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Datasheet for the decision of 23 October 2023

Case Number: T 0924/21 - 3.2.02

Application Number: 14765721.7

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IPC: A61M16/10, A61M15/00, B01D53/56, A61M15/02, A61M16/00, A61M16/12, C01B21/20

Language of the proceedings: EN

Title of invention:
SYNTHESIS OF NITRIC OXIDE GAS FOR INHALATION

Patent Proprietor:
The General Hospital Corporation

Opponent:
Beyond Air, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(c)

Keyword:
Grounds for opposition - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

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Case Number: T 0924/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 October 2023

Appellant: (Patent Proprietor)	The General Hospital Corporation 55 Fruit Street Boston, MA 02114 (US)
Representative:	Samson & Partner Patentanwälte mbB Widenmayerstraße 6 80538 München (DE)
Appellant: (Opponent)	Beyond Air, Inc. 825 East Gate Boulevard, Suite 320 Garden City, NY 11530 (US)
Representative:	Schnappauf, Georg ZSP Patentanwälte PartG mbB Hansastraße 32 80686 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 April 2021 concerning the maintenance of European Patent No. 2968827 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	Y. Podbielski

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the Opposition Division's decision that account being taken of the amendments made by the patent proprietor according to auxiliary request 1, the patent and the invention to which it relates met the requirements of the EPC.

II. Oral proceedings took place on 23 October 2023.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or that the patent be maintained on the basis of one of auxiliary requests 1 to 26, of which auxiliary requests 1 and 2 were filed with the statement of grounds of appeal on 2 September 2021, and auxiliary requests 3 to 26 were filed with the reply to the statement of grounds of appeal of the appellant/ opponent ("the opponent") on 18 January 2022.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

III. The following documents are mentioned in this decision:

D5: WO 2013/181179 A1
D6: WO 2013/052548 A2

IV. Claim 1 of the patent as granted (main request) read as follows:

"An apparatus comprising: a chamber (202) having an inlet valve (204) for receiving a reactant gas and an

outlet valve (206) for delivering a product gas; a sensor for collecting information related to one or more conditions of a respiratory system associated with a patient; a controller (914) for determining one or more control parameters based on the collected information; and one or more pairs of electrodes (210) positioned inside the chamber for initiating a series of electric arcs external to the patient to generate nitric oxide based on the determined control parameters, **characterized in that**, the controller receives information related to ventilatory time of inspiration, and can determine the control parameters based on actual or expected volume of an inspiration."

V. The proprietor's arguments, where relevant to this decision, can be summarised as follows.

Extension of subject-matter

The Opposition Division concluded that, in order not to include added subject-matter, claim 1 should have comprised a ventilator in the sense of a system comprising the controller and the ventilator. While page 16, lines 14 and 15 of the application as filed taught that the information concerning the time of inspiration was received by a controller from a ventilator, this did not require the claim to be defined as a "system" claim comprising the ventilator itself. Neither the application as filed nor the common understanding supported the assertion that the expression "timing of inspiration" only referred to the onset of inspiration while "time of inspiration" referred to both the onset and the duration of inspiration. In the claims as originally filed a ventilator was only specified in dependent claim 15. It was sufficient to define claim 1 such that the time

information was received from a ventilator, just as described on page 16, lines 14 and 15 of the application as filed. This was the case for claim 1 of the main request, which specified that the controller received, i.e. it was configured to receive, ventilatory time information, if the term "ventilatory" meant that the time of inspiration had to stem from a ventilator. The term "ventilatory time of inspiration" could also mean time information related to ventilation; however, also adopting this claim construction, there was no need to include the ventilator in claim 1.

The features of the characterising portion of claim 1 of the main request were based on claims 3, 15 and 28 as originally filed, which were directed to a preferred embodiment focusing specifically on the combination of volume and timing of the inspiration received from a ventilator.

Novelty

The subject-matter of claim 1 of the main request was novel over each of D5 and D6.

The term "valve" was not without meaning. A generic outlet could not be considered an outlet valve if there was no additional disclosure indicating that a flow-limiting function was desired. The term "valve" could be interpreted as implying the possibility of (intentionally) adjusting flow (paragraphs [0031] and [0032] of the patent). In any case a simple conduit for supplying gas into or out of a chamber, whether or not it restricted the gas flow, could not be considered a valve within the normal meaning of the term.

In view of the correct interpretation of the term "valve" neither D5 nor D6 disclosed an outlet valve for delivering a product gas out of a chamber as defined in claim 1 of the main request.

Inventive step

The Opposition Division had correctly concluded that providing an outlet valve for delivering a product gas had a technical effect. It made it possible to control the outflow in the apparatus of the patent, e.g. to increase the pressure in the chamber in a controlled manner. As increased pressure resulted in increased nitric oxide production (Figure 23 and paragraph [0031] of the patent), the outlet valve defined in claim 1 of the main request made it possible to improve the nitric oxide production in a controlled manner.

The common general knowledge did not teach providing an outlet valve in either D5 or D6.

VI. The opponent's arguments, where relevant to this decision, can be summarised as follows.

Extension of subject-matter

The application as filed (page 16, lines 14 to 15) disclosed that the controller received information related to ventilatory time of inspiration from a ventilator. Claim 1 of the main request omitted the expression "from a ventilator". Hence, it did not require information concerning the duration of the inspiration, implied by the expression "time of inspiration", to originate from a ventilator. Such claimed subject-matter was not originally disclosed and constituted an intermediate generalisation.

The expression "ventilatory time of inspiration" did not imply forced ventilation. The adjective "ventilatory", in its broadest technically sensible meaning, related to ventilation, which encompassed natural respiration in the absence of a ventilator. The reference to "time of inspiration" in that expression possibly concerned a lack of conciseness in the claim, but not technical inconsistency. Moreover, if "ventilatory" was interpreted as relating to a ventilator, claim 3 of the main request would be redundant, as it specified that the timing of inspiration was received from a ventilator.

The features of the characterising portion of claim 1 of the main request, i.e. that the controller receives information related to ventilatory time of inspiration and can determine the control parameters based on actual or expected volume of an inspiration, had been selected from several lists. Picking two features from different lists added subject-matter. Moreover, these features constituted an unallowable intermediate generalisation as they related to embodiments of sensors in a respiratory system and extracting them from the context of the respiratory system was not permissible.

Dependent claims 2 to 6 of the request found allowable by the Opposition Division in the impugned decision added subject-matter because the combination of their features with the features of the characterising portion of claim 1 of the request found allowable by the Opposition Division had not been originally disclosed. This objection applied to the claims of the main request on appeal, too.

Novelty

The subject-matter of claim 1 of the main request was not novel over each of D5 and D6.

Both D5 and D6 disclosed apparatuses for generating nitric oxide, comprising a chamber having an inlet valve for receiving a reactant gas and an outlet valve for delivering a product gas.

The terms "outlet valve" and "inlet valve" included any devices suitable for limiting the gas flow, including non-adjustable flow limiters.

Because of their reduced diameter with respect to that of the chamber, the inlet and outlet ports 8 and 10 in Figure 1 of D6 were flow limiters and hence provided the structural features of valves. Moreover, paragraph [0084] of D6 mentioned the possibility of using a control valve to supply air to the chamber. Similarly, paragraph [0054] and Figure 3 of D5 disclosed an outlet (40) comprising a filter (233) for filtering nitric oxide from a product gas before injecting the product gas into a patient's airway. The outlet and filter limited the flow of the product gas. Hence, they constituted outlet valves within the meaning of the claim.

Inventive step

If it was concluded that D5 and D6 did not disclose an inlet or an outlet valve, because they were not adjustable, providing such valves was obvious in view of the common general knowledge. Claim 1 of the main request did not include any feature that would require

a specific flow-limiting function of the valves beyond providing gas flow into and out of the chamber. In addition, the patent as a whole did not disclose any additional effect of the valves in relation to the configuration according to claim 1. In fact, a valve allowing variable flow control (by being able to open and close) had not been shown to have any effect. The patent did not contain any data that would make it possible to conclude that the pressure within the chamber could be increased or decreased solely on the basis of the valves being able to open and close. Effects arising only from features not suggested by the explicit wording of the claims, such as pressure control within the chamber for hyperbaric or hypobaric NO synthesis, could not be taken into account when considering inventive step.

In the absence of a particular effect associated with the valves being adjustable or non-adjustable, the objective technical problem on the basis of such features would have been that of providing an alternative. Such an alternative was obvious, as adjustable valves were known as such.

Reasons for the Decision

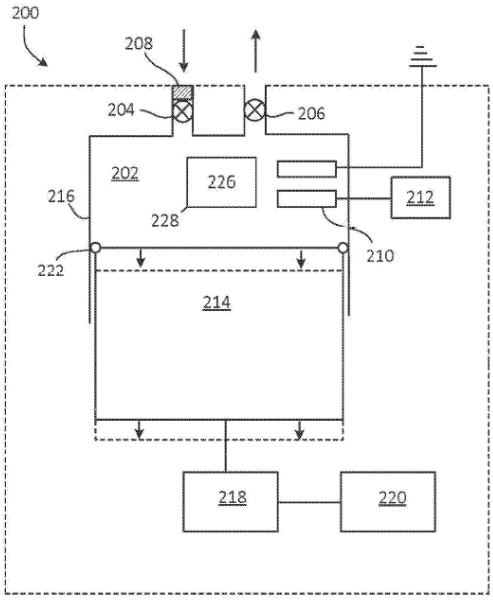
1. The patent

The patent relates to an apparatus for delivering a product gas containing nitric oxide (NO).

According to the patent the inhalation of nitric oxide is beneficial for many conditions (paragraph [0002]). In particular, according to paragraph [0003] of the patent, inhaled nitric oxide has potent vasodilatory

effects limited to the pulmonary vasculature. Hence, the inhalation of nitric oxide can be used for the treatment of acute and chronic pulmonary hypertension.

An apparatus according to claim 1 of the main request is depicted in Figure 2 of the patent reproduced below.



The claimed apparatus comprises a chamber (202), a sensor, a controller and one or more pairs of electrodes (210) positioned inside the chamber for initiating a series of electric arcs to generate nitric oxide.

The chamber has an inlet valve (204) for receiving a reactant gas and an outlet valve (206) for delivering a product gas.

The sensor is for collecting information related to one or more conditions of a respiratory system associated with a patient.

The controller is for determining one or more control parameters based on the information collected by the

sensor, which information includes information related to ventilatory time of inspiration. The determination of the control parameters is based on actual or expected volume of an inspiration.

The electric arcs are generated externally to the patient, based on the control parameters determined by the controller.

Consequently, the production and delivery of nitric oxide can be tailored to the patient's specific needs.

2. Extension of subject-matter

As noted by the Opposition Division in the impugned decision, the subject-matter of claim 1 of the main request is mainly derived from claim 13 and page 16, lines 7 to 24 of the application as filed.

2.1 The opponent and the Opposition Division in the impugned decision considered that claim 1 of the main request impermissibly omitted a ventilator and the limitation that the information related to ventilatory time of inspiration was received from the ventilator.

2.1.1 It is agreed that the adjective "ventilatory", in general, may relate to both a ventilator and ventilation, be it forced or spontaneous; however, in the specific context of the patent, the expression "ventilatory time of inspiration" in claim 1 of the main request implies that the time of inspiration relates to a condition of forced ventilation, in which a ventilator is used. If this were not the case, the word "ventilatory" would be meaningless, as it would not add anything to the expression "time of inspiration". While the "time of inspiration" may refer

to spontaneous and forced ventilation as both disclosed in the application as filed (page 15, lines 5 to 10), the addition of "ventilatory" limits the expression to forced ventilation, in which a ventilator is used. Accordingly, the patent links the "ventilatory time of inspiration" to the use of a ventilator (column 12, lines 32 to 34). It also mentions "ventilator gases" when referring to forced ventilation, in which a ventilator is used (paragraph [0041], as mentioned by the parties). All of these considerations play a role when the person skilled in the art is interpreting the claim. As regards the opponent's argument that claim 3 would be redundant with regard to claim 1 in view of the above interpretation of the expression "ventilatory time of inspiration", the Board notes that, according to claim 3, both the volume and the timing of the inspiration may be received from a ventilator. Hence, claim 3 of the main request is not redundant with regard to claim 1.

Hence, the information related to the "ventilatory time of inspiration", which is collected by a sensor according to the claim, must come from a ventilator. There is no need for an explicit statement in the claim in this respect.

2.1.2 In reaching the conclusion that a ventilator should be included in the apparatus according to claim 1 in order not to comprise added subject-matter, the Opposition Division assumed (point 2.1.2 of the impugned decision) that the expression "time of inspiration" in claim 1 of the main request meant something different from the expression "timing of inspiration", as recited in various passages of the application as filed.

The Board does not share this view; there is no reason

for this assumption. The difference between the two expressions in the application as filed is merely literal in nature: on page 15, lines 2 to 4 of the application as filed, the "time of inspiration", which could be in combination with spontaneous or forced ventilation (page 15, lines 5 to 10), is mentioned; the passage on page 16 (lines 7 to 24) mentions "timing [...] of the inspired gas" and "ventilatory time of inspiration". In these expressions time and timing do not imply any technical distinction.

Hence, at least claims 3, 15 and 28 of the application as filed, which refer to timing of an inspiration received from a ventilator (but do not define a ventilator), provide a basis for the omission of a ventilator from the apparatus according to claim 1 of the main request.

2.2 The opponent argued that the features of the characterising portion of claim 1 of the main request, i.e. that the controller receives information related to ventilatory time of inspiration and can determine the control parameters based on actual or expected volume of an inspiration, added subject-matter.

2.2.1 According to the opponent, the features of the characterising portion of the claim had been selected from several lists, and picking features from different lists introduced added subject-matter.

However, whether the features in question, for which there is a literal basis on page 16 of the application as filed, belong to two different lists is of little relevance. As the proprietor submitted, claims 3, 15 and 28 of the application as filed disclose the volume and the timing of inspiration received from a

ventilator in combination. The wording of these claims effectively links the features of the characterising portion of claim 1. Hence, this objection by the opponent is not persuasive either.

2.2.2 The opponent also argued that introducing the features of the characterising portion of the claim into this claim was an unallowable intermediate generalisation.

However, claim 13 of the application as filed recites a sensor for collecting information related to one or more conditions of a respiratory system associated with a patient. Claim 1 of the main request contains the same wording, and hence also the limitation that the sensor, from which the information recited in the characterising portion of the claim and received by the controller originates, should be suitable for collecting information from the respiratory system. It follows that omitting the definition of the respiratory system itself from claim 1 of the main request does not add subject-matter either.

2.3 The opponent's objections directed to the combination of the features of claims 2 to 6 and of the features of the characterising portion of claim 1 of the request found allowable by the Opposition Division in the impugned decision are not convincing. These objections hinge, *inter alia*, on the definition of a ventilator in claim 1 of the request found allowable by the Opposition Division; however, a ventilator is not defined in claim 1 of the main request. Hence, these objections do not apply to the claims of the main request.

2.4 Hence, the ground for opposition of added subject-matter (Article 100(c) EPC) does not prejudice the

maintenance of the patent on the basis of the main request.

3. Novelty

The opponent argued that the subject-matter of claim 1 of the main request was not novel over each of D5 and D6.

It is common ground that both D5 and D6 disclose apparatuses for generating nitric oxide in a chamber, the chamber having an inlet for receiving a reactant gas and an outlet for delivering a product gas.

The proprietor argued that these documents did not disclose that the chamber had an outlet valve.

3.1 The opponent's objections hinge on the interpretation of the term "valve", which would include non-adjustable flow limiters. The Opposition Division accepted this interpretation in part and stated that the term "valve" had a clear technical meaning which included "non-adjustable throttle valves".

The Board does not share this view. In the context of claim 1 of the main request the term "valve" has to imply the possibility of adjusting flow. This means that, by acting on the valve, the level of flow can be varied. As pointed out by the proprietor, paragraphs [0031] and [0032] of the patent support this understanding of the term. They describe an embodiment of an NO generator with a chamber in a positive displacement pump, having an inlet valve and an outlet valve which can be selectively opened and closed.

The interpretations of the term provided by the

opponent and the Opposition Division would equate the term "valve" in the claim with any adjustable or non-adjustable flow limiter of the chamber. In this respect it would be impossible to establish, on an objective basis, whether the flow-limiting function of a certain flow limiter may be "desired" (by whom?), as the Opposition Division and the proprietor put it. Such a function is inherent in any flow limiter which provides flow restriction with respect to the chamber. Consequently, the interpretations of the term "valve" provided by the opponent and the Opposition Division would render this term devoid of any technical meaning in claim 1 of the main request.

3.2 In view of the correct interpretation of the term "valve" in claim 1 of the main request, the subject-matter of the claim is novel over both D5 and D6, which disclose apparatuses for generating nitric oxide inside a chamber not provided with any outlet valve (Figures 3, 7 and 8 of D5 and Figure 2 of D6). The opponent referred to a passage in paragraph [0084] of D6, which mentions the possibility of using a control valve to supply air to the chamber; however, this passage implies that the valve could be used at the inlet (instead of a pressurised pipeline or a gas cylinder), but it does not disclose an outlet valve. According to both documents D5 and D6 the flow of air through the chamber is controlled by a flow adjustment device (typically in the form of a fan or an air pump) only at the inlet (215 in Figures 3, 7 and 8 of D5, and 66 in Figure 2 of D6).

3.3 Therefore, the ground for opposition of lack of novelty (Article 100(a) EPC) does not prejudice the maintenance of the patent on the basis of the main request.

4. Inventive step

The opponent argued that the subject-matter of claim 1 of the main request was not inventive when starting from D5 or D6, in combination with the common general knowledge.

4.1 As pointed out by the proprietor, an outlet valve, which distinguishes the claimed subject-matter from both D5 and D6, makes it possible to control the outflow from the chamber so that the pressure in the chamber can be increased and released in a controlled manner. This technical effect is inherent in an outlet valve within the meaning of the claim, as explained above. Hence, the person skilled in the art does not need any more explicit disclosure in the patent to be able to derive it.

The distinguishing feature addresses the objective technical problem of having more efficient NO production and subsequent delivery (column 6, lines 23 to 27 of the patent). The problem formulated by the opponent, i.e. that providing an outlet valve was a mere alternative to the configuration in D5 or D6, is not acceptable. A generic flow-limiting means at the outlet of the chamber cannot achieve pressure control comparable to that which can be provided by a valve, irrespective of whether other flow adjustment devices are provided upstream of the outlet of the chamber.

The common general knowledge does not teach an outlet valve of a chamber for producing nitric oxide in relation to the objective technical problem formulated above. Hence, the objections of lack of inventive step raised by the opponent on the basis of D5 or D6 in combination with the common general knowledge are not

successful.

4.2 It follows that the ground for opposition of lack of inventive step (Article 100(a) EPC) does not prejudice the maintenance of the patent on the basis of the main request.

5. In conclusion, none of the grounds for opposition raised by the opponent prejudice the maintenance of the patent on the basis of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated