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In der Anlage erhalten Sie eine Kopie des Berichtigungsbeschlusses zur Entscheidung

Please find enclosed a copy of the decision correcting errors in the decision

T 303/90 - 3.3.2

Veuillez trouver en annexe une copie de la décision rectifiant des erreurs dans la décision

D. Spigarelli 29 -05- 1992



Case Number : T 303/90 - 3.3.2

DECISION
of 25 May 1992 correcting errors in the decision
of the Technical Board of Appeal 3.3.2
of 4 February 1992

Appellant : THE VICTORIA UNIVERSITY OF MANCHESTER
Oxford Road
Manchester M13 9PL (GB)

Representative : Deufel, Paul, Dr.
Patentanwälte Deufel, Hertel, Lewald
Isartorplatz 6
Postfach 26 02 47
W - 8000 München 26 (DE)

Decision under appeal : Decision of Examining Division of the European
Patent Office dated 23 November 1989 refusing
European patent application No. 84 304 945.3
pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : U.M. Kinkeldey
R.L.J. Schulte
A.J. Nuss
E.M.C. Holtz

In application of Rule 89 EPC the Decision given on 4 February 1992 is hereby corrected as follows:

On page 6, paragraph V, point 1, line 2, the word "December" has been substituted by the word "September".

On page 7, point 2, line 1, after the word "claims" have been inserted the words "of the auxiliary requests".

The Registrar:



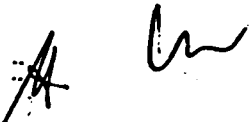
P. Martorana

The Chairman:



P.A.M. Lançon

Schmitt 26.5.92
26.5.92
Ukey



Publication in the Official Journal ~~Yes~~ / No

File Number: T 303/90 - 3.3.2
Application No.: 84 304 945.3
Publication No.: 0 138 304
Title of invention: Contraceptive methods

Classification: A61K 31/155

D E C I S I O N
of 4 February 1992

Applicant: THE VICTORIA UNIVERSITY OF MANCHESTER

Headword: Contraceptive composition/VICTORIA UNIVERSITY

EPC Articles 52(4), 54 and 56

Keyword: "Second medical indication type claim"
"Novelty - (yes)"
"Inventive step - (yes)"

Headnote



Case Number : T 303/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 4 February 1992

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Summary of Facts and Submissions

- I. European patent application No. 84 304 945.3, (publication No. 138 304) filed with 6 claims, relating to a contraceptive method which comprises applying to the mucus in the vagina of a female mammal a mucospissic amount of a bis-biguanide compound and this compound for use as a contraceptive, was rejected by the Examining Division.
- II. The ground for refusal was that certain claims were not allowable under Articles 52(1), 54(1), 54(2) and 57 EPC.

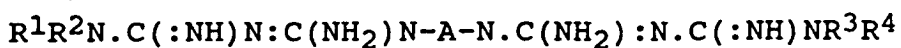
In its decision the Examining Division took the view that Claims 1 and 2 then on file lacked novelty with regard to the prior art document GB-A-705 838 (document (1)) or document GB-A-1 095 902 (document (2)). These documents related to the same compounds as they are now claimed in the present patent application in connection with their contraceptive use. The claimed contraceptive compositions could not be distinguished over the compounds and compositions disclosed in document (1) or (2).

As far as the claims then on file were directed to the use of the known compounds to prevent contraception in human beings allowability of these claims under Article 57 EPC was denied.

- III. The Appellants appealed against the decision of the Examining Division and paid the appeal fee. Further, they filed a written statement setting out the Grounds for Appeal.

In response to a communication issued by the Board, the Appellants, on 17 December 1991, filed a new set of 12 claims. Claims 1 and 2 read as follows:

"1. A contraceptive composition comprising a bis-biguanide compound of the formula



wherein either:

- (i) R^1 and R^3 , which may be the same or different, are each a phenyl radical which is substituted by alkyl, alkoxy, nitro or halogen, R^2 and R^4 are both hydrogen, and A is a 3-9C polymethylene diradical, wherein the polymethylene chain may be interrupted by oxygen atoms and/or by aromatic nuclei; or
- (ii) the bivalent bridge A is:

- (a) alkylene of from 2 to 12 carbon atoms having the valence bonds attached to different carbon atoms,
- (b) $-(CH_2)_m-X-(CH_2)_n-$ wherein m and n each represent an integer from 2 to 6 and Y is O or S,
- (c)



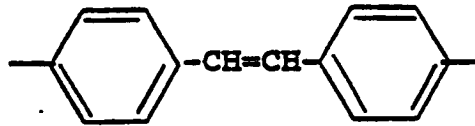
- (d)
-

wherein Z and Z^1 are each alkylene of from 1 to 3 carbon atoms,

- (e)
-

wherein Q is -O-, -S-, -SO- or -SO₂-,

- (f)
-



R¹ and R³ are each:

- (a) alkyl of from 6 to 16 carbon atoms, or
- (b) alkyl-Y-alkylene, wherein Y is O or S and the alkyl and alkylene radicals together contain 3 to 15 carbon atoms, and R² and R⁴ are each hydrogen or 1-6C alkyl;

or an acid addition salt thereof.

2. A contraceptive composition according to claim 1 wherein the bis-biguanide compound is chlorhexidine."

These claims are then followed by groups of two claims wherein Claims 3 and 4 relate to the use of the bis-biguanide compound for the manufacture of a contraceptive composition, Claims 5 and 6 to the bis-biguanide compound for the use as a contraceptive, Claims 7 and 8 to a contraceptive device incorporating the bis-biguanide compound Claims 9 and 10 to a composition adapted for the use as a contraceptive, comprising the bis-biguanide compound and finally Claims 11 to 12 to a bis-biguanide compound of the formula given in Claim 1 adapted for the use as a contraceptive.

Oral proceedings took place on 4 February 1992 during which a first and second auxiliary request were filed.

The first auxiliary request was based on a set of claims wherein Claims 1 and 2 and 5 and 6 of the main request were cancelled so that adapted Claims 1 to 8, related to Claims 3 and 4 and 7 to 12 of the main request.

The set of claims upon which the second auxiliary request was based contained adapted Claims 1 to 4 which corresponded to Claims 3 and 4 and 7 and 8 of the main request.

IV. The arguments put forward by the Appellants were essentially the following:

- (a) The claims relating to the method for contraception were no longer on file and thus the reasons for the refusal of the application in this respect were no longer relevant.
- (b) The therapeutic character of contraception was further underlined by prior art documents submitted, namely Ullmanns Encyklopädie der technischen Chemie, No. 4. neubearbeitete und erweiterte Auflage, Band No.18, pages 79 and 80; The Rote Liste 1989, chapter: Gynäkologika, No.4 Kontrazeptiva (lokale Anwendung) and finally Ullmans Encyklopädie of Industrial Chemistry, volume A7, pages 461 and 462.
- (c) The aim of the application was to seek patent protection in relation to a new contraceptive use of compounds already fully defined and described in documents (1) and (2), whatever forms of various wording might be used to frame the claims in respect of that use. The different forms of wording all related to the invention and protected different embodiments of it. This was in accord with the views expressed by the Enlarged Board of Appeal in its decisions G 5/83, OJ EPO 1985, 64 and G 6/88, OJ EPO 1990, 114.

- (d) The reasoning behind the wording of Claims 1 and 2 of the main request was that the compositions containing the bis-biguanide compounds for the purposes of the present invention were not necessarily the same as those already known for the other uses of the chemical compounds. It was agreed that one could not accept to claim all possible compositions containing the specified bis-biguanides, but it was believed to be fair and appropriate to claim those which were not already described in the art, i.e. those which were specifically designed or adapted for use as a contraceptive. Each use of a compound brought with it specialised requirements in respect of the form in which it was to be used. This would involve matters of the formulation like additives and other components which might be required to adjust properties such as viscosity, pH, concentration of active ingredients, dosage levels and the instructions for use. A formulation which was quite suitable for external use like general hygiene or bactericidal use, could be quite unsuitable for internal use. In Claims 1 and 2 it was intended to import this distinction from compositions already known by the use of the wording "a contraceptive composition comprising"
- (e) The same arguments held true for Claims 9 and 10 containing the same definition of the bis-biguanide compound as in Claims 1 and 2 but open with the wording "the composition adapted for use as a contraceptive, comprising". This wording transcended the novelty of the protection which the Appellants desired.
- (f) The reasoning behind the presentation of Claims 5 and 6 was similar to that discussed above in respect of

Claims 1 and 2 as it was frequently found by experts in any art that the precise form of an active compound could have a significant effect on the use to which it was applied. This might be crystal form, particle size or some other feature which could not be adequately included in a presence of components other than the specified active ingredient itself. This was also in particular the reasoning behind the submission of Claims 11 and 12.

(g) As far as Claims 3 and 4 were concerned they were perfectly designed along the line of the above-mentioned decision G 5/83 (see paragraph IV(c)) when claiming the known compounds for the use of the manufacture of contraceptives.

(h) Claims 7 and 8 related to contraceptive devices comprising the known compounds which had not been described in any prior art document and there should be no problem at all with this type of claims.

V. The Appellants requested that the decision under appeal be set aside and that the patent be granted on the basis of:

1. Claims 1 to 12 (main request), filed ~~17 December~~ ^{September} 1991.
2. Claims 1 to 8 (first auxiliary request),
3. Claims 1 to 4 (second auxiliary request).

Both auxiliary requests were filed during oral proceedings.

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3. Claims 1 to 4 (second auxiliary request).

Both auxiliary requests were filed during oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. Amendments (Article 123(2) EPC)

The amended claims of the auxiliary requests now define the contraceptive application as "vaginal" and further relate to different categories wherein the known bis-biguanide compound or derivatives of this compound are the active substances.

The specification of the present patent application as originally filed discloses a method of application of the bis-biguanide compounds to the mucus of the vagina to increase its viscosity to the extent that it becomes essentially impenetrable to sperm and forms a physical barrier to conception (page 3, lines 18-23 of the originally filed patent application).

The incorporation of the bis-biguanide compounds into a composition or device is disclosed on page 4, lines 18-22 of the originally filed patent application.

There are, therefore, no objections to be raised under Article 123(2) EPC.

3. Novelty (Article 54 EPC)

- 3.1 Main Request

- 3.1.1 Documents (1) and (2) disclose bis-biguanide compounds as defined in Claim 1 wherein the substituents having the values given in (i) are described in document (1) and those wherein the substituents having the values given in (ii) are described in document (2).

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3. Novelty (Article 54 EPC)

3.1 Main Request

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In document (1), page 2, left column, lines 7-16 it is stated that "because of their high degree of antibacterial activity the new substances are useful for many purposes, for example in medical and surgical practice, for sterilisation of instruments or of body tissues.

In document (2), page 5, right column, lines 100-106 and page 6, left column, lines 1 and 2 furthermore antiviral activity against influenza virus and helminthic activity is disclosed. In document (2), page 6, left column, lines 12 to 16, there is further described that depending on the particular purpose involved, the compounds are used in aqueous solutions, as in water or in aqueous detergent solutions or in the form of solutions in organic solvents.

When a pharmaceutical use is involved, a suitable acid addition salt of the compounds is proposed.

- 3.1.2 Claims 1 and 2 and 5 to 12 of the application under appeal are product claims. Claims 1 and 2 relate to compositions comprising the known compounds. A composition comprising a bis-biguanide compound for a medical use is already known from document (2) (see point 3.1.1 above), where there is described an aqueous solution of this compound (page 6, left column, lines 12 to 16). As it becomes apparent from example 3 of the description of the present patent application the bis-biguanide compound is prepared as a 1% solution in water. The composition as claimed as such thus cannot be considered as to be novel and the added word "contraceptive" does not change the product claim into a use claim. The subject-matter of the claim remains the composition, i.e. the product. This, however, is not novel over document (2). Only in the case of a first medical use can the addition of a purpose characteristic give

novelty to a product claim, if the product as such is known in other technical fields. Article 54(5) EPC allows the patentability of a composition for a medical use within the meaning of Article 52(4) EPC when such a medical use is the first one in the state of the art. This excludes the patentability for product claims in the medical field for a second use.

3.1.3 Therefore, Claims 1 and 2 of the main request are not novel. The main request is thus not allowable.

3.2 First Auxiliary Request

The set of claims of this request no longer contains Claims 1 and 2 and 5 and 6 of the main request. There is new Claim 5, however, (former Claim 9) comprised which now reads:

"5. A composition adapted for use as a vaginal contraceptive, comprising a bis-biguanide compound of the formula given in Claim 1 or an acid addition salt thereof."

Instead of qualifying the composition in the manner of Claim 1 of the main request, Claim 5 is directed to a composition adapted for use as a vaginal contraceptive. However, the rationale behind this wording is the same as in the case of Claim 1 of the main request. Therefore, the same reasoning for the non-allowability of Claims 1 and 2 of the main request applies in the case of Claims 5 and its dependent Claim 6 of the first auxiliary request.

3.3 Second auxiliary request

3.3.1 This request contains four claims, Claims 1 and 2 being directed to the use of a bis-biguanide compound or an acid

addition salt thereof in or for the manufacture of a vaginal contraceptive composition, whereas Claims 3 and 4 relate to a vaginal contraceptive device incorporating a bis-biguanide compound of the formula given in Claim 1 or an acid addition salt thereof. These four claims correspond to Claims 3 and 4, 7 and 8, respectively, of the main request.

3.3.2 Since none of the prior art documents describe the use of the bis-biguanide compounds for the purpose of contraception, Claims 1 and 2 of this request are novel.

3.3.3 Claims 3 and 4, relating to a contraceptive device containing the known compounds are to be considered as novel as well, because neither document (1) nor document (2) describes a contraceptive device.

3.3.4 In a further prior art document EP-A-0 024 779 (document (3)), inter alia diguanidines are described and their use in an intra-uterine device.

In view of document (3) novelty is given because the chemical compounds described there are different from those claimed and used in the present case (see cf. page 14, last paragraph).

All claims of the second auxiliary request are thus novel.

4. Inventive Step (Article 56 EPC)

4.1 The main and the first auxiliary request being not acceptable for lack of novelty of certain claims, inventive step has to be considered in respect of the second auxiliary request only.

4.2 The Board considers as the closest prior art both documents (1) or (2) which describe bis-biguanide compounds of the formula of Claim 1 and their use. As mentioned above under point 3.1.1, both documents describe a first medical use for these compounds.

4.3 Starting from either of these documents, the problem underlying the patent application can be seen in providing a further use of the known compounds.

This problem has been solved by the use of the known compounds for the manufacture of a vaginal contraceptive composition.

4.4 The question of the so-called second medical indication was subject-matter of the decision G 5/83 (see paragraph IV (c) above). In this decision the Enlarged Board of Appeal held that the type of claims being allowable in the case of a second medical indication was the use of the known compound for the manufacture of a medicament. There are, therefore, no objections as to the type of claims for the second use.

There is no hint in documents (1) or (2) that the compounds described there might have properties which increase the viscosity of the vaginal mucus or changes its morphology, rheology, water uptake and visco-elastic properties, when the mucus comes into contact with the bis-biguanide compounds. It was surprising that the application of the known compounds to the mucus results in an increase of its viscosity to the extent that it becomes essentially impenetrable to sperm and forms a physical barrier to conception. Also the further newly disclosed property of the known compound to immobilise sperms is not derivable from any disclosure about this compound in documents (1) or (2).

4.5 Document (3) relates to a contraceptive effect of inter alia diguanidines, which is based on an antiproteolytic and antifibrinolytic action of these compounds, which leads to a reduction in metrorrhagia and menorrhagia because of the particular characteristics associated with the reaction of the endometrium and/or the fluid of the uterus to the presence of an intrauterine device. Further these compounds inhibit other proteolytic systems in the endometrium and/or muscle wall of the uterus and thereby reduce and/or eliminate the pain and cramps associated with wearing an intrauterine device and minimises the risk of expulsion thereof. The effect of these compounds is so different from that of the compounds mentioned in the claims of the present application that a skilled person could not have foreseen, from the structure and chemical properties of these compounds, the contraceptive effect of the compounds of the present application as a result of a change of the viscosity of the mucus. Document (3) describes intrauterine devices containing the diguanidines. Although devices of the kind claimed are described in document (3), it is the surprising feature of the bis-biguanide compound which contributes to the inventive step of the devices as claimed in Claims 3 and 4.


5. The claims of the second auxiliary request are thus allowable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of Claims 1 to 4, second auxiliary request, filed during oral proceedings and a description to be adapted.

The Registrar:



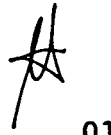
P. Martorana

The Chairman:



P. Lançon

Submitted 27.3.92
Ulmer
27.3.92



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