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Datasheet for the decision of 30 November 2011

Case Number: T 0690/10 - 3.3.02

Application Number: 02769517.0

Publication Number: 1399147

IPC: A61K 31/28

Language of the proceedings: EN

Title of invention:
Therapeutic delivery of carbon monoxide

Applicant:
Hemocorm Limited

Headword:
Delivery of carbon monoxide/HEMOCORM

Relevant legal provisions:
PCT Art. 17(3)(a)
EPC Art. 153(6)
EPC R. 164(2)

Relevant legal provisions (EPC 1973):
EPC R. 112, 30

Keyword:
"Unity of set of claims as originally filed (no)"
"Unsearched subject-matter claimed (yes)"

Decisions cited:
-

Catchword:
-

Case Number: T 0690/10 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 30 November 2011

Appellant: (Applicant)
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 14 October 2009 refusing European patent application No. 02769517.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
L. Bühler

Summary of Facts and Submissions

I. International application No. WO 2002/092075, filed as PCT/GB2002/02268, was refused as European patent application No. 02 769 517.0 by a decision of the examining division on the basis of Rules 164(2) and 64(1) EPC, pronounced at oral proceedings on 22 September 2009 and posted on 14 October 2009.

II. The relevant claims 1 and 2 as originally filed read:

"1. A pharmaceutical composition, for delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound or pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable carrier, wherein the metal carbonyl makes available CO suitable for physiological effect by at least one of the following means:

1) CO derived by dissociation of the metal carbonyl is present in the composition in dissolved form;
2) on contact with a solvent the metal carbonyl releases CO;
3) on contact with a tissue, organ or cell the metal carbonyl releases CO;
4) on irradiation the metal carbonyl releases CO.

2. A pharmaceutical composition according to claim 1, wherein the metal carbonyl compound is a complex of at least one of Fe, Mn, Ru, Rh, Ni, Mo or Co with at least one carbonyl ligand."

III. The documents cited during proceedings before the examining division and the board of appeal included the following:

(3) US—A-5 882 674.

IV. In its communication dated 15 July 2003, the European Patent Office, acting as International Searching Authority (ISA), invited the applicant pursuant to Article 17(3)(a) and Rule 40.1 PCT to pay seven additional search fees.

The ISA found that the subject-matter of the present application concerned compounds, in particular metal carbonyl compounds, releasing carbon monoxide in organisms to increase the CO-concentration and their use in therapy. Such compounds were already disclosed in document (3) (see page 2 of the extra sheet to this communication, lines 6 to 25).

V. Hence, the ISA considered that claim 1 constituted eight different inventions (seven classes of CO-containing metal-complex compounds and one invention concerning formate- or oxalate-derivatives):

1. Claims: 1—17 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Fe, and their therapeutic uses. Compound of the formula $M(CO)_xA_yB_z$ where M is Fe.

2. Claims: 1–16 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Mn, and their therapeutic uses.

3. Claims: 1–17 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Ru, and their therapeutic uses. Compound of the formula $M(CO)_xA_yB_z$ where M is Ru.

4. Claims: 1–16 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Rh, and their therapeutic uses.

5. Claims: 1–16 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Ni, and their therapeutic uses.

6. Claims: 1–16 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Mo, and their therapeutic uses.

7. Claims: 1–17 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal

carbonyl compound wherein the metal is Co, and their therapeutic uses. Compound of the formula $M(CO)_xA_yB_z$ where M is Co.

8. Claims: 18—20
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a formic acid, a formate, a formate ester or amide, an oxalate or an oxalate ester or amide, and their therapeutic uses.

VI. Consequently, the ISA searched only the first of these inventions which was set out in the "Invitation to pay additional fees" (see page 3 of the extra sheet to the communication, end of first paragraph). This invention related to pharmaceutical compositions for the delivery of carbon monoxide to a physiological target comprising the metal Fe, and the therapeutic uses of these compositions.

VII. After entry into the regional phase, the examining division of the European Patent Office in its first communication, dated 14 May 2004, confirmed the lack of unity objection raised by the ISA and asked the applicant whether it wished to obtain a European search report for the other inventions under Rule 112 EPC 1973. If it did, the examining division informed the applicant that it would be required to indicate on which invention it wished further prosecution of the application to be based, and to limit the application accordingly.

In response to this communication, the applicant filed a new set of claims with its letter dated 5 July 2004

and paid one additional search fee to have a search performed on these claims. As a consequence, with respect to the actual objection of lack of unity referring to the application as originally filed, there was still no indication as to the invention to which the additional search should be directed.

A second communication was issued by the examining division on 12 July 2005 stating that the applicant could not amend the application at this stage. The examining division further asked the applicant to indicate on which of the inventions as identified in the annex accompanying the communication under Rule 112 EPC 1973 the additional search should be performed.

In reply to this communication, the applicant requested the refund of the search fee and asked that examination be started on the set of claims filed on 5 July 2004. Arguments in support of unity of invention were also provided.

In its third communication, issued on 8 November 2005, the examining division again confirmed the lack of unity of the application as filed and asked the applicant to restrict the application to the invention searched (the first invention). The opinion of the Enlarged Board of Appeal G 2/92 of 6 July 1993 (OJ EPO 1993, 591) in connection with Rule 112 EPC 1973 was cited (see page 3 of the communication, first paragraph).

The applicant replied by a letter dated 31 July 2006, filed a new set of claims and presented arguments for

unity of invention and to the effect that the amended claims did not relate to unsearched matter.

A fourth communication was issued by the examining division on 8 February 2007. Since the last set of claims still contained unsearched subject-matter, this set of claims had been considered as inadmissible on the basis of Rules 46(1) and 112 EPC 1973 in conjunction with opinion G 2/92. The examining division again requested the applicant to limit the application to the invention searched.

In reply to this communication, the applicant, by letter dated 14 August 2007, expressed its point of view that the last set of claims did not relate to unsearched subject-matter which did not combine with the originally claimed invention or group of inventions to form a single general inventive concept, and explained why opinion G 2/92 did not apply in the present case. It further maintained that the application as filed was unitary. The claims were still not restricted to the only invention searched.

The summons to attend oral proceedings was sent out on 9 April 2009. In the accompanying communication, the examining division again expressed its point of view that the last set of claims (filed with the letter dated 31 July 2006) was inadmissible on the basis of Rules 164(2) EPC (corresponding to Rule 112 EPC 1973) and Rule 64(1) EPC (corresponding to Rule 46(1) EPC 1973). The "special technical feature" serving as the single general inventive concept of the application as originally filed was the use of a metal carbonyl to deliver CO with physiological effect.

However, since compounds capable of releasing carbon monoxide, including those of formula $M(CO)_xA_y$, had already been disclosed for the therapeutic delivery of CO in the state of the art, this concept was not new and could not constitute the "special technical feature" which made a contribution over the prior art.

Therefore, the finding of lack of unity as set out in the ISA's communication and the consequence, i.e. that only the first invention was searched, was to be confirmed (see point 2 of the examining division's communication).

Accordingly, the examining division invited the appellant to "limit the application to the invention covered by the International Search Report".

By letter of 21 August 2009, the appellant confirmed its main request of 31 July 2006 and filed three further requests, and by letter dated 7 September 2009 it informed the examining division that it withdrew its request for oral proceedings.

Nevertheless, the examining division held oral proceedings on 22 September 2009. Nobody appeared for the applicant.

Consequently, the examining division decided to reject the patent application, because the sets of claims as defined by letter of 21 August 2009 did not comply with the requirements of Rule 164(2) and Rule 64(1) EPC (see page 9 of the decision).

VIII. The appellant lodged an appeal against the decision of the examining division and filed grounds of appeal together with copies of the main request and auxiliary requests 1 to 3 already on file, now in the form of copies dated 22 February 2010 and received in the Office on 23 February 2010.

Claim 1 of the main request (identical to claim 1 as filed with letter of 31 July 2006 and confirmed as claim 1 of the main request in the letter of 21 August 2009) reads:

"Use, in manufacture of medicament for the stimulation of neurotransmission or vasodilation by CO as a physiologically effective agent, or for the treatment of hypertension, transplant rejection, post-ischemic organ damage, myocardial infarction, angina, penile erectile dysfunction or adult respiratory distress syndrome of a metal carbonyl compound or a pharmaceutically acceptable salt thereof, wherein the metal carbonyl compound in the medicament makes available CO for physiological effect and is

a compound of the formula $M(CO)_xA_y$ wherein x is at least 1, y is at least 1, M is a metal, the or each A is an atom or group bonded to M by an ionic, covalent or coordination bond and in the case where y > 1 each A may be the same or different, and each A is a ligand which is a halide or has N, P, O or S as the coordinating atom and is selected from: sulfoxides, amino acids and their salts, amines, bi-2-2'-pyridyl, indole, pyrimidine, cytidine, 2-(5'-hydroxymethyl-2'-furyl)-1-benzylindazole, thiols, thiolates, chloride, bromide and iodide, carboxylates,

ethers, alcohols, nitriles, conjugated carbon groups, and biliverdin and bilirubin,
excluding metal carbonyl complexes containing NO."

In claim 1 of auxiliary request 1 (identical to claim 1 of auxiliary request 1 filed with letter of 21 August 2009), with respect to claim 1 of the main request specific ligands A are deleted, namely amines, conjugated carbon groups, and biliverdin and bilirubin.

In claim 1 of auxiliary request 2, in addition, the following text is added:

", and wherein the medicament is adapted for administration by an oral, intravenous, subcutaneous, nasal, inhalatory, intramuscular, intraperitoneal or suppository route."

Claim 1 of auxiliary request 3 reads:

"A method of treatment of a viable mammalian organ extracorporeally during storage and/or transport of an organ for transplant surgery comprising contacting the organ with a metal carbonyl, wherein the metal carbonyl makes available CO suitable for physiological effect."

Claims 1 of the main request and all auxiliary requests are identical to the claims 1 as decided on by the examining division.

IX. Oral proceedings took place on 30 November 2011 in the absence of the appellant's representative, as indicated in its letter of 28 October 2011.

X. The appellant's arguments in the written procedure may be summarised as follows:

The objection of non-unity by the examining division was not correct at all and not correct in particular with respect to the inventions as set out in the International Search Report.

In particular, it seemed unlikely that the current non-unity objection with respect to seven different metals in the metal carbonyl compound would have occurred if claim 2 had not existed.

Additionally, the definition of the invention as provided in claims 1 to 20 of the present application was deemed to be sufficiently specific to allow a search to be carried out for these claims without undue effort from the ISA.

Payment of additional search fees to the European Patent Office (as International Search Authority) was not an attractive option and, consequently, an applicant was entitled to amend claims in such a way that unsearched matter was included.

XI. The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of the sets of claims of the main request, alternatively the auxiliary requests 1 to 3 as filed with the statement of grounds of appeal received on 23 February 2010.

Reasons for the Decision

1. The appeal is admissible.

2. The decision under appeal as pronounced at oral proceedings of 22 September 2009 basically relies on the objection that the sets of claims of the main request and of the auxiliary requests 1 to 3 were not allowable under Rule 164(2) EPC, which followed from a non-unity objection under Article 17(3)(a) PCT in the International Search Report concerning the claims as originally filed (see point III of the decision of the examining division in conjunction with its points 1.1 and 1.7.6).

Rule 64(1) EPC is mentioned in addition; its provisions were not fulfilled either.

Article 17(3)(a) PCT is applicable as amended on 3 October 2001, Rules 13.1 und 40.1 PCT in accordance with the regulations of the PCT, having entered into force on 1 April 2002.

With respect to the EPC and the International Search Report, the current appeal is to be treated under Article 153(6) EPC 2000 which - under the transitional provisions for the EPC 2000 revision - is to be applied to international applications pending at the time of entry into force of the EPC 2000 on 13 December 2007.

Therefore, with regard to the date of the decision of the examining division and to the date of the present decision, the provisions of the EPC 2000 and the Implementing Regulations as adopted by decision of the

Administrative Council of the European Patent Organisation of 7 December 2006 were in force (see thirteenth edition of the EPC, published in July 2007).

However, Rule 112 EPC 1973 applied to the application before 13 December 2007. During that time, all procedural steps required by said rule were fulfilled in the written proceedings. The appellant had been invited to pay additional search fees which finally have not been paid as result of the appellant's request for refund of the originally paid fee, which was then reimbursed by the Office. Thus, no right of the appellant resulting from originally processing the case under EPC 1973 was lost, the procedural situation was perfectly clear and everything had been done by the examining division pursuant to the EPC applicable at that time; only the requested oral proceedings were to be held and the decision was to be taken.

Starting from 13 December 2007, EPC 2000 was in force and, under the transitional provisions, Rule 164(2) EPC applied. Accordingly, the examining division in citing Rule 164(2) EPC set out in its annex to the summons that the appellant had to "limit the application to the invention covered by the International Search Report".

By letter of 21 August 2009, i.e. after 13 December 2007, the appellant confirmed its main request filed with letter of 31 July 2006 and filed three further requests.

Thus, all necessary procedural acts by the EPO required pursuant to Rule 164(2) EPC were also fulfilled, and the decision was to be taken on the basis of this rule.

More recent amendments of Rule 164 EPC (CA/D 20/09 of 27 October 2009, OJ EPO 2009, 582) as printed in the fourteenth edition of the EPC, published in 2010, are not pertinent because they entered into force in 2010 and because they are to be applied to applications for which the (Supplementary) Search Report was drawn up after 1 April 2010.

3. *Unity objection with respect to the application as originally filed*

3.1 Article 82 EPC 1973 (which was not amended in the EPC 2000 revision) deals with the requirement of unity of invention and states the principle that a European patent application should relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Rule 30 EPC 1973 (in comparison to which no substantive amendments were made in the corresponding provision of the EPC 2000, i.e. Rule 44) defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in a European patent application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features". The expression "special technical features" is defined in Rule 30 EPC 1973 as meaning those features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Claim 2 of the application as originally filed constitutes seven equal embodiments representing a

group of inventions which supposedly involve one or more of the same or corresponding "special technical features" defining a contribution which each of the inventions, considered as a whole, makes over the prior art in order to establish a technical relationship that guarantees unity of the application.

Firstly, the "special technical features" that this group of inventions can involve are all or scope of the features of claim 1, because this claim 1 includes the subject-matter of claim 2.

The subject-matter of claim 1 relates to

a pharmaceutical composition,

for delivery of carbon monoxide to a physiological target,

comprising a metal carbonyl compound or pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable carrier,

wherein the metal carbonyl makes available CO suitable for physiological effect

by at least one of the following means:

1) CO derived by dissociation of the metal carbonyl is present in the composition in dissolved form;
2) on contact with a solvent the metal carbonyl releases CO ;
3) on contact with a tissue, organ or cell the metal carbonyl releases CO ;

4) on irradiation the metal carbonyl releases CO.

In the description, it is stressed that "the ligands to the metal may all be carbonyl ligands, as e.g. in $[Mn_2(CO)_{10}]$" (see page 10, lines 18 to 19), which means that such metal carbonyl compounds, including e.g. iron pentacarbonyl, must make available CO suitable for physiological effect by at least one of the means as defined under points 1 to 4 in claim 1, which is part of the common general knowledge of a chemist.

Secondly, there could be a common feature within claim 2 representing the "special technical feature" unifying the seven teachings concerning seven metals, which is not set out explicitly in this context, for instance a teaching relating to the use of a **transition** metal carbonyl to deliver CO with physiological effect.

Document (3) discloses

a pharmaceutical composition (see claim 6 in combination with claim 1),

for delivery of carbon monoxide to a physiological target (see claim 1),

comprising a metal carbonyl compound or pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable carrier (see claim 6 relating to iron pentacarbonyl representing a transition metal and even one of the particular metals mentioned in claim 2 of the application in suit),

wherein the metal carbonyl makes available CO suitable for physiological effect by at least one of the following means, namely on contact with a tissue, organ or cell the metal carbonyl releases CO (see column 1, lines 44 to 53 of document (3), which is in line with the argumentation in the paragraphs before).

Consequently, all the features of claim 1 of the application as originally filed, and even the feature relating to "transition metals" which were common to the metals in claim 2 itself, are anticipated by the teaching of document (3); finally, even one of the metals itself is already mentioned in document (3). Therefore, from the features contained in claim 1, none is left that could be regarded as a "special technical feature" to provide unity for the embodiments representing the group of inventions under claim 2, and there is also no additional feature which could serve as the special technical feature within the meaning of Rule 30 EPC 1973.

Consequently, in accordance with the ISA's argumentation in the invitation to pay additional search fees and the argumentation of the examining division, there remains no special technical feature that could define a contribution which any of the claimed inventions could make over the prior art.

Thus, the original set of claims does not satisfy the requirements of Article 82 EPC. The non-unity objection raised for the initial claims by the International Search Division during the international search, and the resulting invitation to pay further search fees

under Rule 112 EPC 1973 for a search with respect to inventions numbers 2 to 8, were thus justified.

3.2 The appellant's argument that the current non-unity objection would not have occurred if claim 2 of the application had not existed cannot succeed. Nor can the argument that it would have been no undue effort to the ISA to make a search for the subject-matter of the whole application without raising the non-unity objection.

As for the first argument, the fact is that seven specific examples for the metal atoms are mentioned in claim 2. That is the same situation as if seven separate claims had been set out with respect to the seven metals. They define a group of seven different teachings, and it is the first of these seven specific teachings, containing Fe as the metal, that is not new with respect to document (3).

Beyond this fact and the resulting conclusion, the board sees no possibility to consider speculative situations with respect to the subject-matter that could have been claimed, because their implications would be different and are not known.

The second argument relates to Chapter VII-12 of the PCT International Search Guidelines (PCT Gazette No. S-06/1998) giving the possibility to the searching authority to search a group of inventions together and to include the result in the International Search Report, even if they lacked unity. This regulation applies to a situation in which the search examiner is able to make a complete international search for more

than one invention with negligible additional work. Nevertheless, it is fully within the examiner's discretion to decide on this matter and nothing has been submitted by the appellant to suggest that this discretion was misused in the present case. The board cannot find any such reasons either.

4. *Allowability of the main request and auxiliary requests 1 to 3*

In its communication pursuant to Rule 112 EPC 1973 and dated 14 May 2004, the examining division confirmed the lack of unity objection raised by the ISA, which means in particular that the only subject-matter searched remained "invention 1" as follows:

"1. Claims: 1—17 (all partially)
Pharmaceutical compositions for the delivery of carbon monoxide to a physiological target, comprising a metal carbonyl compound wherein the metal is Fe, and their therapeutic uses. Compound of the formula $M(CO)_xA_yB_z$ where M is Fe."

Any claim including any other metal than Fe in the carbonyl compound relates to subject-matter extending beyond the subject-matter as searched.

Since none of the claims 1 of the main request or of the auxiliary requests 1 to 3 is restricted to Fe-containing metal-carbonyl complexes, they all contain unsearched subject-matter.

Consequently, none of these claims is allowable with respect to Rule 164(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald