, notwithstanding that any other claims may be considered by the Court to be invalid.

1.4. We request that the Claimant bears all legal costs and other expenses incurred by the Defendant."

13 With their application to amend the patent, the defendant introduced 13 auxiliary requests (Exhibits ME D356-01 to ME D356-13 and Exhibits ME D356-01mu to Exhibits ME D356-13mu in marked up version).

14 In response to defendant's statement of defence and application to amend the patent, the claimant opposed the application to amend the patent.

15 With their rejoinder to the revocation action and reply to the application to amend the patent, the defendant introduced additional auxiliary requests. The Court did not allow these into the proceedings (order of 15 January 2026).

16 The grounds and defences brought forward by the parties will, to the extent relevant for this decision, be discussed in detail below.

B. Grounds for the decision

I. Summary of the outcome

17 The CD Milan concludes that the action for revocation is admissible. Claim 1 of the patent in suit as granted as well as the dependent claims lack novelty over D2, because the subject matter of the claim is directly and unambiguously disclosed in the prior art document D2. The first auxiliary request is admissible but lacks novelty over D2 as well. Auxiliary requests 2 to 13 lack clarity and are therefore not allowable.

II. Admissibility

18 The revocation action is admissible. The defendant does not put forward any issues regarding the admissibility of the action. The Court does not see any, either.

III. On the merits

1. Technical background of the patent in suit

19 The patent relates to a nasal cannula and a system including a nasal cannula, [0001].

20 The patent describes in [0002] that High Flow Oxygen Therapy (HFOT) has been used with specific face masks (High Airflow with Oxygen Entrainment (HAFOE) face masks). These can limit the patient's ability to eat, drink and communicate, and can lead to feelings of claustrophobia. These factors can lead to poor patient compliance.

21 Nasal cannulas are, according to the patent ([0003]), more comfortable, less claustrophobic and allow the patient to communicate more easily and to drink and eat.

22 The patent in suit cites several documents as prior art in [0003]: WO2009/109005 A1, US2012/318270 A1, US2018/001045 A1, CN102625720 A and US2020/101250 A1.

23 The patent specification explains that nasal cannulas' gas tubes delivering air or gas to the patient can be intrusive, thereby decreasing patient comfort and convenience, [0003]. While the patent does not explicitly criticize the solutions found in the aforementioned prior art documents, it explains that the provision of relative pivotal freedom between the manifold and the gas tube by the swivel connection allows the gas tube to be manoeuvred more easily, thereby helping to increase patient comfort and convenience whilst the patient wears the nasal cannula, [0006].

24 Against this background, the technical problem can be defined as providing a nasal cannula with an improved patient comfort and convenience, as the claimant points out (statement of revocation, margin 13).

25 According to the patent, this problem is to be solved by the device according to claim 1 and the dependent claims of the patent in suit.

2. Feature analysis of claim 1

26 Claim 1 as granted can be broken down as follows, with highlights in italics added by the Court to indicate purpose characteristics:

1. A nasal cannula (1) configured to deliver airflow to a user, comprising:

1.1 a manifold (2);

1.2 a connector *for attaching a gas tube (7) to the manifold*;

1.3 a pair of non-sealing nasal prongs (3) extending from the manifold *for delivering a supply of gas to a user via the gas tube*;

1.4 wherein the connector is configured to form a swivel connection with the manifold *so as to provide relative rotation between the manifold and the gas tube*, characterised in that:

1.5 the swivel connection has an axis of rotation configured to be substantially normal to a face of the user; and

1.6 the nasal cannula further comprising a selective retainer means configured to selectively hold the connector in a plurality of rotary positions relative to the manifold.

27 Figure 6 shows a perspective view of the nasal cannula ([0049]) according to a second embodiment.

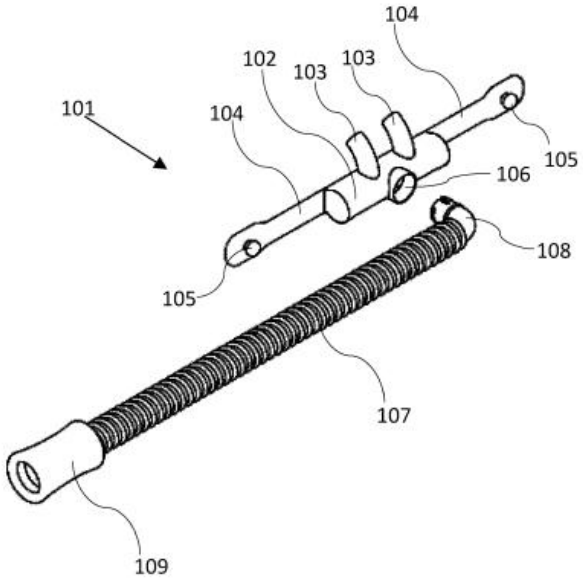


FIG. 6

28 The manifold is shown as component number 102. A pair of nasal prongs 103 extends from the manifold. The nasal prongs are described by [0088] as being non-sealing. They are arranged to enter respective nasal passages of the patient, [0088]. Opposing straps 104 extend from the manifold, arranged to extend around part of the patients face, [0088]. They can be attached to a patient head band, e.g., via end protrusions numbered 105, [0088]. The manifold 102 provides an aperture 106, [0089]. Also shown in Figure 6 is a gas tube 107 with a connector 108 and an end connector 109, connectable to a gas supply [0089].

29 As is correctly not in dispute between the parties, the first embodiment of the nasal cannula shown in Figures 1 and 2 of the patent is not within the scope of claim 1, because the swivel connection's axis as shown in figure 1 and 2 is not substantially normal to the face of the user, contrary to the requirements of feature 1.5.

3. Claim interpretation

30 In view of the discussion between the parties, several features of claim 1 of the patent in suit need to be examined further.

a) Legal standard

31 As the Court of Appeal has made clear (UPC_CoA_335/2023 App_576355/2023, order of 26 February 2024, as rectified by UPC_CoA_335/2023, APL_576355/2023, order of 11 March 2024 – NanoString v 10x Genomics), the patent claim is not only the starting

point, but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection. The patent claim is to be interpreted from the point of view of a person skilled in the art. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European patent.

32 A feature in a patent claim must be interpreted in light of the claim as a whole (UPC_CoA_1/2024, APL_8/2024, order issued on 13 May 2024, para. 29 – VusionGroup v Hanshow). This means that the patent claim as a whole must be examined to deduce which technical function specific features have and provide, individually and as a whole (UPC_CFI_252/2023 (CD Munich), decision issued on 17 October 2024, para. 8.4 – Nanostring v President and Fellows of Harvard College). The function of a structural element must be considered when interpreting a claim feature relating to such an element. However, the interpretation must likewise take into account the physical and spatial configuration of the elements as taught by the patent (UPC_CoA_789/2025, order issued on 6 March 2026, margin 35 - Dyson v Dreame). A purpose specified in the claim defines the protected subject matter in such a way that it must be objectively suitable to achieve the purpose (UPC_CFI_284/2024 (LD Munich), decision issued on 22 August 2025, margin 102 – Brita v AQUASHIELD).

33 The description and the drawings may show that the patent specification defines terms independently and, in this respect, may represent a patent's "own lexicon" (see, e.g., UPC_CFI_252/2023 (CD Munich), decision issued on 17 October 2024, para. 8.4 - Nanostring v President and Fellows of Harvard College). However, embodiments explained in the description shall generally not limit the patent claim (see, e.g., UPC_CFI_248/2024 (LD Munich), decision issued on 22 August 2025, para. 94 – Brita v AQUASHIELD).

34 The skilled person will try to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the Patent. The Patent must be construed in a technically sensible manner, by a 'mind willing to understand, not a mind desirous of misunderstanding' (see, e.g., UPC_CFI_497/2024 and UPC_CFI_571/2024 (CD Milan), decision issued on 23 October 2025, para. 2.2 – bioMérieux v Labrador).

35 Claim construction is a matter of law (UPC_CoA 768/2024, decision issued on 20 April 2025, para. 37 - Insulet v EOFlow; UPC_CoA_899/2025, decision issued on 30 March 2026, margin 66 – Sinocare v A. Menarini Diagnostics).

36 It depends on the circumstances of the individual case if the subject matter of a dependent claim and its features may be used as a source of interpretation when interpreting the main claim. If the dependent claim only adds an additional feature that does not provide a more specific description of the features of the main claim, the dependent claim shall generally not be used to draw conclusions about the interpretation of the main claim (UPC_CoA_528/2024 and UPC_CoA_529/2024, decision of 25 November 2025, margin 45 - Amgen v Sanofi et alii). Generally, dependent claims do not limit the scope of an independent claim. They generally merely show – possibly in connection with an additional benefit - possible embodiments of the independent claim (UPC_CFI_443/2024 (LD Munich), order of 25 November 2024, headnote 2 - Häfele v Kunststoff KG Nehl).

b) The skilled person

37 The skilled person as agreed upon by the parties and the Court, is a mechanical or medical engineer with a university degree and several years of experience in the field of respiratory interfaces, in particular in designing nasal cannulas and face masks.

c) Claim interpretation from the point of view of the person skilled in the art as defined above

38 **aa)** According to claim 1 of the patent as granted, the claimed nasal cannula comprises four components, namely a manifold (feature 1.1), a connector (feature 1.2), a pair of non-sealing nasal prongs (feature 1.3) and a selective retainer means (feature 1.6).

39 The connector is further characterised by the purpose characteristic *"for attaching a gas tube to the manifold"* (feature 1.2) and is configured to form a swivel connection with the manifold (feature 1.4).

40 The pair of non-sealing nasal prongs extends from the manifold (feature 1.3). The pair of nasal prongs is further characterised by the purpose characteristic *"for delivering a supply of gas to a user via the gas tube"*.

41 The selective retainer means is configured to selectively hold the connector in a plurality of rotary positions relative to the manifold, feature 1.6.

42 **bb)** A gas tube is mentioned in claim 1 as granted with regard to the purpose characteristics of certain features but is not in itself a component of the nasal cannula. The term "comprising" in relation to the nasal cannula refers literally only to a manifold, a connector, nasal prongs and selective retainer means. The person skilled in the art

understands from the overall disclosure of the patent in suit that the gas tube is not a mandatory component of the nasal cannula as addressed in claim 1.

43 This is demonstrated by the fact that dependent claim 13 introduces the gas tube as a (new) component of the nasal cannula and makes it clear that the nasal cannula as addressed in claim 1 does not comprise a gas tube.

44 Additionally, claim 13 further characterises the gas tube by addressing additional features ("wherein.."). If the gas tube were already part of the nasal cannula as addressed by claim 1, however, the skilled person would have expected the wording of the claim to be something like "A nasal cannula (1) according to any preceding claim, wherein the gas tube connected to the connector is malleable (…)".

45 The embodiment shown in Figure 6 will not lead the skilled person to a different understanding. While the connector 108 (which is a component included in the nasal cannula as addressed by claim 1 as explicitly required by feature 1.2) is shown here as physically attached to the gas tube 107, this attachment does not require the gas tube to be a component of the cannula as well. Additionally, as explained above, embodiments and figures do generally not limit the patent's scope.

46 The skilled person will derive the same understanding from the description of the patent, where the gas tube is mentioned in several margins (e.g. in [0020], [0022], [0040], [0045]). The skilled person will understand specifically from [0045], that the gas tube is only an optional component of the nasal cannula.

47 Claim 2 does not lead the skilled person to a different understanding, either. Claim 2 specifies that the nasal cannula according to claim 1 further comprises "an elbow between the swivel connection and the gas tube (7) (…)" (with further specifications relating to the elbow). The skilled person understands that the claim requires an additional elbow, but the wording of claim 2 ("between the swivel connection and the gas tube") does not teach the skilled person that the gas tube must be a mandatory component of the nasal cannula as addressed in claim 2.

48 Lastly, [0092] and [0093] which address that the nasal cannula may have or provide a gas tube, and [0096] which relates to the manufacturability of the nasal cannula and addresses the diameter of the gas tube in this regard, may not be seen as limiting claim 1 of the patent in suit and therefore requiring the nasal cannula of claim 1 to necessarily comprise a gas tube.

49 **cc)** The nasal cannula according to claim 1 is configured to deliver airflow to a user. Contrary to the defendant's argumentation (Statement of Defence margin 3.4, Rejoinder to the Reply margin 5.37), there is no explicit or implicit requirement in claim 1 that the gas supply tube not be disconnected, and the patient not be removed from oxygen therapy. While the nasal cannula as depicted in figure 6 most likely allows a

continuous gas flow when the patient moves and therefore the gas tube is moved, the skilled person understands that claim 1 is not limited to the embodiment depicted in figure 6.

50 **dd)** The manifold (feature 1.1) is not explicitly defined in the patent's specification. The skilled person will generally understand the term as referring to a pipe or a chamber branching into several openings. This is in line specifically with figure 6 as shown above, which shows the manifold 102 with one opening 106 and two further openings, nasal prongs 103. The skilled person understands from claim 1 that an airflow (not necessarily continuous) shall pass through the manifold, as is clear from feature 1 in conjunction with feature 1.3 and 1.2. Therefore, it must have at least one inlet (for example the aperture shown in figure 106). The manifold distributes the gas from the inlet to the outlets by allowing said airflow. In the embodiments described in the patent's specification and shown in its drawings, it has two outlets, namely the two nasal prongs.

51 There is no indication in claim 1 that a manifold may not have more than one inlet. [0040] and [0059] describe a single inlet as being optional. The embodiment depicted in figure 6 does – for legal reasons explained above – not limit the claim's scope.

52 The defendant's understanding of the term "manifold" (Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent, margin 3.7), "requiring a function of directing a gas flow from the inlet provided at the connection between the connector and the manifold, to the outlets provided by the pair of non-sealing nasal prongs", does not have a basis in claim 1. While the pair of nasal prongs is further specified by the purpose characteristic *"for delivering a supply of gas to a user via the gas tube"*, this purpose characteristic does – for legal reasons, as explained above – only require that the manifold allows a deliverance of gas to a user via the gas tube. There is no requirement in claim 1 for structuring the manifold in a way that the inlet is at the connection between the connector and the manifold. Neither can such a requirement be inferred from feature 1 ("a nasal cannula configured to deliver airflow to a user"). This feature does not address how this configuration shall be achieved and does not add a specific requirement relating to the configuration of the inlet or the manifold. The inlet is not specifically addressed in claim 1, so it cannot be understood in a way as to limit the term "manifold". The fact that the description mentions that the swivel connection is optionally airtight or optionally allows a certain gas leakage (see [0043] and [0044]) does not lead the skilled person to a different understanding of the term "manifold", as embodiments described in the patent's description do not generally limit the patent's scope.

53 The manifold can be formed by several (e.g. part rigid, part flexible) components, as is clear from the specification in [0010].

54 Contrary to the defendant's view (Statement of Defence margin 6.6), claim 1 does not require that all components which are essential for providing a fluidic connection are seen as part of the manifold. Any component that can provide the functionality of distributing gas from an inlet to two outlets can be deemed a manifold in the sense of claim 1 of the patent in suit.

55 **ee)** The connector (feature 1.2) is a component of the nasal cannula, as the skilled person learns from claim 1. While figure 6 shows the connector attached to the gas tube (which is not, even if it means sounding repetitive, a component of the nasal cannula), it is clear from claim 1 that the connector shall be one of the defining components of the nasal cannula.

56 The connector is further characterised by the purpose characteristic *"for attaching a gas tube to the manifold"*, therefore it must be designed in a way to allow a gas tube to be attached to the manifold via this connector. The purpose characteristic does not require that the connector allows a direct connection of a gas tube to the manifold. The skilled person understands that the explanation in [0089], according to which the connector is received inside an aperture of the manifold, does not limit the claim to a direct connection. An indirect connection will suffice. The connector as addressed in claim 1 only requires a mechanical attachment. Optionally, there might be an additional fluidic coupling, as the skilled person understands from [0059]. The purpose characteristic does not require that the connector allows a fluidic connection between the manifold and a gas tube at the point of attachment (see above, margin 52).

57 The connector does not need to be designed in a way as to allow constant airflow to the user, as has been discussed already above (margin 49).

58 **ff)** The connector is further configured to provide a swivel connection with the manifold, feature 1.4. The skilled person understands from the specification in [0006], that the swivel connection shall provide "relative pivotal freedom". This design shall ensure that the gas tube is manoeuvred more easily. In [0060], the patent explains that a pivotal connection may be alternatively referred to as a swivel connection.

59 **(1)** The skilled person understands that the swivel connection is not a distinct structural component, nor is it a connector in the sense of the patent in suit. Rather, it is formed by the two components manifold and connector.

60 **(2)** The defendant's understanding of the term "swivel connection", limiting it to a connection that enables rotational movement about a single axis of rotation (statement of defence, margin 3.10 et sequi; Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent, margins 3.16 et sequi), does not have any basis in the patent in suit, though. While the rotation is addressed as an important feature of the invention allowing for the intended pivotal freedom, there is no indication in the claims or the specification that only one single

axis rotation would be seen as a swivel connection in the sense of feature 1.4. The parts of the description referenced by the defendant ([0006], 0060], [0082], see Statement of Defence, margin 3.12) do not allow such a limited claim construction. Additionally, for reasons explained above, embodiments explained in the description do generally not allow a limited claim construction.

61 The fact that the patent does not suggest multi-axis rotational arrangements does not lead the skilled person to an understanding that only a single-axis rotational arrangement is addressed by claim 1. Since the claim does not contain a limitation towards a single-axis rotational arrangement, the skilled person concludes that both single-axis and multi-axis rotational arrangements are under the scope of claim 1 of the patent.

62 The skilled person will not arrive at the defendant's interpretation based on feature 1.5, according to which the swivel connection's axis of rotation is configured to be substantially normal to a face of the user. This feature requires that the swivel connection is configured to cause a rotation normal to the face of the user but does not prohibit a swivel connection to be configured to additionally allow differing rotations as well. [0090] explains in this regard the feature's benefits, where the aperture is opposite to the patient, and the connector extends away from the patient. This benefit can be achieved if the swivel connection provides more than one axis of rotation.

63 The Court does not need to adapt the defendant's assessment due to the "Abraham declaration" (exhibit ME D356-15), submitted with the Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent. As outlined above, claim construction is a matter of law. While the Court must provide claim construction on the basis of the knowledge of the person skilled in the art, the Court is not bound by a claim construction offered by a party's expert. The party's expert opinion is seen as part of the party's submission and considered carefully by the Court. However, it is still the Court's duty to assess the patent and find the correct claim construction on the basis of the patent. The Court understands that the defendant's expert provides his claim construction based on the wording of claim 1 and by assessing the disclosure of the patent's description and its figures. For legal reasons explained above, generally neither textual parts of the description nor figures shall limit the scope of the patent. Therefore, the Court differs from the claim construction provided by the defendant and their expert.

64 As will be seen below, the claimant's validity attacks based on D2 are successful. Consequently, the discussion if the swivel connection may have a multi-axis rotation is in effect not relevant for this decision.

65 **(3)** Feature 1.4 addresses the swivel connection between the manifold and the connector. The subfeature "*so as to provide relative rotation between the manifold and*

the gas tube" is a purpose characteristic. As the gas tube is not part of the nasal cannula, as explained above, the skilled person understands that the subfeature addresses a purpose of the swivel connection, but does not address the gas tube as a mandatory component of the nasal cannula of claim 1 of the patent in suit. Rather, the only requirement addressed in feature 1.4 is that a swivel connection is formed by the connector with the manifold.

66 **gg)** The nasal prongs addressed in feature 1.3 are – explicitly – non-sealing nasal prongs. In [0007], the patent describes that a non-sealing nasal cannula is a nasal cannula that does not form air-tight seal with the nares of a patient. Accordingly, the skilled person concludes that non-sealing nasal prongs relate to prongs that allow the patient to insert them into the nares without forming an air-tight seal.

67 The prongs extend from the manifold and are further characterized by the purpose characteristic "*for delivering a supply of gas to a user via the gas tube*".

68 For legal reasons, the Court does not need to assess if the skilled person at the time of priority understood the term "nasal prong" to refer only to non-sealing elements, in contrast to nasal pillows, as the claimant maintains (Reply to the Statement of defence, margins 26 et sequi) and the defendant disputes (Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent, margins 3.10 et sequi), and if it was common general knowledge at the priority date of the patent in suit that interfaces delivering oxygen therapy used non-sealing prongs, as the claimant maintains (Reply to the Statement of defence, margins 30 et sequi, expert report RA7) and the defendant disputes (Rejoinder to the reply to the statement of defence, margins 3.13 et sequi, expert report ME D-356-15). As explained below (margin 98), with regard to D2, the defendant does not dispute that this document discloses non-sealing nasal prongs. Since D2 destroys novelty of claim 1 as granted and auxiliary request 1, and the additional auxiliary requests are not allowable for other reasons, as shown below, the discussion about the common general knowledge relating to non-sealing nasal prongs is not relevant in this case.

69 **hh)** The swivel connection has an axis of rotation configured to be substantially normal to a face of the user, feature 1.5. [0090] and [0091] explain that this means that the connector extends away from the patient, normal to a plane of the face mount portion 110. Therefore, the contact area of the nasal cannula with the patient's face shall be reduced. As explained above (margin 62), feature 1.5 does not constitute a "disclaimer" limiting the scope of claim 1 of the patent to swivel connections that (only) have an axis of rotation configured to be substantially normal to a face of the user.

70 **ii)** The selective retainer means addressed in feature 1.6 must be configured to selectively hold the connector in a plurality of rotary positions relative to the manifold. The specification explains that the selective retainer means may be a friction fit

between the connector and the manifold ([0017], [0085]), or that a detent may be used ([0085]).

4. Novelty of claim 1 as granted

a) Legal standard

71 For the purposes of Art. 54 EPC, an invention shall be considered new if it does not form part of the state of the art. The state of the art, in accordance with Art. 54.2 EPC, shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

72 The CoA has clarified that it is decisive if the subject-matter of the claim with all its features is directly and unambiguously disclosed in the prior art (UPC_CoA_182/2024, App 21143/2024, Order of 25 September 2024, para. 123 – Mammut v Ortovox).

73 With regard to purpose characteristics, the assessment of novelty only requires an assessment if prior art discloses a device with physical characteristics as disclosed in the patent in suit. If prior art discloses such a device, the device as such is disclosed, irrespective of the specific intended use. An exception can only be made where the disclosed device is not suitable or needs to be amended to be suitable for the intended use as foreseen by the patent in suit (UPC_CFI_248/2024 (LD Munich), decision issued on 22 August 2025, para. 144 - Brita vs. Aquashield).

74 When assessing novelty, the Court will examine the disclosure of the prior art document overall and will compare this disclosure to the scope of the patent in suit. If one way of “mapping” leads to the assessment that a piece of prior art is novelty destroying, this leads to the result that the patent must be revoked.

b) Lack of novelty over D2

75 The Central Division Milan concludes that the subject matter of claim 1 of the patent as granted lacks novelty over D2.

76 **aa)** D2 (WO 2015/193833 A2) is a PCT application dated 18 June 2015 titled “PATIENT INTERFACE AND COMPONENT PARTS”, published on 23 December 2015. According to [0001], the disclosure relates to components for medical applications, particularly medical breathing circuits, (…), including but not limited to components associated with or forming parts of a patient interface for delivery of gases to a user’s airway.

77 Figures 3a and 3b show an embodiment of the invention of D2:

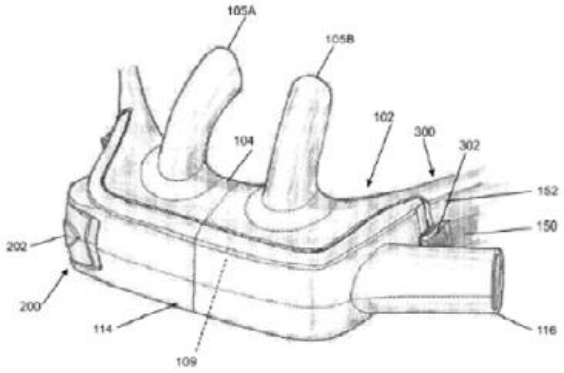


FIGURE 3A

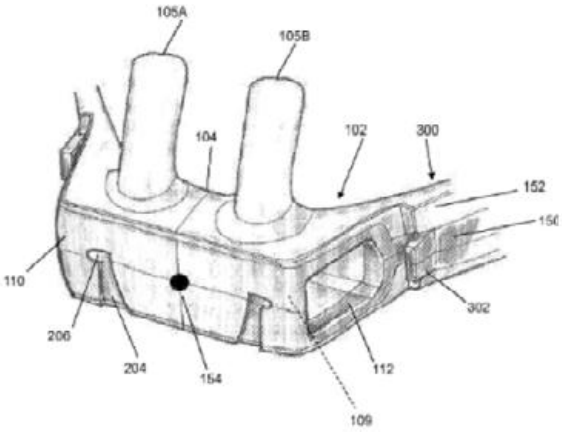


FIGURE 3B

78 As specified by [0613], Figures 3A-3B show an exemplary non-limiting embodiment of a central section of the patient interface 100. Component 102 is a frame portion which comprises a relatively hard or rigid section 150 and a relatively soft or flexible section 152. Component 114 is labelled as a manifold that is e.g. rotatably secured to the frame portion 102 or secured in a way that allows it to rotate or swivel relative to the frame portion 102 or vice versa. According to [0615], components 110 and 112 are first and second frame gas inlets of the frame portion 102, respectively. Component 109 is the gases chamber.

79 [0603] explains that the gases chamber 109 can receive gas from a gas source, and that gas can be channelled to the user through a gas delivery element 105. The gas delivery element 105 delivers gases to the user substantially or completely through the nose, and comprises first and second nasal delivery elements 105A, 105B, such as nasal prongs that are adapted to be fitted into the nares of the user. [0603] specifically mentions that the nasal delivery elements in the illustrated configuration are non-sealing (“engage with the nares to form an unsealed engagement”). The skilled person understands that [0603] is relevant for the disclosure of the embodiment as shown in figures 3A and 3B, because [0603] relates, as stated in [0602], to figure 2. Figure 2 shows a patient interface 100, which includes the central section of the interface as shown in figures 3A and 3B.

80 According to [0615], the manifold inlet 116 is (only) in substantial pneumatic communication with the gases chamber 109 when the manifold inlet 116 is positioned over or near first or second frame gas inlets 110, 112 of the frame portion 102. This can be seen in figures 3A and 3B. The gases chamber 109 of the frame portion 102 communicates with the gas source through a gas conduit 146, shown in Figure 2 ([0611]).

81 According to [0616], the rigid section of the frame portion 102 comprises an axle structure 154 that facilitates rotary motion between the manifold 114 and the frame

portion 102. This axle structure 154 provides a protrusion that can be forced through a complementary aperture of the manifold 114.

82 [0619] explains that the frame portion comprises a detention mechanism. It prevents rotational motion, in certain rotational orientations of the manifold relative to the frame portion 102, [0620]. [0620] explains that the retention mechanism 300 is configured to retain the manifold 114 between the frame 102 and the post 302. The manifold is retained by a friction fit to retain the manifold in the operational position. The friction fit retaining the manifold 114 is high enough to retain the manifold in the operational position when the interface 100 is in use, but the friction fit can be overcome by a user when the user is attempting to rotate the manifold [0620]. The frame portion 102 further comprises recessed tracks 204 with detention regions 206, [0621]. A complementary boss 226 of the manifold 114 can move through these tracks. This facilitates rotation of the manifold 114 with respect to the frame portion 102, [0621]. The boss 226, naturally biased outwardly, enters a detention region 206 (shown in Figure 3B) and is then retained in this region 206, so that further rotational motion of the manifold 114 relative to the frame portion 102 is resisted, [0621].

83 **bb)** D2 discloses all features of claim 1 of the patent in suit directly and unambiguously. The parties differ only on the disclosure of features 1.2, 1.4 and 1.6, mostly due to the differing “mapping” of the features 1.1 (“manifold”) and 1.2 (“connector”) of claim 1 of the patent to D2.

84 **(1)** Feature 1 (“a nasal cannula configured to deliver airflow to a user”) is disclosed in D2. Figures 3a and 3b, shown above, undisputedly depict a nasal cannula.

85 **(2)** Feature 1.1 (“a manifold”) is disclosed. Frame portion 102 constitutes a manifold in the sense of the patent in suit according to the claim interpretation explained above in margins 50 et sequi.

86 It is irrelevant that D2 labels another component, namely component 114, as a manifold. The Court does not misunderstand the importance of a name ascribed to a certain component, as it may be indicative of how the skilled person would understand the function of said component, as the defendant correctly underlines (Statement of Defence, margin 6.4; Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent, margin 5.2). However, to assess the disclosure of a prior art document, the Court will focus on the technical function the disclosed components provide. The names of components may indicate a certain technical function, but the Court will assess the disclosure of the prior art document on the whole (see above, margin 32).

87 As explained above, the function of the manifold in the patent in suit is to provide a channel or chamber for distributing gas via (at least one) inlet and outlets. In D2, this function is provided by the frame portion 102. The frame portion 102 has two gas inlets

(110 and 112, with 112 clearly visible in figure 3B), one of which in certain constellations receives gas via component 114. The frame portion also provides component 109, which is the gases chamber. From the gas chamber, gas is channelled to the user through delivery elements 105a and 105b, which constitute outlets.

88 Contrary to the defendant's argument (Statement of Defence, margin 6.6; Rejoinder to the Statement of Defence, margin 5.4 et sequi, esp. 5.6), the frame portion 102 alone provides the functionality of the manifold. It is not relevant that the gas distribution explained above can primarily be achieved when the frame portion interacts with component 114 in the sense that component 114 blocks the other inlet. While it is correct that at least part of the received gas might flow out of component 102 via the other inlet when the frame portion 102 receives gas via one inlet and the other inlet is not blocked (Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent, margin 5.5), the skilled person understands that in this situation gas would still be delivered from one inlet to the outlets, as not all gas would flow out via the second inlet. It is equally not decisive that a fluidic connection from the inlet 116 to the nasal prongs 105a, b will only be provided in certain constellations, as clarified by [0615]. Claim 1 of the patent in suit does not require a continuous gas flow, as explained above.

89 The fact that the frame portion 102 has two inlets does not lead the skilled person to an understanding that this component could not be a manifold in the sense of claim 1 of the patent. As explained above, claim 1 is not limited to a manifold with just one inlet. Additionally, as the defendant underlined during the oral hearing, D2 only ever discloses one effective inlet.

90 It is not relevant that the frame portion 102 receives a gas via the component 114. Claim 1 does not require the manifold to receive the gas directly. Therefore, the fact that components 114 and 102 interact to receive gas from a gas tube or conduit does not require component 114 to be seen as part of the frame portion 102, or – when mapped to claim 1 of the patent in suit – as part of the manifold in the sense of claim 1.

91 As explained above, the defendant's limiting claim construction that would require the defined function of directing a gas flow from the inlet provided at the connection between the connector and the manifold is not correct. Therefore, it is not relevant that indeed the mechanical connection between component 114 and frame portion 102 is provided by and at component 154 (in the middle of component 102), and the gas flow occurs between components 116 and 110/ 112 on the side of component 102.

92 For legal reasons, it is irrelevant if another component (namely component 114, called a manifold in D2, in cooperation with the frame portion 102), can also be mapped onto feature 1.1, if seen in isolation, as explained above. Therefore, while it is correct that component 114 contributes to the gas flow in the nasal cannula depicted by figures 3a,

3b (as do both the manifold and the connector in the nasal cannula according to claim 1 of the patent in suit), and a combination of both the frame portion 102 and the manifold 114 could be mapped to the feature 1.1 “manifold”, when assessing the whole disclosure of D2 and comparing it to the subject matter of claim 1 of the patent, the skilled person understands that the frame portion 102 in this constellation takes the function of the manifold of the patent in suit.

93 **(3)** A “connector” in the sense of the feature 1.2 is disclosed by the component 114, named a “manifold” in D2.

94 As stated above, the connector must be designed in a way to allow a gas tube to be mechanically attached to the manifold (via the connector). Component 114 undisputedly (see Rejoinder to the reply to the statement of defence margin 5.10) connects to frame portion 102 via the axle structure 154. Component 114 allows a gas tube or a gas conduit to be attached to component 114’s inlet 116. Therefore, it allows to (indirectly) attach a gas tube to component 102. Additionally, it allows a gas flow between a gas tube/ conduit and frame portion 102 in certain constellations, albeit not at the physical location of the axle structure 154. Thus, component 114 is a connector in the sense of the patent.

95 Although component 114 contributes to the frame portion’s function to distribute gas flow, this does not make it a (physical) part of the frame portion 102. As is clear from the disclosure of D2, frame portion 102 and component 114 may even be separable (see [0616]: “(…) In some alternative configurations the axle structure 154 may allow for separation of the manifold 114 and the frame portion 102. (…)”), so, the skilled person will clearly understand that these are separate components which only interact. For the same reasons and as stated above, component 114 is not a part of the manifold in the sense of feature 1.1 of claim 1 of the patent in suit.

96 It is not relevant if D2 directly and unambiguously discloses that the gas source is a gas tube, although the skilled person will understand this from figure 2, Figure 30, [0611] and [0680]. Subfeature “*for attaching a gas tube to the manifold*” is a purpose characteristic, therefore – for legal reasons explained above – any embodiment that allows a gas tube to be attached to the manifold, even if this attachment of a gas tube is not disclosed, will lead to a disclosure of a connector in the sense of feature 1.2. This is clearly the case with regard to component 114.

97 It is irrelevant that the airflow connection provided (in part) by component 114 will only occur in certain orientations, as can be seen from figure 8d of D2. Claim 1 does not require that the connector allows a constant airflow connection between the manifold and the gas tube, as explained above.

98 **(4)** The defendant correctly does not dispute the disclosure of feature 1.3. D2 discloses a pair of nasal prongs in the sense of feature 1.3, namely delivery elements 105a and

105b. [0603] specifies that they form an unsealed engagement with the nares of the patient.

99 **(5)** Component 114, the “connector” in the sense of feature 1.2, forms a swivel connection with the manifold (frame portion 102) in the sense of feature 1.4, as is clearly and unambiguously disclosed by D2. As the skilled person understands from [0613], component 114 is rotatably secured to the component 102 (“(…) The manifold 114 is relative to the frame portion 102, for example rotatably secured to the frame portion 102, or secured in such a way that the manifold 114 can rotate or swivel relative to the frame portion 102, or vice versa, such that the frame portion 102 can rotate or swivel relative to the manifold 114. (…)”). The relative rotation between the manifold 102 and the gas tube 146 is enabled and a direct consequence of the manifold 102 and the connector 114 being rotatably secured to each other, as can directly and unambiguously be deduced from figures 2, 3a and 3b. The defendant’s differing argument is based on the defendant's “mapping” of components 102 and 114.

100 **(6)** D2 also directly and unambiguously discloses feature 1.5 (“the swivel connection has an axis of rotation configured to be substantially normal to a face of the user”). As can be seen from figures 3a and 3b and understood from [0616] and [0621], frame portion 102 comprises an axle structure that facilitates rotary motion between the component 114 and the frame portion 102, and it provides recessed tracks with detention regions 206 (see below), which will allow component 114 to rotate normally to the face of the user. Significantly, the defendant does not even dispute that feature 1.5 is disclosed by D2.

101 **(7)** The skilled person understands that feature 1.6 is disclosed by D2 as well, namely by the retention mechanism 300, the tracks 204 with detention regions 206 and the boss 226 which moves through these tracks, as described in margin 82.

102 The defendant disputes the disclosure of feature 1.6 based on their “mapping” and their understanding that the component named “manifold” in D2 must be understood as the manifold in the sense of the patent in suit. As discussed above, for legal reasons, this understanding is not embraceable.

103 **(8)** In summary, the disclosure of the embodiments of 3a, 3b of D2 can be mapped onto claim 1 of the patent in suit as follows:

Feature 1 A nasal cannula (1) configured to deliver airflow to a user, comprising:	Nasal cannula, see figures 3a, 3b
Feature 1.1 a manifold;	frame portion 102

Feature 1.2 a connector *for attaching a gas tube to the manifold;*	component 114 (called a “manifold”)
Feature 1.3 a pair of non-sealing nasal prongs (3) extending from the manifold *for delivering a supply of gas to a user via the gas tube*;	nasal delivery element 105a, 105b
Feature 1.4 wherein the connector is configured to form a swivel connection with the manifold *so as to provide relative rotation between the manifold and the gas tube, characterised in that*:	component 114 (= the connector) is rotatably secured to component 102 (= the manifold); range of rotary motion between 180 and 360 degrees
Feature 1.5 the swivel connection has an axis of rotation configured to be substantially normal to a face of the user; and	axle structure 154 frame portion 102 provides recessed tracks with detention regions 206 (see below), which will allow component 114 to rotate normally to the face of the user
F 1.6 the nasal cannula further comprising a selective retainer means configured to selectively hold the connector in a plurality of rotary positions relative to the manifold.	selective retainer means = retention mechanism 300, boss 226, as part of the component 114 (=connector), see [0621], interacting with tracks 204 and the detention regions 206

104 Since claim 1 of the patent as granted is not novel over D2, it is irrelevant at this point if the other validity attacks are successful.

105 As the Defendant’s Main Request 1.1 (dismissal of the revocation act, maintaining of the patent as granted) is not successful, the condition to assess the auxiliary requests introduced with the application to amend the patent is met (defendant’s request 1.2).

5. Auxiliary Request 1 is not allowable

106 Auxiliary Request 1 (AR1) is admissible, but not allowable.

107 Auxiliary request 1 is based on claim 1 as granted, with claim 1 of this request amended to require that it is the “swivel connection of the nasal cannula” that comprises a selective retainer means, as explained in the Application to amend the patent, margin 2.1.

108 Claim 1 of **auxiliary request 1** reads as follows (Exhibit ME D356-01mu and Exhibit ME D356-01mu in marked up version; amendment underlined by the Court):

1. A nasal cannula (1) configured to deliver airflow to a user, comprising:

a manifold (2);

a connector for attaching a gas tube (7) to the manifold;

a pair of non-sealing nasal prongs (3) extending from the manifold for delivering a supply of gas to a user via the gas tube;

wherein the connector is configured to form a swivel connection with the manifold so as to provide relative rotation between the manifold and the gas tube, characterised in that:

the swivel connection has an axis of rotation configured to be substantially normal to a face of the user; and

the <u>swivel connection of the</u> nasal cannula further comprising a selective retainer means configured to selectively hold the connector in a plurality of rotary positions relative to the manifold.

a) Admissibility

109 AR1 is admissible.

110 **aa)** The auxiliary requests are not unreasonable in number.

111 The Court understands request 1.3 (“In the event that either of the Defendant’s requests under 1.1 or 1.2 cannot be granted, we request that the patent is maintained in a form based on one or more valid claims of the patent as granted or of any Auxiliary Request, notwithstanding that any other claims may be considered by the Court to be invalid.”) to mean that the defendant asks the Court to eliminate dependent claims of any set of claims within one AR that the Court (individually) deems invalid, as explained in the Application to amend the patent in margin 1.8 and in the Rejoinder to the reply to the statement of defence in margin 6.5. A request asking the Court to assess all possible combinations of independent and dependent claims would be inadmissible.

112 Therefore, the number of ARs to be taken into account here is 13, not a number exceeding 24000 based on all possible combinations of claims as assumed by the

claimant (Reply to the Statement of Defence and Defence to application to amend the patent, margins 135, 136). This is still a reasonable number with regard to the number of validity attacks.

113 **bb)** The order of priority in which the defendant wishes to rely on the proposed amendments is not unclear, contrary to the claimant's assessment (Reply to the Statement of Defence and Defence to application to amend the patent, margin 137).

114 The Court understands the defendants request in the sense that the auxiliary requests introduced with the application to amend the patent shall be assessed in their order of numeration, that is to say AR1, AR 2 and so on. This is set out in margin 1.7 of the Application to amend the patent and in margin 6.6 of the Rejoinder to the reply to the statement of defence. The fact that the defendant reserves the right to re-order the ARs does not make the ARs inadmissible.

115 **cc)** AR1 is not inadmissible based on a lack of substantiation.

116 AR1 does not contravene R 50.2 RoP.

117 R 50.2 RoP provides that any Application to amend the patent shall contain the matters referred to in Rule 30.1 (a), (c) and an explanation as to why the amendments satisfy the requirements of Articles 84 and 123 (2), (3) EPC and why the proposed amended claims are valid (Sentence 1). Rule 30.2 shall apply (Sentence 2).

118 An explanation in this regard does not have to be complete or allowable. Any explanation given suffices to meet the threshold of admissibility, as long as it raises the impression that it could serve as an explanation in this sense (see UPC_CFI_355/2023 (LD Düsseldorf), decision of 28 January 2025, page 42 - FUJIFILM v Kodak, in relation to R 30 RoP; UPC_CFI_255/2023 (CD Paris), decision of 19 July 2024, margin 32 – Meril v Edwards).

119 Against this legal background, the defendant's AR1 is admissible, contrary to the defendant's assessment (Reply to the statement of defence and statement of defence to the application to amend the patent, margins 140 et sequi). The defendant explained in their application to amend the patent (margins 2.1 et sequi) why the requirements of Art, 84 and Art. 123.2 and 123.3 EPC are met. In their Defence to the statement for revocation (margin 8.4 et sequi), they explained that claim 1 as amended by AR1 is novel over the prior art cited by the claimant. While it is true that the defendant did not explain novelty over all the prior art cited in detail, they did give an explanation that they see AR1 as novel over the prior at cited. They also submitted that AR1 is inventive (Defence to the statement for revocation (margin 8.3). This is enough to reach the level of admissibility. The fact that the defendant did not explain their inventive step argument and did not address technical effects provided by AR1 in the Statement of

defence nor in the Application to amend the patent does not render AR1 inadmissible. These issues must be dealt with as a question of allowability of the AR.

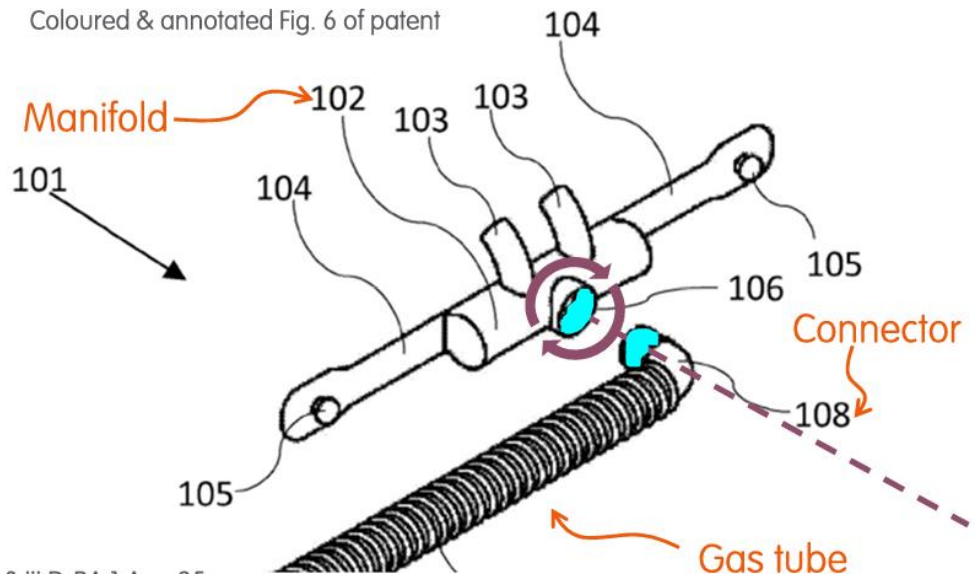
b) Allowability

120 AR1 is not allowable.

121 **aa)** To assess allowability, the Court first needs to interpret claim 1 as amended by AR1.

122 The skilled person understands from features 1.2 and 1.4, that the swivel connection is not a specific component of the nasal cannula, but is achieved by the (mechanical) interaction of the connector and the manifold of the patent in suit. Therefore, the skilled person understands that these interacting parts form the swivel connection and therefore the connector and the manifold must provide the selective retainer means. The skilled person understands from the disclosure of the patent on the whole that feature 1.6 as amended by AR 1 does not give reason to change that claim construction. While feature 1.6, seen in isolation, could be understood to address a swivel connection as a structural component of the nasal cannula, as it shall “comprise” a selective retainer means and the wording “comprising” might be associated with a structural component, the skilled person understands that this “comprising” relates to the components forming the swivel connection.

123 The skilled person understands from claim 1 (as amended by AR 1) that the components connector and manifold in their entirety form the swivel connection. The skilled person is not lead to an understanding that only portions of the manifold and the connector, in particular those corresponding portions that form an attachment and are coloured in blue in the figure below (see Visual aids defendant, slide 5, as discussed during the oral hearing), may form the swivel connection.



124 If (only) these corresponding parts were to be considered to form the swivel connection, the swivel connection would not necessarily meet the requirements of feature 1.5 (“the swivel connection has an axis of rotation configured to be substantially normal to a face of the user; and (…)”): a swivel connection provided by this part or portion of the connector cannot be understood as providing an axis of rotation configured to be substantially normal to a face of the user. This specific axis is provided by the orientation of the aperture in the manifold (in its entirety), the latter of which is not coloured in blue in the figure above and does not form part of the swivel connection in the definition of the defendant.

125 The skilled person understands that the requirements of feature 1.5 are only met if the manifold connects to the connector in an orientation that allows an axis of rotation substantially normal to the face of a user. As can be seen from a comparison of figure 6 and figure 1 of the patent, the latter of which undisputedly does not meet the requirements of feature 1.5 because it shows an axis of rotation parallel to the face of the user, the arrangement of the manifold on the whole is decisive to assess whether the swivel connection has an axis of rotation configured to be substantially normal to the face of a user. The skilled person understands that it does not suffice to look at the manifold’s part coloured in blue above, because the requirements of feature 1.5 can only be met if the connecting portion is arranged in a way facing away from the face portion of the manifold.

126 This understanding is confirmed by claim 12 as amended by AR 1, which addresses that the swivel connection has a first connection portion formed in the rigid manifold structure and a second connection portion formed in the connector. By using the broader wording “has” (not: “consisting of”), claim 12 makes the skilled person understand that the swivel connection is not limited to these connection portions.

127 The same can be said for paragraphs [0071] et sequi of the description, where it is explained that the swivel connection includes a first portion and a second portion. Irrespective of the question if these parts of the description relate only to the first embodiment, which is – undisputedly – outside the scope of the patent, the skilled person understands from the wording of these paragraphs (“includes”) that the swivel connection is not limited to the first and second portion. Furthermore, these paragraphs do not address how the swivel connection explained here would have an axis of rotation configured to be substantially normal to a face of the user.

128 The skilled person gets no indication from the claims or the descriptions that only certain parts or portions of the manifold and the connector shall be seen as the swivel connection. The skilled person understands from feature 1.6 that the swivel connection shall provide the selective retainer means. Therefore, the skilled person will understand that (at the very least) all parts or portions of the manifold and the

connector providing both the mechanical attachment (the connection) as well as selective retainer means must form part of the swivel connection.

129 Contrary to the claimant's assessment (Reply to the statement of defence and Defence to the application to amend, margin 147), the skilled person understands that the claim construction as explained above introduces a limitation to the claim. The selective retainer means according to feature 1.6 cannot be provided "anywhere". Rather, it must be provided by the components forming the swivel connection, thus the manifold or the connector.

130 In sum, the person skilled in the art understands that the swivel connection is not a specific structural element of the nasal cannula, but is formed by two components, namely the connector and the manifold. There is no limitation that only certain parts or portions of the manifold and the connector may provide the swivel connection.

131 **bb)** Based on this claim construction, AR 1 does not lack clarity in the sense of Art. 84 EPC.

132 Art. 84 EPC provides that the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description. The requirement of clarity aims to provide legal certainty to the public. The public must respect the exclusive right the patent grants. Therefore, the scope of the claim must be clear to the public. Figures and the description of the patent may be consulted to construe the claim when assessing if the claim lacks clarity.

133 While lack of clarity is not a reason to revoke a patent, any amendment to a patent must comply with Art. 84 EPC, as is clear from Rule 50.2 RoP (UPC_CFI_248/2024 (LD Munich), decision of 22 August 2025, margin 209 – Brita v AQUASHIELD, regarding R 30.2 RoP). The Court shall not assess clarity issues if they stem from a lack of clarity already present in granted dependent claims on which an amendment is based (see UPC_CFI_613/2024 (CD Milan), decision dated 27 November 2025, margin 121 - Pari v Philips; UPC_CFI_355/2023 (LD Duesseldorf), decision dated 28 January 2025 - Fujifilm v Kodak).

134 As explained above (margins 131 et sequi), the skilled person understands the scope of claim 1 of the patent as amended by AR 1 clearly. The skilled person is not in doubt if the swivel connection relates to a structural element or an assembly of other components (contrary to claimant's assessment in the reply to the statement of defence and defence to the application to amend, margin 147), and understands that the whole components connector and manifold, are addressed by the term "swivel connection" (contrary to claimant's assessment in the reply to the statement of defence and defence to the application to amend, margin 148).

135 **cc)** The Court does not have to decide if AR1 contains added matter, as argued by the claimant (Reply to the statement of defence, margins 150 et sequi). In any case, also AR1 lacks novelty over D2, as will be explained below (margins 136 et sequi). Therefore, the issue of added matter can be left open (see, in this regard, UPC_CFI_284/2024, LD Munich, 22 August 2025, margin 182 – Brita SE vs AQUASHIELD Europe s.r.o. et alii, in relation to a lack of clarity attack).

136 **dd)** AR1 is not new over D2.

137 Based on the claim construction of AR1 presented above (margins 121 et sequi), claim 1 as amended is disclosed by D2.

138 Irrespective of the fact that the axle structure 154 (see margins 81 et sequi) itself does not provide a selective retainer means, the skilled person will understand that the selective retainer means is provided by component 114 and the frame portion 102 (see margin 82 et sequi, especially the retention mechanism 300 as explained in [0620]). Therefore, the skilled person will understand that these components belong to the swivel connection. The fact that the parts of both components being responsible for holding component 114 in certain positions relative to the frame portion 102 are not situated directly at the axle structure 154 where the components 114 and 102 are joined does not lead to the assessment that the swivel connection does not provide retainer means. Rather, since the swivel connection shall comprise retainer means (see above, margin 122 et sequi), a mapping of feature 1.6 as amended leads to the assessment that those portions of components 114 and 102 providing retainer means must be part of the swivel connection as well.

139 Contrary to the defendant's assessment, the fact that the boss 226 and track 204 are not always in contact during the rotational arc (see Rejoinder to the reply to the statement of defence, margin 6.22) does not lead to another assessment. As explained above, the boss and track 204 are in contact in specific constellations, in which they provide a retaining function. Being comprised by the components 102 and 114, which form the swivel connection, they are part of that swivel connection. Feature 1.6 as amended is, therefore, directly and unambiguously disclosed by D2.

140 With regard to the above, it is irrelevant if the visual aids presented by the defendant before the oral hearing contain new arguments in relation to AR 1, as argued by the claimant (submission of 24 February 2026).

6. Auxiliary request 2 is not allowable

141 Auxiliary Request 2 (AR2) is admissible, but not allowable.

142 AR 2 is based on the claims of the patent as granted, with claim 1 of this request being amended to require that "the connector attaches to the manifold (2) via an aperture (6)

formed in the manifold", i.e. incorporating the features of claim 7 as granted. Claim 1 of this request is further limited to require that "the aperture fluidically connects the gas tube to the manifold". Claim 7 is deleted, and the remaining claims and their dependencies renumbered accordingly, as explained in the Application to amend the patent in margins 3.1 and 3.2.

143 Claim 1 of **auxiliary request 2** reads as follows (Exhibit ME D356-02 and Exhibit ME D356-02 mu in marked up version, amendments underlined here by the Court):

1. A nasal cannula (1) configured to deliver airflow to a user, comprising:

a manifold (2);

a connector for attaching a gas tube (7) to the manifold;

a pair of non-sealing nasal prongs (3) extending from the manifold for delivering a supply of gas to a user via the gas tube;

wherein the connector is configured to form a swivel connection with the manifold so as to provide relative rotation between the manifold and the gas tube, characterised in that: the swivel connection has an axis of rotation configured to be substantially normal to a face of the user;

the nasal cannula further comprising a selective retainer means configured to selectively hold the connector in a plurality of rotary positions relative to the manifold;

<u>wherein the connector attaches to the manifold (2) via an aperture (6) formed in the manifold, wherein the aperture fluidically connects the gas tube to the manifold</u>.

144 The newly added feature can be broken down as follows:

1.7.1 <u>wherein the connector attaches to the manifold (2) via an aperture (6) formed in the manifold,</u>

1.7.2 <u>wherein the aperture fluidically connects the gas tube to the manifold</u>.

a) Admissibility

145 AR2 is admissible for the reasons set out above in relation to AR1.

b) Allowability

146 AR2 is not allowable.

147 **aa)** Claim 1 as amended by AR 2 lacks clarity in the sense of Art. 84 EPC.

148 **(1)** Art. 84 EPC provides that the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description. The requirement of clarity aims to provide legal certainty to the public: The public must respect the exclusive right the patent grants. Therefore, the scope of the claim must be clear. Figures and the description of the patent may be consulted to construe the claim when assessing if the claim lacks clarity.

149 **(2)** The scope of claim 1 as amended by AR2 is unclear.

150 **(a)** The skilled person understands from claim 1 as amended by AR2 that the aperture fluidically connects the gas tube to the manifold by (simply) allowing a gas flow from the gas tube to the manifold. Feature 1.7 does not add further requirements to the arrangement of the aperture. In particular, it does not add a requirement relating to the establishment of a fluidic connection between the gas tube and the manifold.

151 **(b)** It is unclear to the skilled person if claim 1 of the patent in suit as amended by AR2 requires the gas tube to be a mandatory component of the nasal cannula.

152 The skilled person will understand from features 1.1 to 1.6 of claim 1 and claim 13 as granted/ claim 12 as amended by AR 2 that a gas tube is not a mandatory component of the nasal cannula, as explained above (margins 42 et sequi). Feature 1.7.2 however teaches the skilled person that the aperture formed in the manifold "connects the gas tube to the manifold". The claim language of feature 1.7.2 teaches the skilled person that the gas tube is a component of the nasal cannula, as the subfeature "wherein the aperture fluidically connects the gas tube to the manifold" requires a connection between the aperture and the gas tube, at least indirectly and temporarily. If the feature was meant as a purpose characteristic, the skilled person would expect the wording "connectable".

153 Contrary to the defendant's assessment (see Visual aids defendant, slide 21), the subfeature does not only articulate the functional role of the aperture defined structurally in feature 1.7.1 using a terminology that had already been present in granted features 1.2, 1.3 and 1.4. As explained above, these features are to be understood as addressing purpose characteristics in relation to a/ the gas tube. However, the newly added feature leaves doubt if feature 1.7.2 shall be understood as a purpose characteristic only. Furthermore, it is not primarily the use of the defined article ("the gas tube") which leads to the lack of clarity, but the word "connects", which is not present in the granted features.

154 Since the gas tube is not explicitly mentioned as a mandatory component of the nasal cannula, the skilled person receives contradictory information from claim 1 (and claim 12) as amended by AR 2 with regard to the gas tube. The skilled person is left in doubt if feature 1.7.2 provides that the gas tube shall be a component of the nasal cannula (thus rendering claim 12 as amended by AR2 at least partly superfluous) or if the newly

added feature shall be read as a purpose characteristic like features 1.2, 1.3 and 1.4 with regard to the gas tube. Contrary to the wording of newly added feature 1.7.2, claim 12 as amended would rather incite the skilled person to understand feature 1.7.2 to include a purpose characteristic. The skilled person would be further led to understand the newly added feature as a purpose characteristic by the fact that the aperture need not provide any specific configuration to establish the fluidic connection, as explained above, but would merely need to be built to allow such a connection.

155 In sum, the skilled person does not arrive at a clear understanding of the newly added feature. Therefore, the newly added feature lacks clarity in the sense of Art. 84 EPC. The clarity requirement of Art. 84 EPC shall prevent a situation where the skilled person is left in doubt if a component is part of the claimed embodiment.

156 The lack of clarity does not depend on a lack of clarity already present in dependent claims as granted. As explained above, it is clear from the patent claims as granted that the gas tube is not a part of the nasal cannula as addressed by claim 1. The lack of clarity does not arise with regard to feature 1.7.1 because of a lack of clarity present in dependent claim 7 as granted. Rather, the lack of clarity addressed above is found in feature 1.7.2, which is based on parts of the description.

157 **bb)** As AR2 is not allowable due to a lack of clarity, the Court does not need to assess if AR2 contains added matter, and if it is novel and inventive.

7. ARs 3 et sequi are not allowable

158 ARs 3 et sequi all lack clarity, therefore they are not allowable.

159 They all contain the following features:

160 <u>wherein the connector attaches to the manifold (2) via an aperture (6) formed in the manifold, (…) wherein the aperture is a single inlet aperture fluidically connecting the gas tube to the manifold</u>.

161 The wording “connecting” (as opposed to “connects”) does not change the clarity issues addressed above. Auxiliary requests AR 3 et sequi do not indicate any clarification if the gas tube is part of the nasal cannula as addressed in claim 1 as (respectively) amended. Therefore, all these auxiliary requests lack clarity, for the reasons set out above. They are therefore not allowable. Accordingly, the patentability of AR 3 et sequi does not have to be assessed further. Equally, the Court does not need to assess if they have been duly substantiated or if substantiation of any or all of these auxiliary requests was late filed.

8. AR2a et sequi

162 AR2a et sequi have not been allowed into the proceedings (see order of 15 January 2026). Therefore, the allowability of the auxiliary requests does not have to be assessed.

9. Condition of defendant's request 1.3 is not met

163 The Court does not need to decide on defendant's request1.3, as its condition is not met. The defendant requests: "In the event that either of the Defendant's requests under 1.1 or 1.2 cannot be granted, we request that the patent is maintained in a form based on one or more valid claims of the patent as granted or of any Auxiliary Request, notwithstanding that any other claims may be considered by the Court to be invalid."

164 This request cannot be understood in such a way that the Court is requested to assess all possible combinations of independent and dependent claims. The defendant has clarified in their Rejoinder (margin 6.5) that this request relates to a scenario in which, for example, the Court finds an independent claim of an Auxiliary Request allowable, whereas one or more dependent claims are found to be invalid. As the Court does not find claim 1 of the main request or any auxiliary request allowable, the condition for assessment of request 1.3 is not met.

10. No implicit request to maintain the patent based on dependent claims

165 There is no (implicit) request to maintain the patent based on any of the dependent claims.

166 As a general rule, the Court will only examine amendments formulated by the patentee, as it is bound by the parties' requests and the grounds submitted by them, Art. 76.1, 76.2 UPCA (see, in this regard, UPC_CFI_829/2024 (CD Munich), decision issued on 24 February 2026, margin 72 - UPM-Kymmene v International N&H Denmark ApS; UPC_CFI_433/2024 (CD Paris), decision issued 7 January 2026, margins 106 et sequi - Microsoft v Suinno; UPC_CFI_613/2024 (CD Milan), decision issued on 27 November 2025, margins 109 et sequi - Pari v Philips).

167 While dependent claims may not be automatically invalid if they are not challenged in a revocation action (UPC_CFI_258/2025 (CD Paris), decision issued on 30 March 2026, margin 19 - Emporia v Seoul Viosys), it is the patentee's responsibility to submit claims or claim sets that mirror the fact that a dependent claim is altered into an independent claim. Therefore, the patentee is typically required to file an application to amend the patent in judicial proceedings or before the granting authority. The patent must formally be restructured to ensure that the new configuration is clear and consistent pursuant to Article 84 of the EPC (UPC_CFI_258/2025 (CD Paris), decision issued on 30 March 2026, margin 21 - Emporia v Seoul Viosys). This restructuring cannot be provided by the Court.

168 In the case at hand, the defendant did not specifically address novelty over D2 of the dependent claims. In the Statement of defence (margin 6.45) and the Rejoinder to the Reply to the Defence to revocation and Reply to the Defence to the Application to amend the patent (margins 5.54, 5.60), the defendant only alleged novelty of the dependent claims (at least) by virtue of their dependency on novel claim 1. As claim 1 is not novel (as shown above), this line of argumentation is not successful. With their submissions, the defendant showed that they did not base their requests on a combination of claim 1 with dependent claims outside of the auxiliary requests and did not specifically defend the validity of the dependent claims. Therefore, there is no implicit request to maintain the patent based on dependent claims, outside of the auxiliary requests.

11. Result

169 It follows that claim 1 of the patent in suit as granted is not novel over D2. Auxiliary request 1 is not patentable as it is not novel over D2, either. Auxiliary requests 2 to 13 lack clarity and are therefore not allowable. Auxiliary requests 2A et sequi have not been allowed into the proceedings.

170 For the reasons explained above (margin 168), the defendant has not shown that the dependent claims are novel over D2.

171 Therefore, the patent in suit is revoked in its entirety with effect on the territory of all Contracting Member States to the Agreement on a Unified Patent Court.

172 The application to amend the patent is dismissed.

12. Costs, value of the case

173 The defendant bears the costs of the proceedings as the unsuccessful party, Art. 69.1 UPCA.

174 The value of the case is set to 250.000 €, as agreed upon by the parties.

Decision

1. European patent 4 185 356 is revoked in its entirety with effect to the territories of all contracting member states of the Unified Patent Court Agreement.
2. The application to amend the patent is dismissed.
3. The defendant shall bear the legal costs incurred by the claimant.
4. The value of the case is set to 250.000 €.

Issued on 10 April 2026

Presiding Judge Andrea Postiglione	ANDREA POSTIGLIONE Firmato digitalmente da ANDREA POSTIGLIONE Data: 2026.04.10 10:18:07 +02'00'
Legally qualified judge and judge rapporteur Anna-Lena Klein	ANNA-LENA KLEIN Firmato digitalmente da ANNA-LENA KLEIN Data: 2026.04.10 09:27:45 +02'00'
Technically Qualified Judge Kerstin Roselinger	Kerstin Roselinger Digitally signed by Kerstin Roselinger Date: 2026.04.10 09:35:42 +02'00'
Deputy-Registrar	BARTOLOTTA GIANLUCA Firmato digitalmente da BARTOLOTTA GIANLUCA Data: 2026.04.10 10:37:39 +02'00'

Information about appeal

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of service of the decision (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

Information about enforcement

Art. 82 UPCA, Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP: An authentic copy of the enforceable decision will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

Instruction to the Registry

A certified copy of the decision shall be sent to the European Patent Office as soon as the decision on the revocation action has become legally binding.