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**Datasheet for the decision
of 4 March 2008**

Case Number: T 0250/05 - 3.3.02

Application Number: 94912377.2

Publication Number: 0692984

IPC: A61L 9/04

Language of the proceedings: EN

Title of invention:

Systemic effects of nitric oxide inhalation

Patentee:

THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

Opponents:

AIR PRODUCTS AND CHEMICALS, INC.
L'AIR LIQUIDE S.A.

Headword:

Use of nitric oxide for systemic treatment/THE BRIGHAM AND
WOMEN'S HOSPITAL, INC.

Relevant legal provisions:

EPC Art. 100(c), 123, 53, 111(1)
EPC R. 103
Act Revising the EPC, Art. 7, Transitional provisions

Relevant legal provisions (EPC 1973):

EPC Art. 52(4)

Keyword:

"Main request, auxiliary requests 1 to 5 contravene
Article 123 EPC; sixth auxiliary request meets the
requirements of Article 123 EPC"
"Medical indication (yes)"
"Remittal"

Decisions cited:

G 0001/93, G 0005/83

Headnote:

1. When following the principles set out in Enlarged Board of Appeal decision G 001/93 for dealing with the "conflicting requirements of Article 123, paragraphs 2 and 3 EPC" in an amended set of claims, it has to be investigated whether the patent as granted contains subject-matter which extends beyond the content of the application as filed within the meaning of Article 123(2) EPC, which also limits the scope of protection conferred by the patent, and which directly affects the assessment of the amended claims in respect of the requirements of Article 123(2) and (3) EPC (points 2.1 to 2.5 of the reasons for the decision).

2. Apart from the fact that Article 54(5) EPC 2000 (entry into force 13 December 2007) does not apply to a patent granted in 2001, Article 123(3) EPC would not allow the change of category of a granted use claim into a product claim, even if drafted as a purpose-related product claim.

(points 3.4 to 3.6 of the reasons for the decision).



Case Number: T 0250/05 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 4 March 2008

Appellant: AIR PRODUCTS AND CHEMICALS, INC.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
23 December 2004 concerning maintenance of
European patent No. 0692984 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J.-P. Seitz

Summary of Facts and Submissions

- I. European patent application No. EP-0 692 984, based on the application No. 94 912 377.2, which was filed as international patent application WO 94/22499, was granted on the basis of two claims.

Claim 1 as granted read as follows:

"1. Use of gaseous nitric oxide (NO) for the manufacture of a pharmaceutical for the systemic treatment of a medical condition via the inhalation route, the nitric oxide being effective via the systemic circulatory system."

Claim 2 as granted read as follows:

"2. Use according to claim 1, wherein the medical condition is systemic blood platelet aggregation and coagulation or an acute coronary syndrom including angina pectoris."

- II. The following document was cited inter alia during the proceedings:

(4) WO 92/10228

- III. Opposition was filed by opponents I and II and revocation of the patent in its entirety was requested pursuant to Article 100(a), (b) and (c) EPC 1973 on the grounds of lack of novelty, lack of inventive step, insufficiency of disclosure and extension of the subject-matter of the patent beyond the content of the application as filed.

IV. The present appeal lies from the interlocutory decision of the opposition division to maintain the patent in suit in amended form based on the auxiliary request 4 filed during the oral proceedings before the opposition division.

The opposition division considered that the expression "the nitric oxide being effective via the systemic circulatory system" in the claims of the main request (filed with the letter of 16 April 2003), and the term "systemic" in connection with the expression "treatment of an acute coronary syndrome" in claim 2 of auxiliary request 1 had no basis in the application as originally filed (Article 123(2) EPC). Conversely, the opposition division found that claim 2 of auxiliary request 2 contravened Article 123(3) EPC owing to the deletion of the term "systemic".

The opposition division was further of the opinion that "the treatment of systemic blood platelet aggregation and coagulation" could not be considered to indicate a therapeutic application. According to the opposition division's findings, auxiliary request 3 "contravene[d] Article 52 EPC (1973) in conjunction with G 1/83, G 5/83 and G 8/83" (point 4 of the reasons for the decision of the opposition division).

As regards the ground pursuant to Article 100(b) EPC 1973, the opposition division found that the invention was sufficiently disclosed, since methods of administering gaseous nitric oxide were exemplified in the patent in suit and were within the general knowledge of the skilled person.

- Furthermore, the opposition division considered that auxiliary request 4 met the requirements of Articles 123, 54 and 56 EPC.
- V. The patent proprietor (appellant patentee) and the two opponents (appellant opponent I and appellant opponent II) lodged an appeal against the decision of the opposition division. The appellant patentee filed, with the grounds of appeal, a main request and auxiliary requests 1 to 4.
- VI. The summons to oral proceedings was accompanied by a communication, dated 2 October 2007, in which the board made some observations to help concentrate the discussions during the oral proceedings. The board pointed out *inter alia* that the meaning of the expressions used in the claims such as "systemic treatment" and "the nitric oxide being effective via the systemic circulatory system" would have to be discussed. The board also stated its preliminary opinion concerning the request of appellant opponent II for reimbursement of the appeal fee owing to an alleged procedural violation by the opposition division.
- VII. Appellant opponent II announced by letter of 11 October 2007 that it would not be attending the oral proceedings scheduled for 4 March 2008.
- VIII. The appellant patentee filed, as a response to the board's communication, a letter dated 4 February 2008 with further auxiliary requests.

- IX. Appellant opponent II filed with its letter of 12 February 2008 further observations on the appellant patentee's requests.
- X. Oral proceedings took place on 4 March 2008.
- XI. The main request contains only two claims. Claim 1 of the main request read as follows:

"1. Use of gaseous nitric oxide (NO) for the manufacture of a pharmaceutical for the systemic treatment of systemic blood platelet aggregation and coagulation via the inhalation route, the nitric oxide being effective via the systemic circulatory system."

"2. Use of gaseous nitric oxide (NO) for the manufacture of a pharmaceutical for the systemic treatment of an acute coronary syndrome, including angina pectoris, via the inhalation route, the nitric oxide being effective via the systemic circulatory system."

The first auxiliary request contains two claims. These correspond to the two claims of the main request in which the expression "the nitric oxide being effective via the systemic circulatory system" has been deleted.

Claim 1 of the second auxiliary request is identical to claim 1 of the first auxiliary request and claim 2 differs from claim 2 of the first auxiliary request in that the term "systemic" has been deleted before the word "treatment".

Independent claim 2 of the third and fourth auxiliary requests is identical to claim 2 of the second auxiliary request.

The fifth auxiliary request contains a single claim. Claim 1 of the fifth auxiliary request is identical to claim 1 of the main request.

The sixth auxiliary request contains a single claim which differs from claim 1 of the main request in that the expression "the nitric oxide being effective via the systemic circulatory system" has been deleted. Hence, this set of claims differs from the set of claims of the first auxiliary request in that claim 2 has been deleted.

Claim 1 of the sixth auxiliary request reads as follows:

"1. Use of gaseous nitric oxide (NO) for the manufacture of a pharmaceutical for the systemic treatment of systemic blood platelet aggregation and coagulation via the inhalation route."

XII. The appellant opponent's I arguments as far as relevant for the present decision may be summarised as follows:

None of the set of claims met the requirements of Article 123 paragraph 2 and/or paragraph 3 EPC, which were in insoluble conflict with regard to the use of the expressions "the nitric oxide being effective via the systemic circulatory system" in both claims of the patent as granted and "systemic" in connection with the treatment of an acute coronary syndrom[e], including angina pectoris in claim 2 of the patent as granted.

The application as filed disclosed separately in three independent claims the different uses of inhaled nitric oxide (claims 1, 7 and 10). Only claim 1, which dealt with systemic blood platelet aggregation and coagulation, referred to a systemic treatment.

The passage on page 2 of the application as filed referring to the "systemic circulatory system" was not a disclosure of the invention but a citation of the prior art document (4).

Moreover, the expression "systemic treatment" was not defined in the application as filed and had therefore to be understood in its commonly accepted meaning as opposed to "local treatment".

The examples only showed the differences in the bleeding effects; the causative effects were not disclosed. An increased bleeding could not give any technical basis for excluding a platelet deaggregation taking place in the pulmonary circulatory system from a platelet deaggregation taking place in the systemic circulatory system.

Claim 1 of the sixth auxiliary request could not be construed as relating to a medical indication since the systemic blood platelet aggregation and coagulation was a physiological condition. The appellant opponent I cited decision G 5/83 and Article 52(4) EPC 1973. Moreover, it submitted that said expression lacked clarity (Article 84 EPC).

Appellant opponent II further submitted with its grounds of appeal that the appeal fee should be reimbursed owing to a substantial procedural violation by the opposition division when admitting several auxiliary requests during the oral proceedings before the opposition division.

XIII. The appellant patentee's arguments as far as relevant for the present decision may be summarised as follows:

The patent in suit was opposed under Article 100(c) EPC; if it was to be considered that the claims of the patent as granted contained subject-matter extending beyond the content of the application as filed, then the conclusions in decision G 1/93 applied in a situation with conflicting requirements of Article 123(2) and (3) EPC.

The contested feature "the nitric oxide being effective via the systemic circulatory system" was implicitly disclosed in the application as filed. Furthermore, it did not mean that the nitric oxide had to be exclusively effective via the circulatory system. The title "systemic effects of nitric oxide inhalation", appearing at the top of page 1 of the application as filed, formed part of the original disclosure.

This feature might very well limit the scope conferred by the granted patent, but it did not provide a technical contribution and hence it could remain in claim 1 of the main request. Furthermore, its deletion (claim 1 of the sixth auxiliary request) did not contravene Article 123(3) EPC, since it was redundant within the context of that claim.

The application as filed disclosed implicitly that the treatment of an acute coronary syndrom[e], including angina pectoris was systemic. Moreover, if this was denied, the deletion of such a feature had to be allowed. It was not technically meaningful to treat angina pectoris via the pulmonary circulatory system.

Systemic treatment within the context of the invention did not mean treatment of the whole body but treatment via the systemic circulatory system.

Article 84 EPC was not a ground for opposition. Moreover, if there were any ambiguities with regard to the terms employed in the claims, then the patent had to be used as its own dictionary. Literal interpretations of the claims were to be avoided.

Claim 1 of the sixth auxiliary request was in a "Swiss form" in line with decision G 5/83. The treatment of systemic blood platelet aggregation and coagulation was only required if there was a pathological condition. The claim did not encompass normal physiological conditions. The treatment of haemophilia was in contradiction with the content of the patent and hence such an interpretation of the claims' wording was speculative.

- XIV. The appellants opponent I and opponent II (opponent II in writing) requested that the decision under appeal be set aside and that the European patent No. 0692984 be revoked. Opponent II further requested in writing that the appeal fee be reimbursed.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the European patent No. 0692984 be maintained on the basis of his main request filed on 25 April 2005, or of one of the following auxiliary requests: 1 to 4 filed together with the grounds of appeal; 5 to 12(B) filed with letter of 4 February 2008.

Reasons for the Decision

1. *Admissibility*

The present appeal is admissible.

2. *Article 123, paragraphs 2 and 3, EPC*

2.1 The patent in suit has been opposed by both opponents as including subject-matter which extends beyond the content of the application as filed (ground for opposition under Article 100(c) EPC).

The appellant patentee does not request the maintenance of the patent as granted but it has invoked Enlarged Board of Appeal decision G 1/93, OJ EPO 1994, 541, dealing with the "conflicting requirements of Article 123, paragraphs 2 and 3, EPC", for the amended set of claims of the main request and the auxiliary requests.

Decision G 1/93 states in the Order:

"1. If a European **patent as granted** contains subject-matter which extends beyond the content of the

application as filed within the meaning of Article 123(2) EPC and which **also limits the scope of protection conferred by the patent**, such patent cannot be maintained in opposition proceedings unamended, because the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent. Nor can it be amended by deleting such limiting subject-matter from the claims, because such amendment would extend the protection conferred, which is prohibited by Article 123(3) EPC. Such a patent can, therefore, only be maintained if there is a basis in the application as filed **for replacing such subject-matter without violating Article 123(3) EPC.** (*emphasis added*)

2. A feature which has not been disclosed in the application as filed but which has been added to the application during examination and which, without providing a technical contribution to the subject-matter of the claimed invention, merely limits the protection conferred by the patent as granted by excluding protection for part of the subject-matter of the claimed invention as covered by the application as filed, is not to be considered as subject-matter which extends beyond the content of the application as filed within the meaning of Article 123(2) EPC. The ground for opposition under Article 100(c) EPC therefore does not prejudice the maintenance of a European patent which includes such a feature."

2.2 Therefore it has to be investigated whether the patent as granted contains subject-matter which extends beyond the content of the application as filed within the meaning of Article 123(2) EPC, which also limits the scope of protection conferred by the patent, and which

directly affects the assessment of the amended claims in respect of the requirements of Article 123(2) and (3) EPC.

- 2.3 It is an undisputed fact that the feature "the nitric oxide being effective via the systemic circulatory system", which is present in claim 1 as granted, was not explicitly disclosed in the application as filed.

The only reference to the systemic circulatory system appears on page 2 of the application as filed, in connection with a reference to the prior art document (4) and the medical uses of nitric oxide (NO) disclosed in said prior art: "These investigators characterize the mammalian circulatory system as consisting of two separate circuits, the systemic circuit and the pulmonary circuit which are controlled by opposite sides of the heart. They report that (since NO gas which enters the bloodstream is rapidly inactivated by combination with haemoglobin) the bronchodilatory effects of inhaled NO are limited to the ventilated bronchi and the vasodilatory effects of inhaled NO are limited to those blood vessels near the site of NO passage into the blood stream: i.e. pulmonary microvessels".

Nor can the feature "the nitric oxide being effective via the systemic circulatory system" be considered to be implicitly disclosed in the application as filed.

The only relevant passage in the application as filed acknowledges that "when platelets pass the pulmonary circulation they could vary [*sic*] well absorb some of the inhaled NO" and states that "an additional

mechanism" is needed for the anticoagulant effect shown in the bleeding tests (bridging paragraph pages 12 and 13). The last sentence of the above-mentioned paragraph reads: "Inhalation of NO must increase a pool of NO or NO releasing compounds in blood, that can release NO slowly for many minutes after NO inhalation has been stopped".

Furthermore, the independent claims of the application as filed relate to separate specific treatments such as "treatment of systemic blood platelet aggregation and coagulation" (claim 1 as originally filed), treatment of acute coronary syndromes including angina pectoris (claim 7 as originally filed), and treatment of acute respiratory syndrome (claim 10 as originally filed).

However, claim 1 as granted, which is formulated as a second medical use claim in the "Swiss form", relates to the treatment of "a medical condition".

Hence, there is no disclosure in the application as filed for the treatment of "a medical condition" by means of "the nitric oxide being effective via the systemic circulatory system".

- 2.4 Additionally, neither the expression "systemic treatment" nor the administration route ("via the inhalation route") delimits the indefinite expression "medical condition" in claim 1 as granted. The fact that the treatment is defined as "systemic treatment" (affecting not only the administration locus but the whole body) merely serves to differentiate it from an exclusively local treatment, affecting the administration locus.

2.5 Therefore, the disputed feature "the nitric oxide being effective via the systemic circulatory system" clearly imposes on the subject-matter claimed in claim 1 as granted an additional condition which serves to exclude from the claim the treatment of medical conditions in which the nitric oxide is effective exclusively via the pulmonary circulatory system.

Consequently, the said feature imposes a technically meaningful limitation on the scope of the patent as granted. Hence, the conclusions set out in point 1 of the Order of decision G 1/93, apply directly to the present case. Correspondingly, the patent cannot be maintained unamended **and** the patent can only be maintained if there is a basis in the application as filed **for replacing** such subject-matter without violating Article 123(3) EPC.

2.6 The sixth auxiliary request (which contains only one claim) meets both prerequisites.

A comparison between claim 1 as granted and claim 1 of the sixth auxiliary request immediately shows that the treatment, defined in claim 1 as granted as "treatment of a medical condition", with "the nitric oxide being effective via the systemic circulatory system", has been replaced in claim 1 of the sixth auxiliary request by "the treatment of systemic blood platelet aggregation and coagulation".

The specification of the treatment as "the treatment of systemic blood platelet aggregation and coagulation" finds a basis in claim 1 of the application as filed,

as well as on pages 4 and 5. Hence, the requirements of Article 123(2) EPC are met.

With the restriction of the medical condition to be treated the scope claimed does not extend the protection conferred by the granted patent.

Additionally, the expression "the nitric oxide being effective via the systemic circulatory system", employed in claim 1 as granted, does not require the nitric oxide to act exclusively in the systemic circulatory system; it requires the inhaled gaseous nitric oxide to cause effects which are not restricted to the pulmonary circulatory system.

Hence, the deletion of the said expression in the amended claim 1 of the sixth auxiliary request does not lead to an extension of the scope of protection, since in order to achieve "the systemic treatment of systemic blood platelet aggregation and coagulation" with inhaled gaseous nitric oxide, the systemic circulatory system has to be involved.

Consequently, claim 1 of the sixth auxiliary request does not contravene Article 123(3) EPC.

- 2.7 The main request and the fifth auxiliary request fail because claim 1 of both requests still contains the feature "the nitric oxide being effective via the systemic circulatory system" (Article 123(2) EPC).

The basis provided by the paragraph bridging pages 12 and 13, mentioned in point 2.3 above, which refers to "an additional mechanism", is insufficient for

unambiguously identifying such mechanism as "the nitric oxide has to be effective via the systemic circulatory system". Furthermore, even considering the statement that inhalation of nitric oxide "must release a pool of NO or NO releasing compounds in blood" (page 13 of the application as filed), it is not mandatory that the nitric oxide is effective in the systemic circulatory system.

Even if the title on the top of page 1 is considered to form part of the application as filed, it merely announces that the description deals with the subject of "systemic effects of nitric oxide inhalation"; thus it can hardly be taken as an acceptable basis for the contested amendment.

Hence, claim 1 of the main request and the fifth auxiliary request does not meet the requirements of Article 123(2) EPC.

2.8 Moreover, this disputed feature provides a technical contribution to the subject-matter of the patent in suit (this has been shown by the analysis made in points 2.2 to 2.7 above), namely that a medical condition can be treated systemically with inhaled nitric oxide owing to systemic effects (in contrast to local effects) mediated via the systemic circulatory system. Hence, the conclusions set out in point 2 of the Order of decision G 1/93 do not apply to the present situation.

The fact that the disputed feature may become redundant within the specific context of the amended claim of the main request only underlines the need for deletion of a

technically meaningful feature which has not been disclosed in the application as filed. This has been done in claim 1 of the sixth auxiliary request, which has been found to be allowable under Article 123 EPC.

- 2.9 Claim 1 of the first auxiliary request is identical to claim 1 of the sixth auxiliary request, which has been found allowable under Article 123 EPC (see point 2.6 above). Hence, independent claim 2 of the first auxiliary request has to be investigated in respect of the requirements of Article 123(2) and (3) EPC.

Claim 2 of the first auxiliary request reads as follows:

"2. Use of gaseous nitric oxide (NO) for the manufacture of a pharmaceutical for the **systemic** treatment of an acute coronary syndrome, including angina pectoris, via the inhalation route." (emphasis added)

It is undisputed that the application as filed does not explicitly disclose "the **systemic** treatment of an acute coronary syndrome, including angina pectoris".

This feature "systemic treatment" in connection with the particular medical condition "acute coronary syndrome, including angina pectoris" appears in the set of claims as granted, since granted claim 2 is dependent on claim 1 as granted.

However, such a combination cannot be unambiguously derived from the application as filed, since the treatment of the medical conditions appearing in independent claim 7 was not specified as "systemic", in

contrast to the treatment of the medical conditions specified in claim 1 as filed. Additionally, claim 7 of the application as filed is in accordance with the corresponding passage in the disclosure, which states without any mention of a "systemic treatment" or of systemic effects that: "Another aspect relates to a method for the prevention or treatment of angina pectoris and other unstable syndromes..." (page 5 of the application as filed).

Finally, not all the treatments listed in the description and the claims of the application as originally filed are "systemic" treatments (see treatment of acute respiratory distress syndrome (ARDS) on page 5 and claim 10).

Hence, claim 2 as granted contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

2.10 Decision G 1/93 (conflicting requirements of Article 123, paragraphs 2 and 3) has also to be considered for the assessment of amended claim 2 taking an approach analogous to that followed in the assessment of claim 1 as granted and amended claim 1 in points 2.1 to 2.8 above.

The specification of the treatment as "systemic" represents a technically meaningful limitation of the scope of protection conferred by the patent, since it introduces a differentiation between "systemic" treatment (affecting the whole body) and "local" treatment (affecting the administration locus). In the context of the uses claimed the term "systemic"

establishes a difference between the treatment of an acute coronary syndrome, including angina pectoris, mediated by (local) effects at the administration locus and the treatment mediated by systemic effects.

Therefore, the disputed feature provides a technical contribution and cannot remain in the amended claim without contravention of Article 123(2) EPC.

Correspondingly, claim 2 of the first auxiliary request contravenes Article 123(2) EPC.

2.11 As regards claim 2 of the auxiliary requests 2 to 4 the following conclusions emerge. Considering the analysis made in points 2.9 and 2.10 above, it becomes evident that the deletion of the technically meaningful feature "systemic" (treatment) from claim 2 contravenes Article 123(3) EPC. This undisclosed, technically meaningful, feature has not been replaced in the amended claim by a more delimiting feature.

Hence, the scope of amended claim 2 in the auxiliary requests 2 to 4, which concerns the "treatment of an acute coronary syndrome, including angina pectoris", is broader than that of the granted claims.

Consequently, the second, third and fourth auxiliary requests fail because the requirements of Article 123(3) EPC are not met.

2.12 Finally, the appellant patentee's arguments that it is mandatory in the patent in suit that the "systemic treatment" of a medical condition results in "the nitric oxide being effective via the systemic

circulatory system" do not hold, since there is no disclosure whatsoever in the application as filed that the systemic treatment with inhaled nitric oxide necessarily excludes "the nitric oxide being effective via the pulmonary circulatory system".

3. *Objections raised under Article 52(4) EPC 1973 and Article 84 EPC against claim 1 of the sixth auxiliary request*

3.1 Appellant opponent I has objected to claim 1 of the sixth auxiliary request for lack of clarity (Article 84 EPC) in view of the use of the expression "treatment of systemic blood platelet aggregation and coagulation" in a second medical use claim.

However, this objection is not admissible since the said expression was already employed in granted claim 2 within an analogous context, and Article 84 EPC is not a ground for opposition.

3.2 The opposition division considered that the "Swiss form" in the only claim of the sixth auxiliary request (filed as third auxiliary request during the oral proceedings before the opposition division) was not allowable. The opposition division referred to Article 52 EPC 1973, and reasoned that "the treatment of systemic blood platelet aggregation and coagulation" was not a medical indication within the meaning of G 5/83, OJ EPO 1985, 64.

In appeal proceedings, appellant opponent I shared the opposition division's view and objected to claim 1 of the sixth auxiliary request as not being an appropriate

second medical use claim in "Swiss form"; it also cited Article 52(4) EPC 1973.

3.3 Having regard to the fact that the patent in suit was granted on 19 September 2001 and the European Patent Convention 2000 entered into force on 13 December 2007, the transitional provisions apply.

3.4 Article 7 of the Act revising the EPC of 29 November 2000 relates to the transitional provisions and reads: "(1) The revised version of the Convention shall apply to all European patent applications filed after its entry into force, as well as to all patents granted in respect of such applications. It shall not apply to European patents already granted at the time of its entry into force, or to European patent applications pending at that time, unless otherwise decided by the Administration Council of the European Patent Organisation" (OJ EPO 2007, Special edition No. 1, 196).

The "Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000" (OJ EPO 2007, Special Edition No. 1, 197) states in its Article 1 (points 1 and 3):

"1. Articles 14(3) to (6), 51, 52, 53, 54(3) and (4), 61, 67, 68 and 69, the Protocol on the Interpretation of Article 69, and Articles 70, 86, 88, 90, 92, 93, 94, 97, 98, 106, 108, 110, 115, 117, 119, 120, 123, 124, 127, 128, 129, 133, 135, 137 and 141 shall apply to European patent applications pending at the time of their entry into force and to European patents already granted at that time. However, Article 54(4) of the

version of the Conversion in force before that time shall continue to apply to these applications and patents".

"3. Article 54(5) shall apply to European patent applications pending **at the time of its entry into force, in so far as a decision on the grant of the patent has not yet been taken**" (emphasis added).

3.5 The patent in suit was granted with only two claims, both drafted as second medical use claims in a "Swiss form".

3.6 Hence, apart from the fact that Article 54(5) EPC 2000 (entry into force 13 December 2007) does not apply to a patent granted in 2001, Article 123(3) EPC would not allow the change of category of a granted use claim into a product claim, even if drafted as a purpose-related product claim.

Therefore, in the present case, amended claims have to remain in the "Swiss form" in order not to contravene Article 123(3) EPC.

As regards the exclusion from patentability of methods of treatment of the human or animal body pursuant to Article 52(4) EPC 1973, Article 53(c) (exceptions to patentability) of the revised European Patent Convention 2000 applies.

3.7 The opposition division's reasoning that "the treatment of systemic blood platelet aggregation and coagulation" does not concern a medical indication, because these are physiological phenomena in the naturally occurring

wound healing process, does indeed relate to a concern about the clarity of the claim's wording.

However, as established in point 3.1 above, objections dealing with the clarity of the contested term are not admissible in the present case, since the said expression was already employed in granted claim 2 within an analogous context and Article 84 EPC is not a ground for opposition.

- 3.8 As stated in Article 69(1) EPC, the extent of protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims (see also the Protocol on the Interpretation of Article 69 EPC of 5 October 1973, revised by the Act revising the EPC of 29 November 2000).

Hence, the wording used in the claims may be construed in the light of the description for resolving any possible ambiguity of the claims.

- 3.9 Claim 1 of the sixth auxiliary request has been drafted in a "Swiss form". This claim relates to:

- (a) The use of **gaseous nitric oxide (NO)** (gaseous nitric oxide is the active drug)

- (b) for the manufacture of **a pharmaceutical** (the word "medicament" is not employed in this particular context because the inhaled gaseous nitric oxide itself is the medicament)

- (c) for the **systemic treatment of systemic blood platelet aggregation and coagulation**

- (d) **via the inhalation route** (route of administration is specified; as a consequence the active drug/medicament is "inhaled gaseous nitric oxide").

This claim wording was rejected by the opposition division, which considered feature (c) to relate to a physiological condition and not to a medical indication. Therefore, in view of the analysis made in points 3.2 and 3.6-3.8 above, the description has to be employed for the purpose of resolving any ambiguity caused by the wording.

Paragraph [0005] of the granted patent reads as follows: "In accordance with the present invention, it has been discovered for the first time that nitric oxide is effective to prevent or treat both systemic and pulmonary emboli, effect systemic platelet deaggregation and is also effective as systemic anticoagulant".

Paragraph [0007] of the granted patent: "Thus, in one aspect the invention relates to a method for the prevention or treatment of both systemic and pulmonary emboli, for preventing and reversing platelet aggregation and for anticoagulant therapy...".

The examples of the patent in suit, which concern bleeding experiments after inhalation of gaseous nitric oxide, further support these anticoagulant effects.

Therefore, the feature (c) addresses the treatment of those medical conditions which require preventive and/or therapeutic treatments by means of platelet deaggregation and anticoagulation.

Correspondingly, the claim is correctly drafted in a form which is in accordance with the "Swiss form" according to decision G 5/83. Owing to this legal fiction, the claimed subject-matter does not encompass methods of treatment of the human or animal body. Hence, the claimed subject-matter is not excluded from (or, according to EPC 2000, does not concern any exception of) patentability.

- 3.10 The submission of appellant opponent I, that the said claim could also encompass the treatment of haemophilia is not sustainable, since such an interpretation rests on a pure speculation which contradicts the disclosure of the patent in suit and finds no support in the skilled person's general knowledge about nitric oxide.

4. *Remittal*

The decision under appeal rejected the (now) sixth auxiliary request (filed as third auxiliary request during the oral proceedings before the opposition division) as not allowable for formal reasons.

Therefore, the subject-matter claimed in said request was not investigated by the opposition division with regard to the grounds of opposition pursuant to Article 100(a) EPC (novelty and inventive step).

Appellant opponent I requested, at the oral proceedings before the board of appeal, remittal to the department of first instance. In particular, appellant opponent I submitted that, owing to the parties' dispute regarding the wording of the claim, it was not in a position to argue the novelty issue, particularly with regard to the ARDS syndrom[e], before knowing the reasoning pertaining to the formal matters previously addressed during the oral proceedings.

Under these circumstances the board considers it appropriate to allow the subject-matter of the claim of the sixth auxiliary request to be considered by two instances with regard to the substantive issues of novelty and inventive step (Articles 54 and 56 EPC).

Consequently, the board uses its discretion under Article 111(1) EPC by remitting the case to the opposition division for further prosecution on the basis of the claim of the sixth auxiliary request.

5. *Reimbursement of appeal fees*

Appellant opponent II requested with its grounds of appeal the reimbursement of the appeal fee in view of an alleged substantial procedural violation by the opposition division (Rule 67 EPC 1973, Rule 103(1)(a) EPC 2000).

Rule 103(1)(a) EPC 2000 provides for the reimbursement of appeal fees in the event of interlocutory revision or where the board of appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation.

The opposition division admitted into the proceedings an amended set of claims after a pause for deliberation. However, until the debate is not closed at oral proceedings and a formal decision is not announced, it is at the discretion of the opposition division to admit further requests, since the matter is still pending before it.

Therefore, the opposition division did not commit any substantial procedural violation in the decision underlying the present appeal, but made normal use of its discretionary power.

Therefore the appeal fee of appellant opponent II is not to be reimbursed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside
2. The case is remitted to the first instance for further prosecution on the basis of the sixth auxiliary request filed with the letter dated 4 February 2008.

The Registrar

The Chairman

N. Maslin

U. Oswald