

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 18 September 2013**

Case Number: T 0434/12 - 3.3.02
Application Number: 97105021.6
Publication Number: 786264
IPC: A61M 15/00, A61P 11/00,
A61P 11/08
Language of the proceedings: EN

Title of invention:

Devices for treating pulmonary vasoconstriction and asthma

Patent Proprietor:

THE GENERAL HOSPITAL CORPORATION

Opponents:

Air Products and Chemicals, Inc.
AIR LIQUIDE SANTE (INTERNATIONAL) et Air Liquide Santé France
Luno, Inc.
WESTFALEN AG
TMG Technische Medizin und Gas GmbH

Headword:

Use of NO against vasoconstriction/ THE GENERAL HOSPITAL
CORPORATION

Relevant legal provisions:

EPC Art. 100(c), 123, 76(1), 84, 53(c)
EPC R. 80
RPBA Art. 12, 13

Relevant legal provisions (EPC 1973):

EPC Art. 52(4)

Keyword:

"Admission of requests: main request, auxiliary requests 1 to
11, 9A'' '' and 9''' '''' (yes)"
"Admission of auxiliary requests 8B, 8C, 8D, 9B, 9C, 9A, 9A',
9A'', 9A''', 9A'' ''', 9A'''' ''', 10A, 10B (no)"
"Allowability of admitted requests (no)"

Decisions cited:

T 0443/01

Catchword:

-



Case Number: T 0434/12 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 18 September 2013

Appellant-patentee: THE GENERAL HOSPITAL CORPORATION
(Patent Proprietor) 55 Fruit Street
Boston, MA 02114 (US)

Representative: Dörries, Hans Ulrich
df-mp
Fünf Höfe
Theatinerstrasse 16
D-80333 München (DE)

Appellant 01: Air Products and Chemicals, Inc.
(Opponent 1) 7201 Hamilton Boulevard
Allentown, PA 18195-1501 (US)

Representative: Muir, Benjamin M. J.
Beck Greener
Fulwood House
12 Fulwood Place
London WC1V 6HR (GB)

Appellant 02: AIR LIQUIDE SANTE (INTERNATIONAL) and
(Opponent 2) Air Liquide Santé France
75 Quai d'Orsay
F-75007 Paris (FR)

Representative: Pittis, Olivier
L'Air Liquide, S.A.
Direction de la Propriété Intellectuelle
75, Quai d'Orsay
F-75321 Paris Cedex 07 (FR)

Appellant 04: WESTFALEN AG
(Opponent 4) Industrieweg 43-63
D-48155 Münster (DE)

Representative: Weiss, Peter
Dr. Weiss & Arat
Zeppelinstrasse 4
D-78234 Engen (DE)

Appellant 05: TMG Technische Medizin und Gas GmbH
(Opponent 5) Hafenstrasse 63
D-47809 Krefeld (DE)

Representative: Wagner, Matthias
Müller-Gerbes Wagner Albinger
Patentanwälte
Friedrich-Breuer-Strasse 72-78
D-53225 Bonn (DE)

Party as of right: Luno, Inc.
(Opponent 3) P.O. Box 67-374
Los Angeles, CA 900067 (US)

Representative: Clegg, Richard Ian
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted
6 February 2012 concerning maintenance of
European patent No. 786264 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 786 264, based on European patent application No. 97105021.6 which was filed as a divisional application of European patent application No. 92902708.4 which was filed as an international application published as WO 92/10228, was granted with forty-nine claims.

Claims 1 to 14 as granted related to an apparatus for introducing NO gas into the respiratory system of either a "mammal" or to a "patient".

Independent claim 15 as granted reads as follows:

"15. A gaseous mixture consisting of nitric oxide and an inert gas, preferably N₂, for use in a method of treating bronchoconstriction in a mammal, wherein said mixture is mixed with a continuous flow of an oxygen containing gas to give an inhalable mixture."

Independent claim 16 as granted reads as follows:

"16. A gaseous mixture consisting of nitric oxide and an inert gas, preferably N₂, for use in a method of treating bronchoconstriction in a mammal, wherein said mixture is mixed with an oxygen containing gas in a continuous flow to give an inhalable mixture."

Independent claim 17 as granted reads as follows:

"17. A gaseous mixture containing nitric oxide, oxygen and less than 1 ppm NO₂, for use in therapy."

Independent claim 22 as granted reads as follows:

"22. Use of gaseous nitric oxide (NO) or a gaseous mixture consisting of nitric oxide and an inert gas, preferably N₂, for the production of an inhalable medicament for treating or preventing bronchoconstriction in a mammal."

Independent claim 23 as granted reads as follows:

"23. Use of a gaseous mixture consisting of NO and an inert gas (preferably N₂), for the production of an inhalable medicament for treating or preventing bronchoconstriction or reversible pulmonary vasoconstriction in a mammal, wherein the inhalable medicament is prepared by mixing the gaseous mixture with a continuous flow of an oxygen containing gas."

Independent claim 24 as granted reads as follows:

"24. Use of a gaseous mixture consisting of NO and an inert gas (preferably N₂), for the production of an inhalable medicament for treating or preventing bronchoconstriction or reversible pulmonary vasoconstriction in a mammal, wherein the inhalable medicament is prepared by mixing the gaseous mixture with an oxygen containing gas in a continuous flow."

Independent claim 25 as granted reads as follows:

"25. Use of a nitric oxide-releasing compound for the production of a medicament for treating or preventing bronchoconstriction in a human."

Independent claim 31 as granted reads as follows:

"31. Use of NO or a nitric oxide-releasing compound for the production of a medicament for improving gas exchange in the lungs of a mammal."

Dependent claim 32 as granted reads as follows:

"32. The use according to claim 25 or 31, further comprising identifying a mammal, in particular a human, in need of such treatment or prevention; or such improved gas exchange."

Independent claim 35 as granted reads as follows:

"35. A mixture comprising a therapeutically-effective amount of gaseous nitric oxide and a pharmacoactive compound in the form of a liquid or solid suspended in gas."

Independent claim 36 as granted reads as follows:

"36. The mixture according to claim 35 for use as a medicament, in particular as an inhalable medicament."

Independent claim 40 as granted reads as follows:

"40. Use of an oxygen-containing gas mixture comprising NO at a therapeutically-effective concentration and containing less than 1 ppm NO₂, for the preparation of a medicament for the treatment or prevention of bronchoconstriction or for the treatment or prevention of reversible pulmonary vasoconstriction in a mammal."

Independent claim 45 as granted reads as follows:

"45. Use of the apparatus according to any one of claims 1 to 14 for the preparation of a gaseous mixture containing NO."

Independent claim 47 as granted reads as follows:

"47. A method of providing an inhalable medicament by mixing NO with a continuous flow of an oxygen-containing gas."

Independent claim 48 as granted reads as follows:

"48. A method of providing an inhalable medicament by mixing NO with an oxygen-containing gas."

II. Oppositions were filed and revocation of the patent in its entirety was requested pursuant to Articles 100(a) (on the grounds of lack of novelty and lack of inventive step, as well as non-patentability under Article 53(c) EPC 2000), 100(b) (lack of sufficiency of disclosure) and 100(c) EPC (added subject-matter).

III. An intervention under Article 105 EPC was filed on 4 December 2009 by TMG Technische Medizin und Gas GmbH (opponent O5), which was not contested as to its admissibility.

IV. The following documents were cited *inter alia* in the opposition and appeal proceedings:

D2 Higenbottam et al., Am. Rev. Resp. Dis. Suppl. 1988; 137:107

D13 Borland et al., Eur. Respir. J., 1989; 2: 56-63

D30 Air Pollution, Heart Disease and Stroke, American Heart Association, printout from website dated 09 July 2008

D33 Yoshida et al., Int. Arch. Occup. Env. Health; no. 52, p 103-115, 1983

D44 Kagawa, Environ. Research, 1982, 27: 485-490

D45 Pepke-Zaba et al., Lancet, 9. November 1991, 338: 1173-1174

D138 Recommendations for occupational safety and health standards 1988, US Department of Health and Human Services, August 25, 1988, vol. 37, No 5-7

V. The present appeal lies from an interlocutory decision of the opposition division (posted on 6 February 2012) maintaining the patent in amended form based on auxiliary request 4 filed with the letter of 9 December 2011 (Articles 101(3)(a) and 106(2) EPC).

Auxiliary request 4 filed with the letter of 9 December 2011 contains one independent claim and two dependent claims. Claim 1 reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a mammal in need thereof."

The opposition division admitted at the oral proceedings held on 13-14 December 2011 the amended sets of claims (main request and auxiliary requests 1 to 7) filed with the patentee's letter dated 9 December 2011 (see minutes of the oral proceedings, point 10, see opposition division's decision, point I of the reasons).

The opposition division considered that the amended sets of claims filed with the letter of 9 December 2011 simplified the case in relation to the requests on file before the oral proceedings, in particular in view of the deletion of the claims directed to apparatus.

However, the opposition division did not admit the filing at the oral proceedings on 13 November 2011 of an amended set of claims for auxiliary request 2, in which claims 6 to 8 were deleted (Article 114(2) and Rule 116(1) EPC) (see opposition division's decision, point VI).

Additionally, the opposition division refused the opponents' request for apportionment of costs under Article 104 EPC (see point XI of the reasons).

The opposition division considered that claim 1 of the main request did not contain added matter pursuant to the grounds of opposition under Article 100(c) EPC.

However, the opposition division considered that the subject-matter claimed in claim 1 of the main request lacked novelty vis-à-vis document D2 (Article 54 EPC). In particular, air contained less than 1 ppm NO₂ (document D30) and it had not been shown that the Douglas bags in document D2 would go above 1 ppm NO₂. Moreover, there was no evidence that "*the authors*" (performing the experiments in document D2) had waited 5 to 15 minutes before administering the gases, as in documents D13 and D45. In the opposition division's view the gas administered immediately after its mixing in the bag would inevitably contain less than 1 ppm NO₂.

The opposition division further considered that auxiliary requests 1 and 3 failed for the same reasons as the main request since they shared the same claim 1. However, the opposition division found that claims 1 and 2 of auxiliary request 2 did not contain added matter pursuant to grounds of opposition under Article 100(c) EPC.

The opposition division's decision does not contain any opinion in relation to added matter for the method claims 6 and 7 since, as is apparent from the minutes of the oral proceedings before the opposition division, the opposition division started with the discussions about the novelty of said claims instead of allowing the discussion of objections pursuant to Article 100(c) EPC that opponent O2 intended to raise against the method claims 6 and 7 of the auxiliary request 2 (see points 58 and 59 of the minutes). The opponents raised objections of lack of novelty vis-à-vis documents D33 and D44 and the opposition division considered that the methods claimed in claims 6 and 7 of auxiliary request 2 lacked novelty vis-à-vis documents D33 and D44.

The opposition division considered that the subject-matter claimed in claim 1 of auxiliary request 4 met the requirements of Article 123(2) EPC. In the opposition division's view, claim 1 concerned a second medical use claim in Swiss-type form and cited decision T 250/05 of 4 March 2008. Moreover, the subject-matter claimed in claim 1 was novel over the cited prior art since document D2, as well as the alleged prior uses concerning some of the affidavits on file, related to

the use of NO for the treatment of pulmonary hypertension (decision T 443/01 of 16 November 2004 was cited) which was different from the use of NO for improving gas exchange in the lungs. Moreover, the opposition division was of the view that the claimed use was "*not implicit from D2*" since the treated patients ("*patients with problems with cardiac output and pulmonary hypertension*") did not necessarily have problems with gas exchange. Additionally, the opposition division defined document D2 as the closest prior art and considered that the subject-matter claimed in auxiliary request 4 involved an inventive step (Article 56 EPC).

- VI. The patentee (appellant) lodged an appeal against said interlocutory decision and filed grounds of appeal. With its grounds of appeal it filed auxiliary requests 1 to 11. It also filed a copy of decision T 1902/01 as document D137, and document D138. Moreover, it requested that the decision under appeal be set aside ("*to the extent it was adversely affected*") and that the patent be maintained on the basis of the main request filed with the letter of 9 December 2011 (a copy of the main request was filed with the appellant-patentee's letter of 17 July 2012), or alternatively on the basis of one of auxiliary requests 1 to 11 filed with the grounds of appeal. It further declared that auxiliary requests 2 and 4 corresponded to auxiliary requests 1 and 2 filed with the letter of 9 December 2011, auxiliary request 6 corresponded to the amended auxiliary request 2 which had not been admitted at the oral proceedings before the opposition division, and auxiliary requests 7 to 11 corresponded to auxiliary requests 3 to 7 filed with letter of 9 December 2011).

Additionally, the appellant-patentee submitted that the first-instance decision on lack of novelty vis-à-vis documents D33 and D44 of the subject-matter claimed in claims 6 and 7 of auxiliary request 2 filed on 9 December 2011 (auxiliary request 4 filed with the grounds of appeal) had violated its right to be heard under Article 113 EPC and that the opposition division had erroneously exercised its discretion not to admit amended auxiliary request 2 (auxiliary request 6 filed with the grounds of appeal).

Moreover, the appellant-patentee addressed with its grounds of appeal the issue of added matter pursuant to Articles 100(c) and 123(2) EPC, in relation to the expression "in need thereof" in auxiliary requests 2 and 7, and in relation to the amendments in each claim 1 of auxiliary requests 10 and 11.

VII. Claim 1 of the main request filed with the letter of 9 December 2011 reads as follows:

"1. A gaseous mixture containing nitric oxide, oxygen and less than 1 ppm NO₂, for use in therapy."

Claims 4, 5, 6, 8, 13 and 14 of the main request filed with the letter of 9 December 2011 read as follows:

"4. Use of a gaseous mixture consisting of NO and an inert gas (preferably N₂) for the production of an inhalable medicament for treating or preventing reversible pulmonary vasoconstriction in a mammal, wherein the inhalable medicament is prepared by mixing

the gaseous mixture with a continuous flow of an oxygen containing gas."

"5. Use of a gaseous mixture consisting of NO and an inert gas (preferably N₂) for the production of an inhalable medicament for treating or preventing reversible pulmonary vasoconstriction in a mammal, wherein the inhalable medicament is prepared by mixing the gaseous mixture with an oxygen containing gas in a continuous flow."

"6. Use of NO for the production of a medicament for improving gas exchange in the lungs of a mammal."

"8. Use of an oxygen-containing gas mixture comprising NO at a therapeutically-effective concentration and containing less than 1 ppm NO₂, for the preparation of a medicament for the treatment or prevention of reversible pulmonary vasoconstriction in a mammal."

"13. A method of providing an inhalable medicament by mixing NO with a continuous flow of an oxygen-containing gas."

"14. A method of providing an inhalable medicament by mixing NO with an oxygen-containing gas in a continuous flow."

As regards the claims of the auxiliary requests filed with the grounds of appeal the following situation arises:

Each claim 1 of auxiliary requests 1, 2, 3 and 7 is identical to claim 1 of the main request. Each claim 1 of auxiliary requests 4, 5 and 6 is identical to

claim 4 of the main request and each claim 2 of auxiliary requests 4, 5 and 6 is identical to claim 5 of the main request. Claim 1 of auxiliary request 8 differs from claim 6 of the main request in that the expression "in need thereof" has been added at the end of the claim. Claim 1 of auxiliary request 9 differs from claim 1 of auxiliary request 8 in that the term "mammal" has been replaced by the term "human".

Claim 1 of auxiliary request 10 reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a human suffering from persistent pulmonary hypertension of the newborn."

Claim 1 of auxiliary request 11 reads as follows:

"1. Use of NO for the production of a medicament for improving transpulmonary O₂ transport in a human suffering from persistent pulmonary hypertension of the newborn."

VIII. Opponent 01 (appellant 01), opponent 02 (appellant 02), opponent 04 (appellant 04) and opponent 05 (appellant 05) lodged appeals against the opposition division's decision and filed grounds thereto. They requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

IX. With its grounds of appeal appellant 01 further requested the review of the opposition division's decision in relation to apportionment of costs and that the costs incurred by the opponents at the first-

instance proceedings be awarded against the appellant-patentee (it specified that the costs were caused by the last-minute deletion of claims).

Appellant O1 raised *inter alia* objections within the meaning of Article 84 EPC against claim 1 of the set of claims serving as the basis for the maintenance of the patent in amended form (i.e. auxiliary request 4 filed on 9 December 2011). It also raised objections of added matter pursuant to Article 100(c) EPC (Articles 123(2) and 76(1) EPC).

- X. Appellant O2 raised with its grounds of appeal objections of added matter pursuant to Articles 100(c) and 123(2) EPC against the set of claims serving as the basis for the maintenance of the patent in amended form.
- XI. With its grounds of appeal appellant O4 raised objections pursuant to Articles 100(c) EPC (in conjunction with Articles 123(2) and 76(1) EPC), 54 and 56 EPC.
- XII. With its grounds of appeal appellant O5 raised objections under Articles 84, 54 and 56 EPC against the subject-matter claimed in the set of claims serving as basis for the decision maintaining the patent in amended form.
- XIII. With a letter dated 24 October 2012 appellant O2 filed a response to the patent proprietor's appeal. It requested that the board reject the claim's requests under Articles 100(a) (in conjunction with Articles 54, 56 and 53(c) EPC 2000) and Article 100(c) EPC (in conjunction with Article 123(2) EPC) and revoke the

patent in its entirety. In particular, the expressions "continuous flow of an oxygen containing gas", "oxygen containing gas in a continuous flow", and the specific content of NO₂, the gas mixtures and the sources of NO, were addressed.

- XIV. With a letter dated 14 November 2012 appellant O1 filed a response to the appellant-patentee's appeal. With said letter it also filed further documents (D142 to D148).

Moreover, appellant O1 denied that a procedural violation pursuant to Article 113 EPC had been committed during the first-instance proceedings, as alleged by the appellant-patentee. In particular, opponent O3 had already raised with its grounds of appeal a lack of novelty objection against the subject-matter of claims 47 and 48 as granted (they correspond to claims 6 and 7 of auxiliary request 2 filed on 9 December 2011) vis-à-vis document D44 (cited as document D10 in opponent's O3 grounds of appeal). Furthermore, it requested that the board reject the claims' requests and revoked the patent in its entirety. The reasons concerned grounds pursuant to Articles 100(c) and 100(a) EPC (in conjunction with Articles 54, 56 EPC).

- XV. With a letter dated 16 November 2012 appellant O4 filed a response to the appellant-patentee's appeal. It denied that a procedural violation pursuant to Article 113 EPC had been committed during the first-instance proceedings, as alleged by the appellant-patentee, and gave reasons thereto. It requested the revocation of the patent in its entirety.

- XVI. With a letter dated 27 December 2012 appellant 04 requested accelerated proceedings and gave reasons thereto. It also filed a copy of the "*Antrag auf Erlass einer einstweiligen Verfügung*" in support of its request.
- XVII. With a letter dated 9 January 2013 appellant 05 filed a reply to the appellant-patentee's appeal. It raised objections under Articles 84, 54 and 56 EPC. Moreover, it denied that a procedural violation pursuant to Article 113 EPC had been committed during the first-instance proceedings, as alleged by the appellant-patentee, and gave reasons thereto.
- XVIII. With a letter dated 16 January 2013 the appellant-patentee filed a reply to the opponents' appeals.
- XIX. With a letter dated 15 February 2013 appellant 04 again requested accelerated proceedings and filed a further document in support of its request.
- XX. A summons to oral proceedings to be held on 17 and 18 September 2013 was sent to the parties on 18 April 2013. The board sent a communication pursuant to Article 15(1) RPBA as an annex to the summons to oral proceedings.

In said communication the board expressed *inter alia* the view that it was evident from the content of the file that the admissibility of the intervention filed under Article 105 EPC on 4 December 2009 by TMG Technische Medizin und Gas GmbH (appellant 05) was not contested and that the opposition division had treated

the intervention as an opposition, which meant that the opposition division had considered the intervention to be admissible (Article 105(2) EPC).

In said communication the board also mentioned that for those claims which were identical to the claims as granted the grounds of opposition under Article 100(c) EPC had to be investigated before a discussion on novelty and inventive step could take place. The board also pointed out that for the amended claims not only added matter was an issue for discussion but also Articles 123(3) and 84 EPC were in principle within the framework of the discussion.

The board also expressed a preliminary opinion in relation to the issues concerning the alleged procedural violation put forward by the appellant-patentee, and the opposition division's decision in relation to apportionment of costs.

XXI. With a letter dated 24 May 2013 the appellant-patentee filed further auxiliary requests, namely auxiliary requests 8B, 8C, 8D, 9B and 9C.

Claim 1 of auxiliary request 8B reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a mammal."

Claim 1 of auxiliary request 8C reads as follows:

"1. Use of NO **or a nitric oxide-releasing compound** for the production of a medicament for improving gas

exchange in the lungs of a mammal in need thereof."
(*emphasis added*)

Claim 1 of auxiliary request 8D reads as follows:

"1. Use of NO **or a nitric oxide-releasing compound** for the production of a medicament for improving gas exchange in the lungs of a mammal." (*emphasis added*)

Claim 1 of auxiliary request 9B reads as follows:

"1. Use of an oxygen-containing gas mixture comprising NO at a therapeutically-effective concentration and containing less than 1 ppm NO₂, for the preparation of a medicament for the treatment or prevention of reversible pulmonary vasoconstriction in a mammal."

Claim 1 of auxiliary request 9C reads as follows:

"1. Use of a gaseous mixture consisting of NO and N₂ for the production of an inhalable medicament for treating or preventing reversible pulmonary vasoconstriction in a mammal, wherein the inhalable medicament is prepared by mixing the gaseous mixture with a continuous flow of an oxygen containing gas."

The appellant-patentee gave reasons in support of the admission of the new auxiliary requests and their allowability. It also maintained its position in relation to the alleged procedural violation in opposition proceedings which concerned the non-admission of amended auxiliary request 2 filed at the oral proceedings before the opposition division, and it gave further arguments. Alternatively, it requested the

board to admit auxiliary request 6 (which corresponded to said auxiliary request 2 in opposition proceedings) into the appeal proceedings in accordance with Articles 12(4) and 13(1) RPBA.

XXII. With a letter dated 15 August 2013 appellant 04 submitted arguments in relation to Articles 100(c) EPC "in connection with Articles 123(3) and 84 EPC". It also submitted further arguments in relation to novelty and inventive step.

Moreover, appellant 04 objected to the admission of the auxiliary requests filed with the appellant-patentee's letter of 24 May 2013.

With said letter, appellant 04 filed several annexes, in particular copy of a letter dated 27 June 2013 signed by Mr Müllejans and an expert opinion by Mr Zacharowski dated 17 May 2013.

XXIII. Oral proceedings took place on 17 and 18 September 2013.

At the beginning of the oral proceedings the appellant-patentee withdrew its request for reimbursement of the appeal fee and appellant 01 withdrew its request for review of the opposition division's decision in relation to apportionment of costs.

Moreover, during the course the oral proceedings before the board, the appellant-patentee filed further auxiliary requests 9A, 9A', 9A'', 9A''', 9A''''', 9A''''''', 9A''''''''', 9A''''''''''', 10A and 10B.

Claim 1 of auxiliary request 9A reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a human."

Claim 1 of auxiliary request 9A' reads as follows:

"1. Use of NO for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human."

Claim 1 of auxiliary request 9A'' reads as follows:

"1. Use of NO for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human via pulmonary vasodilation."

Claim 1 of auxiliary request 9A''' reads as follows:

"1. Use of NO **or a nitric oxide releasing compound** for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human." (*emphasis added*)

Claim 1 of auxiliary request 9A'''' reads as follows:

"1. Use of NO **or a nitric oxide releasing compound** for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human via pulmonary vasodilation." (*emphasis added*)

Claim 1 of auxiliary request 9A''''' reads as follows:

"1. Use of NO for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human via inhalation."

Claim 1 of auxiliary request 9A'''''' reads as follows:

"1. Use of NO **or a nitric oxide releasing compound** for the production of a medicament for improving lung function by facilitating gas exchange in the lungs of a human via inhalation." (*emphasis added*)

Claim 1 of auxiliary request 9A'''''''' reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a human via inhalation."

Claim 1 of auxiliary request 10A reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a human suffering from persistent pulmonary hypertension of the newborn via pulmonary vasodilation."

Claim 1 of auxiliary request 10B reads as follows:

"1. Use of NO for the production of a medicament for improving gas exchange in the lungs of a human suffering from persistent pulmonary hypertension of the newborn via inhalation."

XXIV. The appellants-opponents' (O1, O2, O4 and O5) arguments, as far as relevant for the present decision, may be summarised as follows.

- *Main request and auxiliary requests 1 to 11 filed with the grounds of appeal*

. *Main request*

Appellant O1 recalled the passages stated by the appellant-patentee as the basis for claim 1 of the main request (in particular page 8) and submitted that they did not represent an allowable basis for the subject-matter claimed (Article 100(c) EPC), which was an unallowable generalisation of the specification in the parent application as filed. The use of NO in generic terms was disclosed in the parent application as filed only in connection with the particular treatment of vasoconstriction and asthma. Moreover, there was no allowable basis for the gaseous mixture defined in claim 1. Appellant O1 also objected to claims 4 and 5 of the main request under Article 100(c) EPC, and submitted that page 22 of the parent application as filed did not provide an allowable basis for the mixtures. Moreover, the features appearing in these claims had been picked up from isolated passages in the parent application as filed, and thus these claims related to unallowable combinations of features. Appellant O1 also objected to claim 6 of the main request under Articles 100(c) and 76(1) EPC. In particular, the use of NO was linked in the parent application as filed to pulmonary vasodilatory effect (*inter alia* page 18, lines 8 to 14). Moreover, under the heading "pharmacological effect of NO" on page 23 of the parent application as filed, it was mentioned that inhaled NO caused "**relaxation of pulmonary vascular smooth muscle**" and that permitted "an **increase**

in pulmonary blood flow and **gas exchange**" (emphasis added). The wording employed on page 11, lines 14 to 29 ("to facilitate gas exchange within the lung", "improve lung function") was different to that on page 23, and also differed to the wording employed in claim 6 of the main request.

Appellant O1 also submitted that claim 1 encompassed any possible treatment for NO and that it was not restricted to the treatment disclosed in the description. As regards claim 6 it also added that some of the passages cited by the appellant-patentee as a basis for gas exchange referred to very specific patients and could not be generalised. As regards the disclosure on page 8 of the parent application as filed, reference was made to particular values of F_{iO_2} but section (d) was not isolated from sections (a) to (e). Additionally, the passages cited by the appellant-patentee mentioned N_2 . The treatment disclosed was mandatorily associated with pulmonary vasoconstriction (page 6, lines 20 to 23). Claim 6 was not limited to a vasodilatory treatment or to oxygen transport. The claim did not even mention that NO was to be inhaled.

Patients suffering from ARSD and patients suffering from PPH had some parts of the lung which diffused O_2 well and others which did not, and in the patients suffering from PPHN the problem was not that O_2 did not diffuse well, but the patent ductus arteriosus. Improvement of gas exchange could not be generalised for any kind of patient. The values of F_{iO_2} were not always proof of any kind of gas exchange in the lung.

Appellant O2 agreed with appellant O1's arguments in relation to added matter pursuant to Article 100(c) EPC in connection with Articles 123(2) and 76(1) EPC. Additionally, it submitted that less than 1 ppm NO₂ also meant NO₂ not being present at all. However, the gaseous mixture in claim 1 was a binary mixture NO and O₂ for which the presence of N₂ was not compulsory, contrary to the disclosure in the parent application as filed. Moreover, there was no basis in the parent application as filed for any therapeutic use of NO. The use of NO was disclosed only in connection with the treatment of vasoconstriction. Furthermore, claims 4, 5, 13 and 14 also contained added matter pursuant to Article 100(c) EPC in conjunction with Articles 123(2) and 76(1) EPC since they related to two different alternatives for continuous flow not disclosed in the parent application as filed. Additionally, page 11, lines 14-29, of the parent application as filed did not disclose the use of NO for improving gas exchange, as contended by the appellant-patentee, but the term "improving" was employed on page 11 only in connection with lung function ("to improve lung function") and the expression "gas exchange" was employed on page 11 only in connection with "facilitating" ("to facilitate gas exchange"). The different expressions were not necessarily equivalent in their meaning. Additionally, gas exchange was disclosed in the parent application as filed only in connection with treatment of vasoconstriction or bronchoconstriction, which were not mentioned in the claim. The whole parent application as filed disclosed the effect of vasodilation and consequent improvement of gas exchange. To claim improvement of gas exchange without referring to vasodilation was unallowable.

Moreover, appellant O2 submitted that it was clearly mentioned on page 8, lines 4 and 5 that the NO gas was administered to a mammal with pulmonary vasoconstriction or asthma. The results shown in Fig. 2 had been explained on page 31, lines 26 to 28, which was to be understood together with page 29, line 26 onwards. The teaching in relation to NO in the application as filed was that it was selective to the lungs, but patients suffering from PPHN were different from patients suffering ARDS or PPH. They were not interchangeable.

Additionally, there was no disclosure relating to the two alternatives specified in claims 4 and 5 of the main request. An inhaler was not a ventilator, and thus the combination of features was unallowable.

Appellant O4 objected to claims 1 to 3 (in relation to the gaseous mixture), claims 7 and 9 (in relation to "a human in need of..." or "mammal in need of...", respectively) and to claim 6 (unallowable singling out) on grounds pursuant to Article 100(c) EPC.

Appellant O5 shared the views of the other appellants-opponents. Additionally, it expressly further objected to claims 4 and 5 of the main request under Articles 100(c) EPC, 123(2) and 76(1) EPC, since they related to the use of a gaseous mixture consisting of NO and an inert gas and included the features of "mixing the gaseous mixture with a continuous flow of an oxygen gas" and "by mixing the gaseous mixture with an oxygen containing gas in a continuous flow", respectively. Moreover, claims 4 and 5 related to the

use for "treating or preventing reversible pulmonary vasoconstriction", whereas the disclosure on page 35, lines 12 to 13, which recited "NO in nitrogen will then be introduced into the breathing circuit by continuous flow", concerned the treatment of newborns. Therefore, there was no allowable basis for those mentioned claims. Analogous comments were made in relation to page 38 of the parent application as filed.

Additionally, appellant 05 mentioned that improvement of oxygenation was not mentioned in claim 6 of the main request.

Asked by the board whether they had objections within the meaning of Article 52(4) EPC 1973 (Article 53(c) EPC 2000) against the claims of the main request, appellants 01, 04 and 05 answered in the negative. Appellant 02 answered that it objected to method claims 13 and 14, since they necessarily included the monitoring during administration *in vivo* to the patient. It referred to board of appeal decisions T 1599/09 of 12 June 2013, T 0082/93 of 15 May 1995 and T 923/08 of 2 August 2011, and to Enlarged Board of Appeal decision G 2/07, OJ EPO 2012, 130. Moreover, claim 7 implied a diagnostic step.

. *Auxiliary request 1*

The objections to the main request applied *mutatis mutandis* to auxiliary request 1, since it differed only in that claims 13 to 15 had been deleted.

. *Auxiliary request 2*

The objections to the main request applied *mutatis mutandis* to auxiliary request 2, since it differed only in that the expression "in need thereof" had been added to claim 6.

Appellant O1 submitted that there was no basis in the parent application for the amendment in claim 6 and that it also objected to this amended claim under Article 84 EPC. It also objected to the amendment under Rule 80 EPC.

The other appellants-opponents shared the views of appellant O1 or had no additional comments.

. *Auxiliary request 3*

Auxiliary request 3 differed from auxiliary request 2 in that claims 13 to 15 had been deleted. Therefore, the same objections applied.

. *Auxiliary request 4*

Auxiliary request 4 differed from the main request essentially in that claims 1 to 3 had been deleted, claim 3 corresponded to claim 6 of the main request in that the expression "in need thereof" had been added, and claims 8 to 11 had been deleted. Therefore, the objections raised for the main request and auxiliary request 2 applied *mutatis mutandis*.

. *Auxiliary request 5*

Auxiliary request 5 differed from auxiliary request 4 in the amended method claims 6 and 7.

Appellant O2 submitted that it was now evident that the methods claimed in claims 6 and 7 included a therapeutic step, and thus were unallowable under Article 52(4) EPC 1973 (Article 53(c) EPC 2000).

Appellant O5 submitted that the ventilation circuit did not have any relation to the continuous flow and thus there was a further contravention of Article 76(1) EPC. The mixture did not take place in the ventilation circuit.

. *Auxiliary request 6*

Auxiliary request 6 differed from auxiliary request 4 in that claims 6 to 8 had been deleted. The objections against auxiliary request 4 applied *mutatis mutandis*.

. *Auxiliary request 7*

Auxiliary request 7 differed from the main request essentially in that claims 4, 5, and 13 to 15 had been deleted. Claim 4 corresponded to claim 6 of the main request in which the expression "in need thereof" had been added, and thus was identical to claim 6 of auxiliary request 2. Therefore, the arguments in relation to the main request and auxiliary request 2 applied *mutatis mutandis* to auxiliary request 7.

. *Auxiliary request 8*

Claim 1 of auxiliary request 8 was identical to claim 6 of auxiliary request 2. Thus, the same arguments applied.

. *Auxiliary request 9*

Claim 1 of auxiliary request 9 differed from claim 1 of auxiliary request 8 in that the word "mammal" had been replaced by the word "human". Thus, the arguments were maintained *mutatis mutandis*.

Moreover, appellant O1 stated that the passage on page 11 mentioned a mammal and not a human.

. *Auxiliary request 10*

Appellant O1 objected to the admission of auxiliary request 10, since its claim could represent a case of double patenting in relation to the patent granted on the divisional application deriving from the patent in suit (pending under appeal number T 809/10 before the present board). The appellant-patentee did not have any legitimate interest in prosecuting such a claim in the present case.

Additionally, NO was disclosed in the parent application as filed to be a selective vasodilator agent useful for PPHN, but the claim addressed improvement of gas exchange in the lungs. Therefore, there was added matter within the meaning of Articles 123(2) and 76(1) EPC. Moreover, the arguments submitted pursuant to Article 100(C) EPC in relation to higher-ranking requests applied *mutatis mutandis*. The combination of the different passages cited by the appellant-patentee was unallowable. Moreover, it was not questioned that the amount of oxygen was reduced in the blood of newborns suffering from PPHN; what was

questioned was that the parent application required vasodilation for achieving any improvement and the claim did not. Patients suffering from PPHN did not necessarily have a dysfunction of the lung *per se*. The parent application as filed did not contain any definition for "improving gas exchange". Hypoxia in newborns could also be the result of constriction of the umbilical cord. Reduction in arterial oxygen saturation was not the same as deficits in gas exchange. Moreover, in newborns suffering from PPHN, pulmonary hypertension persisted after birth and led to a right-to-left shunt through persistent foetal channels (patent foramen ovale and patent ductus arteriosus). In PPHN, pulmonary vascular resistance was increased, preventing normal pulmonary blood flow and leading to hypoxia. A vicious cycle was thus initiated causing further vasoconstriction and loss of compliance. However, what was claimed in claim 1 was not the treatment of PPHN but the use of NO for improving gas exchange in the lungs of a patient suffering from PPHN, i.e. the condition treated was deficits in gas exchange.

Appellant O2 shared the views of appellant O1 in relation to the admissibility of auxiliary request 10, and further submitted that a human patient could be an adult or an infant, but PPHN was a syndrome of newborns. Thus, there was also a problem of lack of clarity under Article 84 EPC for claim 1, which called into question the admissibility of such a request. Moreover, it objected to claim 1 under Article 123(3) EPC, since its subject-matter was not covered by granted claims 31 and 32, which did not relate to treatment of PPHN syndrome. Page 7, lines 10 and 11 of the parent application as filed mentioned improved transpulmonary O₂ transport in

an infant, but PPHN was mentioned in lines 28 and 29 of page 7 only in connection with acute pulmonary vasoconstriction. Thus, the parent application as filed disclosed the treatment of pulmonary vasoconstriction caused by PPHN and did not disclose the improvement of gas exchange in patients suffering from PPHN. The patient treated on page 36 onwards was a single patient with very particular characteristics and the treatment concerned specific mixtures of NO and N₂. There was no general teaching disclosed in the parent application as filed which represented a valid basis for claim 1 of auxiliary request 10. If, following the appellant-patentee's arguments, the blood vessels did not open, then there was necessarily vasoconstriction, and only if vasodilatation occurred they then did open in order to allow improvement of gas exchange. However, this was not reflected by the claim's wording (Article 84 EPC, lack of essential features). Claim 1 of auxiliary request 10 also encompassed treatment in which NO caused gas exchange without influencing vasodilation; this was not in accordance with the content of the application as filed. The parent application as filed did not disclose improvement of gas exchange as a separate effect from vasodilation, or deficits of gas exchange other than those linked to vasoconstriction.

Appellant 04 stated that the use claim derived from claim 31 as granted, but such a use of NO was not disclosed for treating PPHN. Since the expression "human suffering from" was used in claim 1 together with PPHN syndrome there was a lack of clarity in relation to the age of the patient treated. A newborn was normally a baby up to 28 days old, but how old was a "human suffering from PPHN"?

Moreover, administration of inhaled NO, alone, would lead to the babies' death.

Appellant 05 shared the views of the other appellants-opponents.

. *Auxiliary request 11*

Appellant 01 objected to claim 1 of auxiliary request 11 under Articles 123(2) and 76(1) EPC. The disclosure on page 7, lines 10 and 11 about improving transpulmonary O₂ transport was in connection with vasodilatory treatment. Moreover, the arguments submitted for the previous request in relation to admissibility applied *mutatis mutandis*.

Appellant 02 also submitted that the arguments for the previous requests applied *mutatis mutandis*. Page 7, lines 10 and 11, was point (5) of the disclosure starting on page 6, line 30 and which concerned "a pulmonary vasodilatory treatment". Only a vasodilatory treatment was disclosed in the parent application as filed, whereas the claim also addressed other options for treating the deficits in oxygenation. Moreover, claim 1 lacked clarity since it was unclear in comparison to what was to be the improvement in transpulmonary O₂ transport. Additionally, the claim contravened the requirements of Article 123(3) EPC since its object was different from what had been claimed in the parent as granted.

- *Auxiliary requests 8B, 8C, 8D, 9B, 9C*

. *Auxiliary request 8B*

Appellant O1 contested the admissibility of auxiliary request 8B, since it did not represent a response to the communication sent as an annex to the summons. Claim 1 of auxiliary request 8B was already present as claim 6 in the main request, thus there was no justification for not filing earlier the set of claims of auxiliary request 8B.

Appellant O2 shared the views of appellant O1. Auxiliary request 8B corresponded to auxiliary request 8 filed with the grounds of appeal (identical to auxiliary request 4 before the opposition division) in which "in need thereof" had been deleted from claim 1. Since this amendment, i.e. deletion of "in need thereof", had already occurred in independent claim 6 of the main request, the rationale for it had already existed before the board's communication.

Appellant O5 further stated that it was known to the appellant-patentee long before the summons to the oral proceedings that there was a problem with the expression "in need thereof". To file this variation for auxiliary request 8 at such a late stage of the proceedings was unjustified.

. Auxiliary requests 8C and 8D

Appellant O1 submitted that Article 100(c) EPC had been within the framework of appeal proceedings since the beginning. The appellant-patentee had cited the second paragraph on page 11 of the parent application as filed as the basis for claim 6 of the main request. When reading said paragraph it immediately became evident

that the expression employed was "the use of a source of nitric oxide". Therefore, it was self-evident that by choosing the wording "use of NO" in the claim, problems would arise.

Appellant O2 further submitted that granted claim 31 related to two different embodiments separated by the particle "or" (use of NO or a nitric oxide-releasing compound). If there was a problem pursuant to Article 100(c) EPC for the first alternative, to re-introduce the second alternative was not a direct reply. Nothing in the board's communication or during the oral proceedings before the board justified the re-introduction of the alternative concerning a nitric oxide-releasing compound. To admit these two sets of claims would be contrary to the RPBA.

Appellant O4 also submitted that the embodiment concerning the NO releasing compound had not been prosecuted either in the claims before the opposition division or in the claims filed with the grounds of appeal. Therefore, there was no justification for re-introducing now something the appellant had long abandoned.

. *Auxiliary requests 9B and 9C*

The appellants-opponents submitted that auxiliary request 9B could have been filed earlier since claim 1 was independent claim 8 of the main request. Moreover, claim 1 was *prima facie* not allowable. Analogous comments also applied to auxiliary request 9C. The fact that the appellant-patentee had chosen to have a patent with such a multitude of independent claims should not

give him an unwarranted advantage when submitting auxiliary requests at such a late stage.

- Auxiliary requests 9A, 9A', 9A'', 9A''', 9A''''', 9A''''''', 9A''''''''', 9''''''''''', 10 A and 10B filed during the oral proceedings before the board

. Auxiliary request 9A

Appellant O1 submitted that claim 1 of auxiliary request 9A differed from claim 1 of auxiliary request 9 in that the expression "in need thereof" had been deleted. Therefore, the objections raised against the admissibility of auxiliary request 8B applied *mutatis mutandis*.

Appellant O2 shared the views of appellant O1.

Appellant O4 added that this request had to be rejected as filed too late.

. Auxiliary request 9A'

Appellant O1 submitted that this request might have been filed in an attempt to address the objections of added matter, but the introduced amendments brought new problems under Article 123(3) EPC which rendered the claim *prima facie* unallowable. This request should not be admitted. Claim 31 as granted related to improving gas exchange and now claim 1 related to improving lung function. These were two different things.

Appellant O2 submitted that the amended claim was manifestly unclear (Article 84 EPC) and thus the

request should not be admitted. Claim 1 was also *prima facie* not allowable under Articles 123(2) and 76(1) EPC. There were no instructions whatsoever in the patent about how to determine when an improvement of the lung function took place "by facilitating the gas exchange" (Article 84 EPC). There was also an additional problem of Article 123(3) EPC. The filing of such manifestly unallowable claims at the oral proceedings before the board slowed down the appeal proceedings and might even prevent a decision being announced at the end of the oral proceedings.

Appellant O4 stated that admission of auxiliary request 9A' filed at the oral proceedings before the board put an undue burden on the appellants-opponents since it was not immediate evident where the amendments introduced were derived from. Furthermore, admission of the auxiliary requests filed at the oral proceedings would give an unwarranted advantage to the appellant-patentee who had waited until now to file them. Manifestly unclear and unallowable claims filed so late should not be admitted. The amended claim of auxiliary request 9A' also brought further problems in relation to Article 100(b) EPC.

Appellant O5 shared the views of the other appellants-opponents in relation to non-admission because the claim was *prima facie* not allowable.

Additionally, appellant O1 stated that the situation depicted in board of appeal decision T 1621/09 of 22 September 2011 (cited by the appellant-patentee as dealing with the admission of new arguments and amendments to a party's case) related to a completely

different situation. Article 100(c) EPC had been within the framework of the present appeal case from the beginning. It was the appellant-patentee who had put forward the passages on page 11 as the basis for claim 6 of the main request, and the appellants-opponents had argued that those passages were not an allowable basis. Moreover, when filing amended claims in opposition and opposition appeal proceedings, all the requirements of the EPC had to be regarded.

Additionally, appellant O2 stated that during the first day of the oral proceedings the appellant-patentee had filed nine auxiliary requests. Thus the appellant-patentee's request for adjournment could not be justified as being necessary for preparing auxiliary requests in order to respond to the objections of added matter. Moreover, it was not the fault of the appellants-opponents if the case was complex and the granted patent had such a multitude of independent claims. It was not the appellants-opponents' fault either that the auxiliary requests did not converge but diverged in several directions. Moreover, if the amended claims presented ambiguous and unclear wordings inherently caused by the bad drafting of the description of the parent application as filed and the patent, that too was not the appellants-opponents' fault. Additionally, the appellant-patentee was responsible for the content of its application as filed, which was devoid of any definition concerning "improvement of lung function", "facilitating gas exchange", etc. The application forming the basis of the patent in suit was twenty-two years old. Therefore, an adjournment did not make any sense in the present

case except in serving the patentee's interests not to reach a final decision.

Appellant O4 also stated that there were no "new lines of attack", since the assessment of amendments pursuant to Article 100(c), 123(2) and 76(1) EPC was within the framework of the appeal. Moreover, the comments submitted with the letter of 15 August 2013 were justified in view of the new filing of requests by the appellant-patentee.

. *Auxiliary request 9A''*

The appellants-opponents submitted that their comments in relation to auxiliary request 9A' applied *mutatis mutandis* to auxiliary request 9A''. Therefore, it should not be admitted into the proceedings.

. *Auxiliary request 9A''' and 9''''*

The appellants-opponents submitted that their arguments in relation to admissibility for auxiliary requests 9A' and 8C applied *mutatis mutandis* to auxiliary request 9A'''. Therefore, it should not be admitted into the proceedings.

. *Auxiliary request 9A''''*

The appellants-opponents submitted that their arguments in relation to the admissibility of auxiliary request 9A' applied *mutatis mutandis*.

. *Auxiliary request 9A''''''*

The appellants-opponents did not add any further comments in relation to this request, since the arguments submitted for previous requests in relation to admissibility applied.

. *Auxiliary request 9A''''''''*

Appellants O1 and O4 did not have any further comments in relation to the admissibility of this auxiliary request.

Appellant O2 submitted that auxiliary request 9'''''''' could have been filed earlier since the claim from which claim 1 of auxiliary request 9A'''''''' derived had been already objected to during the oral proceedings before the opposition division since it did not specify that NO was inhaled (see minutes of the oral proceedings before opposition division, point 48). This auxiliary request was clearly unallowable (in particular under Article 84 EPC), and thus it should not be admitted into the proceedings. In the parent application as filed NO was never inhaled alone (Article 76(1) EPC).

Appellant O5 endorsed the arguments of appellant O2.

. *Auxiliary request 10A*

Appellant O1 contested the admissibility of auxiliary request 10A since it was *prima facie* unallowable. The claim manifestly lacked clarity.

The other appellants-opponents endorsed the arguments of appellant O1.

. Auxiliary request 10B

The appellants-opponents contested the admissibility of auxiliary request 10B for analogous reasons to those given for the previous auxiliary requests. Moreover, appellant O2 submitted that its extremely late filing (second day of the oral proceedings) made it inadmissible.

- Allowability of auxiliary requests 9A'''''' and 9A''''''''

The appellants-opponents objected to auxiliary request 9A'''''' under Articles 100(c), 123(2), 76(1), 123(3) and 84 EPC. They also raised objections under Article 100(b) EPC.

In particular, there had been a change in the scope claimed, which was contrary to Article 123(3) EPC. Moreover, there was added matter within the meaning of Article 76(1) EPC, since the passages on page 11 cited by the appellant-patentee related to gas mixtures and not to NO alone, and lack of clarity since the claim also encompassed facilitating gas exchange for humans with normal arterial O₂ saturation values. There was no clear definition of "facilitating gas exchange". The skilled person would not know if he was working inside or outside the claim.

Additionally, there was no clear teaching in the parent application as filed concerning how to improve the lung function. Page 11 referred to a manual (set of instructions specifying how to use the source of NO to

improve lung function), but such instructions were not contained in the patent in suit (Article 100(b) EPC).

As regards the appellant-patentee's comments about table 5 on page 44 of the parent application as filed, appellant O1 added that a normal subject without disease subjected to conditions which caused hypoxia (owing to a lower inspired oxygen than the inspired oxygen when normally breathing air) got vasoconstriction. It was self-evident that one could not increase with NO the partial pressure of oxygen in a normal subject breathing air. Table 5 did not demonstrate whether gas exchange was facilitated.

Appellant O2 shared the views of appellant O1 and pointed to a better outcome of CO₂.

. *Auxiliary request 9''''''''*

The appellants-opponents stated that the arguments submitted for the previous request and for higher-ranking requests also applied *mutatis mutandis*.

XXV. The appellant-patentee's arguments, as far as relevant for the present decision, may be summarised as follows.

- *Main request and auxiliary requests 1 to 11 filed with the grounds of appeal*

. *Main request*

Claim 1 of the main request referred to a gaseous mixture with less than 1 ppm of NO₂. The basis could be found on page 8, lines 3 to 23 of the parent application as filed. The reference to the treatment of pulmonary vasoconstriction and asthma on page 8 was made after the word "preferably". Moreover, page 21, line 21 onwards, gave a non-exhaustive list of options for the use of inhaled NO. Moreover, the core of the invention was the use of NO and the skilled person would know that oxygen was required as a component of the gaseous mixture so that the patient would not die. In this context it referred to page 8, paragraph (d), of the parent application as filed, page 19, comments about Fig. 2, page 29, lines 12 to 18, and to page 30, lines 25 to 27, page 35, lines 15 to 17, and page 39, line 1, in relation to F₁O₂ values.

As regards claims 4 and 5 of the main request, the teaching was directly and unambiguously derivable from the parent application as filed. The use of NO was also meant to be the use of NO in a mixture with an inert gas. The appellant-patentee also mentioned pages 17, 22, 23 (in relation to the design to fix and mix two sources).

During the first day of the oral proceedings the appellant-patentee contested the admission of the appellants-opponents' objections in relation to the term "improving" in claim 6 of the main request and to the specification of the condition to be treated as "treating or preventing..." in claims 4 and 5 of the main request, pursuant to Article 100(c) EPC in conjunction with Articles 123(2) and 76(1) EPC.

Moreover, as regards claim 6 of the main request, the appellant-patentee cited page 7, lines 10 to 13, where an improved transpulmonary O₂ transport had been proven in an infant. Thus one main goal disclosed in the parent application as filed was to improve gas exchange. It also cited page 11, lines 14 to 29, where facilitating gas exchange within the lung was mentioned as an example of improving the lung function. The appellant-patentee also cited page 18, lines 8 to 34 (e.g. to "improve oxygen transport" in some patients), and page 23, line 22 onwards, which explained how NO gas worked. Additionally, the appellant-patentee also submitted that the source of NO mentioned on page 11 related to two alternatives: a mixture of compressed gases including NO and a NO-generating compound. Gas exchange was one preferred aspect in the parent application as filed and this effect was particularly mentioned for NO gas on page 18 of the parent application as filed. NO gas was used in the examples for lambs, babies and adults. The improvement of gas exchange was mentioned on page 39 of the parent application as filed as demonstrating the utility of NO. The situation was not an unallowable singling out. It also mentioned the results of the experiments depicted in Fig. 6 concerning NO inhalation in an adult with severe ARDS. The appellant-patentee also submitted that "improvement" of lung function was reflected by an "increase" in pulmonary blood flow and gas exchange (page 23, lines 26-27). The skilled person would check F_iO₂ (i.e. the proportion of O₂ gas, by volume). Moreover, the skilled person would read claim 6 with a will to understand it as relating to a treatment of patients in need of an improvement in gas exchange. That claim 7 of the main request explicitly mentioned

"in need of such improved gas exchange", and claim 6 of the main request did not, was because claim 6 was directly derived from the wording in claim 31 as granted and claim 7 from granted claim 32.

The appellant-patentee also submitted that the second paragraph on page 11 did not expressly mention inhalation, and page 23 gave a list of options for the treatment. There was no reason to restrict the claim to inhalation.

The appellant-patentee pointed again to the following pages of the parent application as filed in relation to NO and claim 6 of the main request: pages 23, 29, 33, 36, 39 and 44. Moreover, oxygenation of blood was what mattered. In relation to the appellants-opponents' argument that gas exchange was achieved by vasodilation, the appellant-patentee referred to page 18, lines 29 to 34, where an increase of blood flow to ventilated alveoli was mentioned in connection with improved oxygen transport, and to page 23, lines 23 to 27.

The appellant-patentee also submitted that the assessment of the disclosure for added matter pursuant to Article 100(c) EPC should not be misunderstood as an assessment of sufficiency of disclosure.

The appellant-patentee stated that claim 7 had not been attacked in the written proceedings under Article 52(4) EPC 1973 (Article 53(c) EPC 2000). Moreover, the "diagnostic method" was not part of the claim and the claim was in the Swiss-type form. As regards method claims 13 and 14, they were methods of mixing gases and

nothing more. It also cited Enlarged Board of Appeal decision G 1/04, OJ EPO, 2006, 334.

. *Auxiliary request 1*

The arguments in favour of the main request applied *mutatis mutandis* to auxiliary request 1, since it differed only in that claims 13 to 15 had been deleted.

. *Auxiliary request 2*

The arguments in favour of the main request applied *mutatis mutandis* to auxiliary request 2. Moreover, the appellants-opponents had not been consistent in their objections in relation to the absence or presence in claim 6 of the expression "in need thereof". Either it was a "non-feature". or it introduced added matter, but it could not be both at the same time. The amendment had been introduced in view of the opponents' objections based on grounds of opposition. Thus it was in line with Rule 80 EPC. Moreover, the amended claim was clear for the skilled person who would be able to identify those patients who were in need of such a treatment, namely a patient who had problems with oxygen exchange. Moreover, it was rather doubtful that the claim was open to an objection under Article 84 EPC since the expression already appeared in granted claim 32. In this context the appellant-patentee cited board of appeal decisions T 1459/05 of 21 February 2008 and T 493/09 of 27 February 2013.

. *Auxiliary request 3*

The arguments in favour of auxiliary request 2 were maintained for auxiliary request 3.

. Auxiliary request 4

The arguments in favour of the main request and auxiliary request 2 applied *mutatis mutandis* to auxiliary request 4.

. Auxiliary request 5

In relation to amended claim 6 the appellant-patentee cited page 35, lines 12 to 14, page 38, lines 38 to 42, page 39, line 1, page 46, lines 5 to 8 (continuously drive fresh gas into the ventilator circuit) and Fig. 7.

. Auxiliary request 6

The arguments in favour of auxiliary request 4 applied *mutatis mutandis* to auxiliary request 6.

. Auxiliary request 7

The arguments in favour of the main request and auxiliary request 2 applied *mutatis mutandis* to auxiliary request 7.

. Auxiliary requests 8

The arguments submitted for the requests of higher ranking were maintained without any further comments.

. Auxiliary request 9

The objection raised by appellant O1 in relation to the replacement of the term "mammal" by the term "human" had not been raised before. It was not justified to raise it now since the set of claims had been on file since October 2011. If it had been filed earlier it could have been taken into account by filing an auxiliary request. Additionally, the specification of the background on page 2, line 31, of the parent application as filed clearly focused on human patients. The diseases mentioned on page 4 were human diseases, and the treatments disclosed on pages 6 and 7 were all for treating human patients. The uses of NO disclosed on page 11 were all meant for treating humans. That the patient was a human was based on the whole parent application as filed: on page 7, lines 20 onwards, page 8, paragraph (b), line 34, page 9, lines 1 and 2, line 14, page 18, lines 29 to 34, page 19, line 4, page 21, lines 13 to 32 and the experimental section dedicated to an animal model and to human patients. That the patients were human was directly and unambiguously disclosed in the parent application as filed.

. Auxiliary request 10

Auxiliary request 10 filed with the grounds of appeal corresponded to auxiliary request 6 filed with the letter dated 9 December 2011 and to auxiliary request 13 of 30 October 2011. The opposition division had admitted all the requests filed with the letter of 9 November 2011. It was during the oral proceedings before the board that the appellants-opponents had raised objections to the admissibility of the request.

These objections were inadmissible under Articles 12 and 13 RPBA.

Moreover, there was a legitimate interest, since the patent deriving from the parent application had been revoked (decision T 443/01 of 16 November 2004, same board in another composition), and thus, owing to *ex tunc* effect, the revoked patent had never existed.

The subject-matter of the claims of the patent deriving from the divisional application of the patent in suit was not the same as that of the claims of the auxiliary requests in the present case. There was no double patenting.

In relation to the basis for the treatment defined in claim 1 in the parent application as filed, the appellant-patentee cited *inter alia* page 7, lines 10 to 13, page 16, lines 22 to 29 (stabilisation of newborns with PPHN meant improvement of gas exchange), page 21, line 26, page 23, lines 24 to 26 (improving gas exchange was directly applicable to babies suffering from PPHN which could turn cyanotic), and the examples, in particular page 33 onwards, which showed that opening up blood vessels in ventilated areas and improving gas exchange could alleviate the condition of the babies suffering from PPHN (this had been a revolution at the time of the parent application).

As regards the objections under Article 84 EPC, the appellant-patentee stated that the skilled person would not have any problem with the expressions used in the claim. The treatment concerned newborns; PPHN was a well-established syndrome. A patient suffering from PPH

was not a patient suffering from PPHN. These were two different categories of patients, easily identifiable by a doctor. The PPH patients did not have an open ductus arteriosus. The appellant-patentee again cited pages 33, 36, 39 and 40. Administration of inhaled NO opened up vessels in the lungs. If the vessels in the lungs opened up, there was improvement in gas exchange in the lungs. Most infants suffering from PPHN had collapsed lung areas and they did not have perfect adult lungs. One could also increase gas exchange by vasodilation in the lungs.

The appellant-patentee also submitted that it would be unfair if a mechanism of action had to be necessarily included in the claim. Moreover, the assessment of added matter in relation to amendments had nothing to do with the assessment of enablement of the invention.

Additionally, the skilled person knew about the toxicity of NO₂ or NO in certain amounts, but the claim was a medical use claim for the active agent NO. Thus it was not necessary to define the complete medicament. The medical condition treated concerned deficits in gas exchange, and this was a physiological condition which had been singularised in the parent application as filed.

Asked by the board whether the appellant-patentee contested that NO addressed vasoconstriction in PPHN, the appellant-patentee answered that it did not work without vasodilation.

. Auxiliary request 11

The appellant-patentee submitted that if you "improved transpulmonary O₂ transport" you had improved gas exchange. Thus, there was no problem of Article 123(3) EPC. The meaning of the claim was that the patient was doing better than before treatment. Thus, there was no problem of Article 84 EPC.

- Auxiliary requests 8B, 8C, 8D, 9B, 9C

. Auxiliary request 8B

Auxiliary request 8B was based on auxiliary request 4 filed before the opposition division and filed again as auxiliary request 8 with the grounds of appeal. The expression "in need thereof" had been deleted from claim 1. During the opposition proceedings the opponents had not raised an objection of lack of clarity against said expression. It was only in appeal proceedings that the opponents had raised such an objection. The appellant-patentee submitted that it had assumed at first that this expression was not open for objections under Article 84 EPC since it was present in claim 32 as granted. However, the preliminary opinion had mentioned that Article 84 EPC might be an issue of discussion. Therefore, auxiliary request 8B had been filed with the letter of 24 May 2013, as soon as possible after receipt of the board's communication dated 18 April 2013. Objections under Article 100(c) EPC against the expression "in need thereof" had been submitted for the first time by appellant O4 with its letter of 15 August 2013.

. Auxiliary requests 8C and 8D

Auxiliary requests 8C and 8D had been filed as a response to the board's communication referring to Article 123(3) EPC. Moreover, during the oral proceedings before the board the appellants-opponents had submitted that claim 6 of the main request, and therefore also claim 1 of auxiliary request 8, related to an unallowable singling out. The amendments in auxiliary requests 8C and 8D were an attempt to reply to such objections.

The appellant-patentee denied that it had previously abandoned the embodiment concerning a NO releasing compound.

. Auxiliary requests 9B and 9C

Auxiliary request 9B had been filed in an attempt to reply to the board's communication and auxiliary request 9C had been filed in order to take into account some comments in the board's communication in appeal case T 809/10 (dealing with the patent deriving from the divisional application of the application underlying the patent in suit).

- Auxiliary requests 9A, 9A', 9A'', 9A''', 9A''''', 9A''''''', 9A''''''''', 9''''''''', 10 A and 10B filed during the oral proceedings before the board

. Auxiliary request 9A

The appellant-patentee submitted that this request had been filed as a response to objections under Article 100(c) EPC and referred to its arguments in relation to auxiliary request 8B.

. Auxiliary request 9A'

The appellant-patentee submitted that auxiliary request 9A' had been submitted as a reaction to objections of added matter heard for the first time at the oral proceedings. It would not be fair if auxiliary request 9A' was not admitted into the proceedings.

The appellant-patentee recalled the text in Article 13(3) RPBA and stated that it applied to amendments in a party's case and not only to the amendments submitted by the patentee. Moreover, the appellant-patentee submitted that it had not filed the auxiliary requests at the oral proceedings in order to cause an adjournment of the proceedings and that the amendments could be dealt with by the appellants-opponents without any need for an adjournment. Moreover, the amendments had been filed in the course of the oral proceedings in order to react to three new attacks against claim 6 of the main request for added matter concerning "gas exchange", "the lack of the mechanism of vasodilation" and "singling out NO". Additionally, claim 1 of auxiliary request 1 had not extended the scope of protection (Article 123(3) EPC), since it was more specific, and the amendments had been introduced to overcome objections in relation to added matter. The improvement in lung function was attained by "facilitating gas exchange in the lungs" as stated in the claim. Moreover, the term "facilitating" was not unclear. The skilled person would know how to determine whether he was working in or outside the claim, for instance by determining arterial oxygenation, oxygen saturation or blood flow shunting.

Furthermore, on the second day of the oral proceedings before the board the appellant-patentee submitted that it had been the opponents' conduct which had caused the late filing of these auxiliary requests. There had been no abuse of proceedings by the appellant-patentee. The appellant-patentee cited board of appeal decisions T 1069/08 of 8 September 2011 (non-admission in oral proceedings before the board of a new argument in relation to inventive step, page 22 onwards) and T 1621/09 of 22 September 2011.

Moreover, on the second day of the oral proceedings before the board the appellant-patentee submitted the following request:

"we herewith request adjournment of the oral proceedings scheduled for 17 and 18 September 2013 in view of the new lines of attack brought by the opponents under Article 100(c) EPC for the first time during the oral proceedings of 17 September 2013, these attacks specifically being

- a) the allegation that the reference to "improving gas exchange" in claim 6 of the main request violated Article 100(c) EPC, since page 11 of the application as filed referred to "facilitating gas exchange";*
- b) the allegation that there is a need to refer to pulmonary vasodilation in the claim; and*
- c) that the reference to NO without a reference in the claim to a "NO releasing compound" was an inadmissible singling out under Article 100(c) EPC,*

and re-entry into written proceedings, thereby giving the proprietor an appropriate term for considering the

new attacks and responding to them in writing by arguments and/or new auxiliary requests."

If the board was not inclined to postpone the oral proceedings, then the board should take into account the circumstances under which the auxiliary requests had been filed at the oral proceedings and admit them into the proceedings. The appellants-opponents' objections could not have been anticipated by the appellant-patentee.

. Auxiliary request 9A''

Auxiliary request 9A'' had been submitted as a direct response to the discussion during the oral proceedings. The comments submitted for the previous requests also applied.

. Auxiliary requests 9A''' and 9A''''

The appellant-patentee stated that its submissions for previous auxiliary requests also applied to these auxiliary requests.

. Auxiliary request 9A'''''

The amendments in auxiliary request 9A''''' had been introduced as a direct response to the appellants-opponents' objections during the oral proceedings before the board. In particular, the expression "via inhalation" had been introduced (page 23, lines 23 to 27) and the other amendments brought the wording closer to that on page 11 of the parent application as filed.

Further basis was to be found on page 39, lines 25 to 34.

. *Auxiliary request 9A''''''*

The appellant-patentee stated that its submissions for the previous auxiliary requests also applied to this auxiliary request.

. *Auxiliary request 9A''''''*

This auxiliary request had been filed as a direct response to the discussions during the oral proceedings before the board. The amendment did not introduce any lack of clarity. The expression "via inhalation" clearly referred to the application route for NO. Moreover, if this auxiliary request containing one single claim had not been filed earlier, that was because the appellant-patentee had not wished to unnecessarily encumber the appeal proceedings. Only in the course of the discussion during the oral proceedings before the board had it become evident that the lack of specification of the administration route could imply that the sets of claims on file before the oral proceedings might fail.

. *Auxiliary request 10A*

The arguments in favour of the admission of the previous auxiliary requests applied *mutatis mutandis* to auxiliary request 10A. Moreover, the introduced amendments were clear for the skilled person. The human suffering from PPHN was a newborn.

. Auxiliary request 10B

This request had been filed as a reaction to the objections raised in the first day of the oral proceedings before the board.

- Allowability of auxiliary requests 9A'''''' and 9A''''''''

Claim 1 of auxiliary request 9A'''''' did not contravene the requirements of Article 123(3) EPC since the expression "for improving the lung function" was qualified by the expression "by facilitating gas exchange". Moreover, there was no added matter within the meaning of Article 76(1) EPC, since page 11, lines 27 and 28 specified that it was "by inhalation of NO". Additionally, the appellant-patentee cited page 23, which referred to NO as the active agent, and to the examples. In this respect it submitted arguments analogous to those already submitted for previous requests. As regards the clarity issue, the appellant-patentee submitted that the skilled person would be able to know whether he was working inside or outside the claim. The examples showed how ventilation took place in certain areas of the lung and how gas exchange took place. The concept of gas exchange in the lungs concerned loading up oxygen in the lungs and implied oxygen transport in blood. The appellant-patentee referred to table 5, and explained that people with normal gas exchange did not experience improvement of gas exchange after NO administration. It also referred to table 4 which showed no changes in pulmonary arterial pressure on non-constricted human lungs. Appellant-patentee also referred to "Anlage 1" filed

with appellant 04's grounds of appeal for the definition of gas exchange.

The appellant-patentee also submitted that the skilled person could readily determine if somebody had a gas exchange improvement in the lungs (e.g. by catheterisation). It was daily practice on the part of pulmonologists and anaesthetists.

As regards the objection of insufficiency of disclosure, it submitted that the appellants-opponents' arguments did not hold, since the patent contained detailed information and sufficient experimental data to allow the skilled person to put the invention into practice without undue burden. It cited decision T 19/90, EPO OJ 1990, 476. The instructions mentioned on page 11 merely concerned the administration of inhaled NO and the precautions in relation to formation of NO₂.

The appellant-patentee stated that the arguments submitted for the previous requests were maintained for auxiliary request 9A''''''''.

XXVI. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 9 December 2011 or, alternatively, on the basis of one of auxiliary requests 1 to 11 filed with the grounds of appeal, or alternatively on the basis of one of auxiliary requests 8B, 8C, 8D, 9B or 9C filed with the letter of 24 May 2013, or on the basis of one of auxiliary requests 9A, 9A' to 9A'''''''' or 10A filed during the oral proceedings on 17 September 2013, or

auxiliary request 10B filed during the oral proceedings on 18 September 2013.

XXVII. The appellants (opponents) requested that the decision under appeal be set aside and that European patent No. 0 786 264 be revoked.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admission of main request and auxiliary requests 1 to 11 filed with the grounds of appeal*

The admission of the main request and auxiliary requests 1 to 9 filed with the grounds of appeal was not contested by the appellants-opponents and the board sees no reason to differ.

Auxiliary requests 10 and 11 were filed with the grounds of appeal and are considered to be admissible under Article 12(4) RPBA.

Moreover, there is no situation of *res judicata* in respect of board of appeal decision T 443/01 of 16 November 2004 (same board in another composition) which decided on the substance in relation to one single claim with a different wording from that of each of the claims of auxiliary requests 10 and 11. Additionally, as the patent deriving from the parent application was revoked by board of appeal decision

T 443/01, there is no double patenting. Additionally, the fact that there is a further appeal pending, namely T 809/10 (same board as in the present case), concerning the patent deriving from the divisional of the application underlying the patent in suit in the present appeal, does not mean that the claims relate to the same subject-matter, particularly since the claims' wording is different.

Therefore, auxiliary requests 10 and 11 are admitted into the proceedings.

- 1.3 *Admission of "new lines of attack" during the oral proceedings before the board in relation to added matter. Request for postponement of the oral proceedings.*

The appellant-patentee's request for adjournment of the oral proceedings in view of several "new lines of attack" against claim 6 of the main request (see facts and submissions, point XXV) was refused by the board at the oral proceedings.

The present *inter partes* appeal proceedings lie from an interlocutory decision of the opposition division maintaining the patent in amended form on the basis of an auxiliary request which is identical to auxiliary request 8 filed with the patentee's grounds of appeal. The patentee and four of the five opponents lodged appeals against the first-instance decision. Therefore, the situation of *reformatio in peius* does not arise in relation to the examination by the board of any of the sets of claims on file. Moreover, Article 100(c) EPC is within the framework of the present appeal proceedings

and all the sets of claims on the basis of which the appellant-patentee has requested maintenance of the patent contain amended claims. Additionally, as is evident from the facts and submissions, the patent as granted contains a multitude of independent claims. It is undeniable that one of the main duties of the board is to review the first-instance decision as to its merits, but the fact that the opposition division decided to conduct the oral proceedings on the 13-14 September 2011 in a certain way for reasons of economy and efficiency of the proceedings, and thus decided to focus on one single independent claim (claim 1 for the main request), or one single ground of opposition (novelty for the method claims 6 and 7 of auxiliary request 2) in order to find out whether or not a set of claims failed, does not restrict the framework of the present *inter partes* appeal proceedings to those claims or those reasons which were specifically discussed at the oral proceedings before the opposition division.

Moreover, independent claim 6 of the main request derives from granted claim 31 which was amended in the course of opposition proceedings. Therefore, the board has the power and the duty (Article 114(1) EPC) to assess whether or not independent claim 6 of the main request fails pursuant to grounds under Article 100(c) EPC, in conjunction with Articles 123(2) and 76(1) EPC, since a patent should not be maintained in amended form on the basis of unallowable amendments. Maintaining a patent in appeal proceedings on the basis of unallowable amendments introduced during opposition and/or opposition appeal proceedings would be contrary to the spirit and purpose of the European Patent

Convention (Article 23 RPBA). Thus, a literal interpretation of Article 13(1) RPBA should be avoided in the present case.

Additionally, the appellant-patentee itself cited page 11 of the parent application as filed as the basis for claim 6 of the main request. Therefore, the board must investigate first those cited passages of page 11 before being able to conclude whether or not they represent an allowable basis for the amendments. In doing so the board is not restricted to the reasoning submitted by the parties in writing before the oral proceedings. The oral proceedings may serve to clarify some additional aspects related to the arguments submitted in writing in relation to Articles 123(2) and 76(1) EPC. This preserves the parties' right to be heard (Article 113(1) EPC). Under the circumstances depicted above, artificially restricting the discussion about the allowability of amendments would have deprived the oral proceedings of their meaning, and adjourning the oral proceedings would have made the proceedings interminable. After all, the filing date of the application from which the patent in suit derives is 5 December 1991.

The fact that the appellants-opponents presented orally a more detailed reasoning in relation to Article 123(2) and 76(1) EPC than their reasoning in writing can be easily explained by the high number of independent claims in the main request and the fact that the opposition division focused only on claim 1, ignoring the other claims.

The so-called "new lines of attack" correspond to the necessary discussion of added matter which directly arises when undertaking a comparison between the wording of independent claim 6 of the main request and *inter alia* the text on page 11 of the parent application as filed, cited by the appellant-patentee as being its allowable basis under Article 76(1) EPC. Therefore, the board is convinced that it was to be expected that in the course of the oral proceedings before the board the features and expressions appearing on page 11 of the parent application as filed would have to be compared with the expressions in independent claim 6 of the main request, and thus the appellant-patentee should have been prepared accordingly.

However, the board does not consider that the appellant-patentee has committed an abuse of proceedings by filing the auxiliary requests in the course of the oral proceedings before the board. The question which in fact arises in this *inter partes* appeal case relates to an evaluation of the fairness of the proceedings. The fact that there was a detailed discussion during the oral proceedings before the board in relation to claim 6 of the main request was taken into account when assessing whether the filing of auxiliary requests was justified in the course of the oral proceedings.

1.4 *Admission of auxiliary requests 8C, 8D, 9A''', 9A''''', 9A''''''''*

All these auxiliary requests were filed after the summons to oral proceedings and the board's communication sent as an annex thereto. Auxiliary

requests 8C and 8D were filed with the letter of 24 May 2013, and auxiliary requests 9A''', 9A'''' and 9A'''''' were filed at the oral proceedings before the board. Each claim 1 of these sets of claims incorporates the embodiment relating to the use of a nitric-oxide releasing compound. However, this embodiment was not prosecuted in any of the claims in the sets of claims before the opposition division at the oral proceedings on 13 and 14 December 2011 or in any of the claims of the main request and auxiliary requests filed with the grounds of appeal. Therefore, the filing of auxiliary requests directed to its re-introduction represents a clearly inadmissible amendment to the party's case (Article 13 RPBA).

Moreover, the board's communication sent as an annex to the summons to oral proceedings does not contain any board's direction justifying the filing of such requests (Article 12(1)(c) and 12(2) RPBA). Finally, the reintroduction of an embodiment which was no longer being prosecuted does not represent a valid response to the objections of added matter raised against the use of NO, which was defined as a separate embodiment in claim 31 as granted.

Therefore, auxiliary requests 8C, 8D, 9A''', 9A'''' and 9A'''''' are not admitted into the proceedings.

1.5 *Admission of auxiliary requests 8B and 9A*

Auxiliary request 8B was filed with the letter of 24 May 2013. Claim 1 of said request is identical to independent claim 6 of the main request filed with the letter of 9 December 2011, which was maintained as main

request with the grounds of appeal. Moreover, the fact that claim 1 of auxiliary request 8B differs from claim 1 of auxiliary request 8 filed with the grounds of appeal merely in that the expression "in need thereof" has been deleted does not justify the late filing of auxiliary request 8B since, as already mentioned, the wording of its claim 1 is identical to that of independent claim 6 of the main request. Therefore, this auxiliary request could have been filed earlier, at the latest with the appellant-patentee's reply to the opponents' grounds of appeal (Article 12 RPBA).

Auxiliary request 9A contains one single claim which is identical to claim 1 of auxiliary request 9 in that the expression "in need thereof" has been deleted. Therefore, analogous reasons to those stated above for auxiliary request 8B apply. Moreover, the discussion during the oral proceedings regarding added matter in independent claim 6 of the main request does not justify the filing at oral proceedings of an auxiliary request containing as claim 1 the same claim as claim 6 of the main request, with the only difference that the word "mammal" has been replaced by the word "human".

Therefore, auxiliary requests 8B and 9A are not admitted into the proceedings.

1.6 *Admission of auxiliary requests 9B and 9C*

Auxiliary request 9B was filed with the letter of 24 May 2013 and contains one single claim, which is identical to independent claim 8 of the main request. Therefore, it could have been filed earlier in the

appeal proceedings, at the latest with the appellant-patentee's reply to the opponents' grounds of appeal. However, claim 1 of auxiliary request 9 filed with the grounds of appeal contains only one claim, which derives from independent claim 6 of the main request. Therefore, the appellant-patentee should not get an unwarranted advantage through the late filing, in the course of appeal proceedings, of a large number of auxiliary requests diverging in several directions because the set of claims as granted contained a large number of independent claims.

Analogous comments apply to auxiliary request 9C filed with the letter of 24 May 2013, which contains one single claim, deriving from independent claim 4 of the main request.

Therefore, auxiliary requests 9B and 9C are not admitted into the proceedings.

1.7 *Admission of auxiliary requests 9A', 9A'', 9A''''', 9A''''''', 10 A and 10B*

Auxiliary requests 9A', 9A'', 9A''''', 9A''''''' and 10A were filed in the course of the two-day oral proceedings before the board. In *inter partes* proceedings the right of all parties to fair proceedings and equitable treatment has to be considered. However, even assuming that these auxiliary requests were filed as a reaction to the discussion during the oral proceedings regarding added matter in relation to independent claim 6 of the main request, the appellant-patentee does not have an unlimited right to file amended sets of claims contemplating several

variations and possibilities, but which do not necessarily address the crucial points of the objections raised by the other parties, or which are *prima facie* manifestly unallowable.

Accordingly, auxiliary request 9A' cannot be admitted into the proceedings since it represents only a partial response to the discussion during the oral proceedings before the board, and auxiliary request 9A'' cannot be admitted since claim 1 is *prima facie* unallowable owing to its manifestly unclear wording which makes the claimed improvement dependent on a mode of action (Article 84 EPC).

Auxiliary request 10A cannot be considered to be admissible since it is *prima facie* unallowable for analogous reasons to those given for auxiliary request 9A'' owing to its manifestly unclear wording (Article 84 EPC).

As regards auxiliary request 10B, which was filed on the second day of the oral proceedings before the board, its very late filing was not justified. Its admission would have opened new issues for discussion at such a very late stage of the proceedings and would have caused a need for adjournment. Therefore, auxiliary request 10B was not admitted into the proceedings (Article 13(3) RPBA).

By contrast, auxiliary requests 9A'''' and 9A''''''', which were filed on the first day of the oral proceedings before the board, represent a fair attempt to respond to the crucial points in the discussion of added matter during the oral proceedings before the

board in relation to claim 6 of the main request, which applied *mutatis mutandis* to claim 1 of auxiliary requests 8 and 9.

Moreover, the opponents' objections to independent claim 3 of auxiliary request 2 during the oral proceedings before the opposition division (reflected in point 48 of the minutes of these oral proceedings) were directly applicable to claim 1 of auxiliary request 4 before the opposition division. Additionally, the opposition division's decision does not contain any specific reasoning in relation to claim 1 of auxiliary request 4 other than "The above comments on Article 123(2) and inhalation apply equally". However, a careful reading of the opposition division's decision shows that the references to Article 123(2) EPC and "inhalation" are made in relation either to a claim which is explicitly directed to a particular "gaseous mixture" (pages 5 and 6 of the opposition division's decision) or to claims explicitly containing the feature "inhalable medicament" (pages 7 and 8 of the opposition division's decision) and thus its reasoning cannot be directly applied to claim 1 of auxiliary request 4 before the opposition division. Moreover, it has to be recalled that the decision of the opposition division does not contain any findings in relation to added matter for independent claim 6 of the main request either, which served as basis for claim 1 of auxiliary request 4 before the opposition division.

This lack of completeness and consistency in the opposition division's decision has resulted in the present case in the detailed discussion of added matter regarding claim 6 of the main request, and each claim 1

of auxiliary request 8 (identical to auxiliary request 4 before the opposition division) and auxiliary request 9, both filed with the grounds of appeal, not being possible until the oral proceedings before the board.

Therefore, under its discretionary power the board admits auxiliary requests 9A'''' and 9A'''''' into the proceedings.

2. The patent in suit derives from European patent application 97105021.6, filed as a divisional application of European patent application 92902708.4 which was filed as an international application published as WO 92/10228 (parent application as filed).

2.1 The parent application, which was granted as EP-B1-0560928, underwent opposition proceedings and was revoked by board of appeal decision T 443/01 of 16 November 2004 (same board as the present board in another composition).

2.2 The documents concerning the description and examples as originally filed are identical for the two applications (parent and divisional); the sets of claims of the applications as filed differ from each other.

3. *Main request*

3.1 Claim 1 of the main request, which is identical to claim 17 as granted, is drafted as a first medical use claim since neither the therapy nor the medical condition to be treated is specified. Moreover, claim 1

addresses the medical use of a gaseous mixture containing nitric oxide, oxygen and less than 1 ppm NO₂.

The methods of treatment disclosed in the parent application as filed are those which "are useful for preventing (if given prior to the onset of symptoms) or reversing **acute pulmonary vasoconstriction**, such as **result from** pneumonia, traumatic injury, aspiration or inhalation injury, fat embolism in the lung, acidosis, inflammation of the lung, adult respiratory distress syndrome, acute pulmonary edema, acute mountain sickness, **asthma**, post cardiac surgery acute pulmonary hypertension, persistent pulmonary hypertension of the newborn, perinatal aspiration syndrome", etc., as well as those cases of "chronic **pulmonary vasoconstriction** which have a reversible component, ..." (page 7, lines 20-35) (emphasis added).

Therefore, the medical condition disclosed as treated in the parent application as filed is pulmonary vasoconstriction with different aetiologies.

Moreover, this disclosure on page 7 finishes on top of page 8 and is followed by the specification: "Nitric oxide gas is preferably administered to a **mammal with pulmonary vasoconstriction**, or asthma in accordance with one or more of the following" (page 8, lines 4-6) (emphasis added). Furthermore, the gaseous mixture is defined on page 8, lines 17 to 23, as follows: "the nitric oxide is inhaled as a mixture including nitric oxide, oxygen (O₂), and nitrogen (N₂) gases, ... the concentration of NO₂ is monitored and kept within safe limits (e.g. less than 1 ppm)".

Therefore, there is no basis in the parent application as filed for the use of the gaseous mixture defined in claim 1 of the main request, which goes beyond the treatment of pulmonary vasoconstriction, and there is no basis in the application as filed for the medical use of the gaseous mixture in claim 1, which does not necessarily contain N₂.

Additionally, the list of options given on page 21 for inhaled NO is disclosed under the heading "NO Inhalation Therapy for **Pulmonary Vasoconstriction**". Moreover, what is claimed in claim 1 is the first medical use for a particular gaseous mixture and not the first medical use of NO alone. Therefore, page 21 does not serve as a basis for claim 1 of the main request.

Consequently, claim 1 of the main request contains added matter under Article 100(c) EPC.

3.2 Although the main request fails alone for the reasons given in point 3.1 above, the assessment of independent claim 6 of the main request is also made in view of the fact that it is the subject-matter deriving from this claim which is prosecuted in independent claims present in the auxiliary requests which are admitted into the proceedings.

3.3 Claim 6 of the main request derives from claim 31 as granted. The claim seeks protection for a second medical indication of NO, without any restriction in relation to the mode of administration. Moreover, the claim does not specify any particular disease but refers to the purpose "for improving gas exchange".

Moreover, the claim has to be read in a technically meaningful manner. Therefore, the medical indication addressed concerns the treatment of any "deficits in gas exchange", which encompass also those which are not necessarily attributable to pulmonary vasoconstriction or to bronchoconstriction.

However, the parent application as filed discloses the use of "a source of nitric oxide in the manufacture of a medicament or a device for improving lung function (e.g. to reverse bronchoconstriction, or to facilitate gas exchange within the lung) in a mammal" (page 11, lines 14 to 18). The source of nitric oxide is defined as "a mixture of compressed gases including NO...or any other known source of the chemical NO, so long as it is **delivered to the site within the airways** where it can provide a beneficial effect..." (page 11, lines 19 to 23). Additionally, the passages on page 11 cited above do not provide an allowable basis for improving any gas exchange deficits, but require an improvement of lung function as the technical effect from which the possible facilitation of gas exchange within the lung results.

In fact, there is no basis in the application as filed for the use of NO other than inhaled.

The passage entitled "Pharmacological effect of nitric oxide" on page 23 of the parent application as filed explains: "It is likely that **inhaled NO** acts by diffusing into the vascular space adjacent to the alveoli and causing relaxation of pulmonary vascular smooth muscle, thus permitting an increase in pulmonary

blood flow and gas exchange". The passage further explains that the increases in the patients' blood oxygen levels are achieved by local or selective vasodilation (paragraph bridging pages 23 and 24).

Moreover, the particular patient in the example on pages 38 and 39 of the parent application as filed experiencing improvements in gas exchange had been administered a particular gas mixture of NO and N₂, and the patient was suffering from deficits in gas exchange owing to a very specific aetiology: "This trial demonstrated the utility of nitric oxide in improving gas exchange in this patient with pulmonary hypertension and congenital heart disease" (page 39, lines 31 to 33). Therefore, the examples are not an allowable basis for claim 6 of the main request either.

Therefore, claim 6 of the main request contains added matter within the meaning of Articles 100(c) EPC and 76(1) EPC, since the subject-matter claimed does not derive directly and unambiguously from the parent application as filed.

3.4 Consequently, the main request fails on grounds of added matter (Articles 100(c) and 76(1) EPC).

4. *Auxiliary requests 1, 2 and 3*

Each claim 1 of auxiliary requests 1, 2 and 3 is identical to claim 1 of the main request. Therefore these three auxiliary requests fail since their claim 1 contains added matter under Article 100(c) EPC for the reasons given in paragraph 3.1 above.

5. *Auxiliary requests 4, 5, 6, 7 and 8*

Each independent claim 3 of auxiliary requests 4, 5 and 6, claim 4 of auxiliary request 7, and claim 1 of auxiliary request 8 differ from claim 6 of the main request in that the expression "in need thereof" has been added at the end of the claim.

Therefore, the reasons given in point 3.3 for claim 6 of the main request directly apply, since the fact that the mammal is in need of gas exchange only confirms the technically meaningful reading of claim 6 of the main request explained in point 3.1 above.

Therefore, auxiliary requests 4, 5, 6, 7 and 8 fail since claim 3 (auxiliary requests 4, 5 and 6), claim 4 (auxiliary request 7) or claim 1 (auxiliary request 8), respectively, contain added matter under Articles 100(c) and 76(1) EPC.

6. *Auxiliary request 9*

Claim 1 of auxiliary request 9 differs from claim 3 of auxiliary requests 4, 5 and 6, claim 4 of auxiliary request 7 and claim 1 of auxiliary request 8 merely in that the term "mammal" has been replaced by the term "human". Therefore, the reasons given for the previous requests directly apply to auxiliary request 9.

Consequently, auxiliary request 9 fails since claim 1 contains added matter under Articles 100(c) EPC and 76(1) EPC.

7. *Auxiliary request 9A''''''*

Claim 1 of auxiliary request 9A'''''' seeks protection for a second medical use of NO via inhalation. The medical condition to be treated is not defined in the claim and the technical effect is defined as "for improving lung function by facilitating gas exchange in the lungs of a human". Thus, following a technically meaningful reading of the claim, the medical condition to be treated relates to deficits in lung function which do not have to be the same as deficits in gas exchange, neither from the point of view of the patient's lungs nor from the point of view of the aetiologies. Therefore, the amendments in claim 1 of auxiliary request 9A'''''' extend the protection beyond that conferred by independent claim 31 as granted, from which the claim derives (Article 123(3) EPC).

The fact that the improvement in lung function is attained according to the claim's wording "by facilitating gas exchange in the lungs of a human" may represent a direct response to the objections of added matter (under Article 100(c) EPC) raised in respect of claim 1 of auxiliary request 8 (or claim 6 of the main request), but the allowability of amendments in opposition and opposition appeal proceedings is governed not only by Article 123(2) EPC but also by Article 123(3) EPC.

Consequently, auxiliary request 9a'''''' fails since it contravenes Article 123(3) EPC.

8. *Auxiliary request 9A''''''''''*

Claim 1 of auxiliary request 9'''''' differs from claim 1 of auxiliary request 9 in that the administration is "via inhalation". Therefore, all the arguments concerning the lack of an allowable basis in the parent application as filed for the treatment of deficits in gas exchange, defined independently of their aetiology, directly apply.

Consequently, auxiliary request 9A'''''' fails since it contains added matter under Articles 100(c) and 76(1) EPC.

9. *Auxiliary request 10*

Claim 1 of auxiliary request 10 relates to a second medical use claim in which the definition of the medical condition to be treated is manifestly unclear. Thus, it is unclear whether the claim addresses the treatment of PPHN syndrome exclusively in newborns with a patent ductus arteriosus, or the treatment of deficits in gas exchange which appear in human patients (babies) of undetermined age suffering from persistent pulmonary hypertension originating from PPHN. This lack of clarity hinders the assessment in relation to Articles 123(2) and 76(1) EPC and 123(3) EPC.

Therefore, auxiliary request 10 fails since claim 1 does not meet the requirements of Article 84 EPC.

10. *Auxiliary request 11*

Claim 1 of auxiliary request 11 seeks protection for the use of NO in relation to PPHN without even mentioning that it has to be either a gaseous mixture

containing NO, or inhaled NO. Therefore, for this reason alone, the claim fails. Additionally, all passages cited in which PPHN is mentioned in the parent application as filed concern the treatment of pulmonary vasoconstriction (*inter alia* page 7 and page 21). Therefore, claim 1 contains added matter under Articles 100(c) EPC and 76(1) EPC since it represents an unallowable generalisation.

Additionally, the claim contravenes the requirements of Article 123(3) EPC because the treatment of deficits in gas exchange, caused for instance by lung malfunction, is different from the specific treatment of vasoconstriction in PPHN syndrome, where the newborns have a patent ductus arteriosus. Therefore, the subject-matter claimed in auxiliary request 11 is not necessarily covered by granted claim 31.

Consequently auxiliary request 11 fails (Articles 100(c), 123(2), 76(1) and 123(3) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

N. Maslin

U. Oswald