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File Number: T 401/90 - 3.3.2
Application No.: 84 304 946.1
Publication No.: 0 138 305
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 401/90 - 3.3.2

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

Appellant : THE VICTORIA UNIVERSITY OF MANCHESTER
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Decision under appeal : Decision of Examining Division of the European
Patent Office dated 26 March 1990 refusing
European patent application No. 84 304 946.1
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

Summary of Facts and Submissions

- I. European patent application No. 84 304 946.1, (publication No. 138 305) filed with 7 claims, relating to a contraceptive method which comprises applying to the mucus in the vagina of a female mammal a mucospissic amount of a polymeric 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.

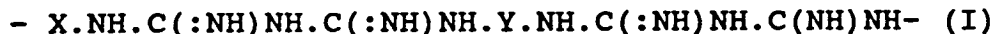
In its decision the Examining Division took the view that Claims 1 to 3 then on file lacked novelty with regard to the prior art document GB-A-702 268 (document (1)). This document related to the same compound as was now claimed in the present patent application in connection with their contraceptive use. The claimed contraceptive composition could not be distinguished over the compounds and compositions disclosed in document (1).

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 September 1991, filed a new set of 18 claims. Claim 1 reads as follows:

"1. A contraceptive composition comprising a polymeric biguanide compound which in the form of its free base is a linear polymer in which the recurring unit is represented by the formula:-



wherein X and Y stand for bridging groups in which together the total number of carbon atoms directly interposed between the adjacent nitrogen atoms is greater than 9 and less than 17, or an acid addition salt thereof".

Claims 2 and 3 are dependent on Claim 1 and relate to preferred embodiments of the compound. These claims are then followed by groups of three claims wherein Claims 4 to 6 relate to the use of the polymeric biguanide compound for the manufacture of a contraceptive composition, Claims 7 and 9 to the polymeric biguanide compound for the use as a contraceptive, Claims 10 to 12 to a contraceptive device incorporating the polymeric biguanide compound, Claims 13 to 15 to a composition adapted for the use as a contraceptive, comprising the polymeric biguanide compound and finally Claims 16 to 18 to a polymeric 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 to 3 and 7 to 9 of the main request were cancelled so that adapted Claims 1 to 12, related to Claims 4 to 6 and 10 to 18 of the main request.

The set of claims upon which the second auxiliary request was based contained adapted Claims 1 to 6 which corresponded to Claims 4 to 6 and 10 to 12 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 document (1), 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 to 3 of the main request was that the compositions containing the polymeric 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 polymeric 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 to 3 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 13 to 15 containing the same definition of the polymeric biguanide compound as in Claims 1 to 3 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 7 to 9 was similar to that discussed above in respect of Claims 1 to 3 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 16 to 18.

(g) As far as Claims 4 to 6 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 10 to 12 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 18 (main request), filed 17 September 1991,
2. Claims 1 to 12 (first auxiliary request),
3. Claims 1 to 6 (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 now define the contraceptive application as "vaginal" (Auxiliary requests) and further relate to different categories wherein the known polymeric 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 polymeric 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 2, lines 15-26 of the originally filed patent application).

The incorporation of the polymeric biguanide compounds into a composition or device is disclosed on page 3, lines 21-25 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 Document (1) discloses polymeric biguanide compounds as defined in Claim 1.

It is stated at page 1, right column, lines 13-15, that the compounds possess good antibacterial and antifungal properties.

There is further described that the compounds are freely soluble in water in the form of their salts giving nearly neutral solutions (page 2, right column, lines 87-89).

3.1.2 Claims 1 to 3 and 7 to 18 of the application under appeal are product claims. Claims 1 to 3 relate to compositions comprising the known compounds. A composition comprising a polymeric biguanide compound for a medical use is already known from document (1), where there is described an aqueous solution of this compound (see point 3.1.1 above). As it becomes apparent from example 2 of the description of the present patent application the polymeric biguanide compound is prepared as an appropriate aqueous 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 (1). 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, Claim 1 of the main request is 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 to 3 and 7 to 9 of the main request. There is new Claim 7, however, (former Claim 13) comprised which now reads:

"7. A composition adapted for use as a vaginal contraceptive, comprising a polymeric 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 7 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 to 3 of the main request applies in the case of Claims 7 and its dependent Claims 8 and 9 of the first auxiliary request.

3.3 Second auxiliary request

3.3.1 This request contains six claims, Claims 1 to 3 being directed to the use of a polymeric biguanide compound or an acid addition salt thereof in or for the manufacture of a vaginal contraceptive composition, whereas Claims 4 to 6 relate to a vaginal contraceptive device incorporating a polymeric biguanide compound of the formula given in Claim 1 or an acid addition salt thereof. These six claims correspond to Claims 4 to 6, 10 to 12, respectively, of the main request.

3.3.2 Since none of the prior art documents describe the use of the polymeric biguanide compounds for the purpose of contraception, Claims 1 to 3 of this request are novel.

3.3.3 Claims 4 to 6, relating to a contraceptive device containing the known compounds are to be considered as novel as well, because document (1) does not describe 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 prior art document (1) describes polymeric biguanide compounds of the formula of Claim 1 and their use. As mentioned above under point 3.1.1, the document describes a first medical use for these compounds.

4.3 Starting from this document, 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 There is no hint in document (1) that the compounds described there might have properties which increase the viscosity of the vaginal mucus or changes its morphology,

rheology, water uptake and viscoso- elastic properties, when the mucus comes into contact with the polymeric 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 document (1).

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 4 to 6.

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 6, second auxiliary request, filed during oral proceedings and a description to be adapted.

The Registrar:

The Chairman:

P. Martorana

P. Lançon