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**D E C I S I O N**  
**of 11 January 1994**

**Case Number:** T 0820/92 - 3.3.2

**Application Number:** 87902913.0

**Publication Number:** 0298990

**IPC:** A61K 37/56

**Language of the proceedings:** EN

**Title of invention:**

Continuous delivery of luteinizing hormone releasing hormone compositions in combination with sex steroid delivery for use as a contraceptive

**Applicant:**

The General Hospital Corporation

**Opponent:**

-

**Headword:**

Contraceptive method/THE GENERAL HOSPITAL

**Relevant legal norms:**

EPC Art. 52(4), 57

**Keyword:**

"Patentability of a contraceptive method involving a concurrent therapeutic step (no)"

"Presence of one step prohibited under Article 52(4) EPC prevents method being allowable"

**Decisions cited:**

T 0144/83, T 0320/87, T 0019/90, T 36/83, T 0290/86, T 0208/84,  
T 0068/85, T 0081/84, T 0019/86, G 0005/83, T 0780/89,  
T 0116/85, T 0182/90

.../...

**Headnote:**

In the case of a method involving administration of two or more substances (here: an LHRH contraceptive composition and oestrogenic and/or progestational steroids) the question for the purposes of Article 52(4) EPC is not whether the main or even the only reason for carrying out the whole of the claimed method is non-therapeutic. Rather a method claim falls under the prohibition of Article 52(4) EPC already if the purpose of the administration of one of the substances is a treatment by therapy, and the administration of this substance is a feature of the claim (cf. point 5.9 of the Reasons).

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Case Number: T 0820/92 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 11 January 1994

**Appellant:** The General Hospital Corporation  
55 Fruit Street  
Boston, MA 02114 (US)

**Representative:** Sheard, Andrew Gregory  
Kilburn & Strode  
30 John Street  
London WC1N 2DD (GB)

**Decision under appeal:** Decision of the Examining Division of the European  
Patent Office dated 14 April 1992 refusing  
European patent application No. 87 902 913.0  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** U.M. Kinkeldey  
**Members:** L. Galligani  
S.C. Perryman

## Summary Facts and Submissions

- I. European patent application No. 87 902 913.0 filed as an International patent application and published under No. WO 87/05514 was refused by the Examining Division.

The decision was taken on the basis of Claims 1 to 13 filed by letter dated 26 April 1991.

- II. The ground for refusal was that Claims 8 to 13 did not comply with the requirements of Article 57 EPC.

The decision was essentially based on the following reasons:

- (a) Claims 8 to 13 related to a method for preventing pregnancy in female mammals, *inter alia* human females (cf. Claim 9). The claims encompassed the personal and private use of the contraceptive (cf. Claim 10: oral intake).
- (b) Notwithstanding the lack of an explicit exclusion from patentability in the European Patent Convention (EPC) and the absence of case law thereupon, it was current practice of the European Patent Office (EPO) not to allow claims to methods of contraception of a human female where such methods involved the personal and private use of a substance. This was because the said use did not fall within the definition of industrial application set forth in Article 57 EPC.
- (c) Decision T 144/83, OJ EPO 1986, 301, referred to by the Applicant, was not concerned with a method of contraception, but with a cosmetic method. Although the said decision implied that the private oral

administration of non-therapeutic substances was acceptable under Article 57 EPC, the highly personal and confidential nature of contraception clearly distinguished the methods for preventing pregnancy from cosmetic methods and from the administration of food.

- III. The Appellant lodged an appeal against this decision and paid the appeal fee. First and second auxiliary requests were filed by the Appellant with the Statement of Grounds of appeal.
- IV. In an official communication pursuant to Article 110(2) EPC the Board indicated two further questions to be taken into consideration, namely, (i) whether the combination of a contraceptive method with a therapeutic method was excluded from patentability under Article 52(4) EPC and (ii) whether any of the requests on file met the requirements of Article 84 EPC.
- V. During oral proceedings which took place on 11 January 1994 a new main request and a first and second auxiliary request were filed in one version for all States.

Claim 1 of the main request reads as follows:

"A delivery system for preventing pregnancy in a female mammal, comprising:

- (1) a first delivery system, for administration to said mammal during the follicular phase of the menstrual cycle, comprising a contraceptive effective amount of an LHRH composition and a physiologically effective amount of an estrogenic steroid; and,
- (2) a second delivery system, for administration to said mammal during the luteal phase of the menstrual cycle, comprising a contraceptive effective amount of an LHRH composition, a

physiologically effective amount of an estrogenic steroid and a physiologically effective amount of progestational steroid."

Claims 2 to 7 relate to specific embodiments of the delivery system according to Claim 1.

Claim 8 of the main request reads as follows:

"A method for preventing pregnancy in a female mammal, comprising:

- (a) administering via a delivery system a contraceptive effective amount of an LHRH composition and a physiologically effective amount of an estrogenic steroid to said female during the follicular phase of the menstrual cycle, beginning at the onset of normal menses in said female; and,
- (b) replacing first said delivery system at the end of said follicular phase with a second delivery system, wherein said second delivery system administers a contraceptive effective amount of an LHRH composition, a physiologically effective amount of an estrogenic steroid and a physiologically effective amount of progestational steroid to said female during the luteal phase of the menstrual cycle, until the beginning of the normal menses in said female."

Claims 9 to 13 relate to specific embodiments of the method according to Claim 8.

The first auxiliary request differs from the main request in that Claim 8 reads as follows:

"The use of an LHRH composition, an estrogenic steroid and a progestational steroid in the preparation of an

agent for preventing pregnancy in a female mammal, the agent comprising:

- (1) a first delivery system, for administration to said mammal during the follicular phase of the menstrual cycle, comprising a contraceptive effective amount of an LHRH composition and a physiologically effective amount of an estrogenic steroid; and,
- (2) a second delivery system, for administration to said mammal during the luteal phase of the menstrual cycle, comprising a contraceptive effective amount of an LHRH composition, a physiologically effective amount of an estrogenic steroid and a physiologically effective amount of progestational steroid."

Dependent Claims 9 to 14 therein relate to specific embodiments of the said use.

The second auxiliary request differs from the main request in that Claims 8 to 13 are deleted.

The Appellant's arguments with respect to the objection raised by the Board under Article 52(4) EPC are essentially as follows:

- (a) While the oestrogenic and progestational steroids were not added in the delivery system of the present application as contraceptive, but to correct any biological functions adversely effected by the LHRH, the overall effect of the claimed delivery system was a **contraceptive** effect. Therapy was not the subject-matter of the claims. The method claims, in particular, were directed to the prevention of pregnancy and not to a therapeutic application. The presence in the delivery system of physiologically effective amounts of oestrogenic and progestational steroids was to be regarded



merely as an "advantage" of the system by which any health problems caused by the main contraceptive ingredient (LHRH composition) were alleviated.

(b) Reference was made to the case law of United Kingdom, France and Germany to show that:

- (i) pregnancy was not a disease;
- (ii) contraception was not regarded as a form of disease therapy;
- (iii) contraception was therefore not a method of medical treatment by virtue of national case law or medical definition.

Thus, since the present method claims were directed only to the prevention of pregnancy, no exclusion under Article 52(4) EPC should apply.

(c) According to the established European case law, any exceptions to patentability should be construed narrowly (see, for example, T 320/87 OJ EPO 1990, 71, point 6 and T 19/90 OJ EPO 1990, 476, point 4.5).

In cases T 144/83 (*loc.cit.*) and T 36/83 (OJ EPO 1986, 295) where no clear distinction was possible between the therapeutic and the cosmetic effect the Board did not allow this to work to the disadvantage of the Applicant and allowed the method for cosmetic treatment.

In decision T 290/86 (OJ EPO 1992, 414) the Board emphasised the importance of the wording of a claim for deciding whether or not a claimed invention should be excluded from patentability under

Article 52(4) EPC. In the light of the latter decision, the exclusion from patentability under Article 52(4) EPC would be justified only if the present method claims were directed to "the use of steroids for preventing or alleviating the side effects of LHRH". However, the present claims were directed to a method for preventing pregnancy; thus, they should be allowed.

- (d) according to decision T 208/84 (OJ EPO 1987, 14), even if the idea underlying an invention might be considered to reside in a mathematical method (which was *per se* excluded from patentability under Article 54(2)(a) EPC), a claim directed to a technical process in which the method was used did not seek protection for the mathematical method as such and, therefore, was not excluded from patentability. In the light of said decision, no exclusion under Article 52(4) EPC should apply in the present case because the claimed method of contraception did not seek protection for the therapeutic effect of the added oestrogenic and progestational steroids.

The Appellant also submitted other arguments relating to the grounds of rejection by the Examining Division.

- VI. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request, or the first auxiliary request or second auxiliary request, as submitted during the oral proceedings.

## Reasons for the Decision

1. The appeal is admissible.
2. *Formal admissibility of the new sets of claims (Article 123(2) EPC)*

The Claim 1 of each request has been amended to make clear that the delivery systems actually comprise an LHRH composition and one or more steroids, thus overcoming the clarity objection raised in the first official communication by the Board. This amendment finds its basis in the original application documents (see, for example, page 12, lines 11 to 18 and page 4, second paragraph).

Moreover, in Claim 1 of all requests and in Claim 8 of the main and first auxiliary request the effective amount of the oestrogenic and progestational steroid has been qualified by the introduction of the adverb "physiologically". This amendment finds a basis in the original application documents (see, for example, page 10, lines 21 to 22 and page 11, lines 4 to 5).

Thus, no objection under Article 123(2) EPC arises.

3. *Clarity (Article 84 EPC)*

The claimed subject-matter is adequately defined to meet the requirements of Article 84 EPC. The adopted functional language ("contraceptive effective amount" and "physiologically effective amount") is allowable and in line with the case law (see in particular T 68/85, OJ EPO 1987, 228).

4. *Patentability of the product Claims 1 to 7 of all requests*

During substantive examination the Examining Division acknowledged the patentability under Article 52(1) EPC of the delivery system according to Claims 1 to 7 (see appealed decision, point 8). Also in the Board's view, none of the available prior art documents, alone or in combination, discloses or suggests the claimed delivery system. This is, therefore, considered patentable under the provisions of Articles 54 and 56 EPC.

No other objections to the patentability of these claims were seen.

5. *Main request: the method Claims 8 to 13.*

5.1 Claim 8 is directed to a method for preventing pregnancy in a female mammal. The contraceptive effect on the female mammal is ensured through the administration of an LHRH composition.

The administration of the large doses of LHRH compositions which are necessary to block ovulation in the female produces a reversible and complete biochemical castration at pituitary level which results in a total suppression of gonadotropin and ovarian steroids secretions (estradiol and progesterone) (see present description pages 2 to 3). This pituitary quiescence leads to the side effects of oestrogen deficiency, including hot flashes, vaginal dryness and, most ominously, osteopenia and osteoporosis (see description, page 3, lines 23 to 29; page 10, lines 26 to 28 and page 11, second paragraph).

The oestrogenic and progestational steroids are administered according to the claimed method **not** to

maintain or reinforce the contraceptive effect of LHRH, **but** only to "mimic the physiological secretion of steroids in the menstrual cycle" (see page 5, lines 5 to 7 of the description) and thereby to counteract the above side effects. In fact, "physiologically" effective amounts of the said steroids are administered in order to compensate for the total suppression of their secretion caused by the LHRH composition.

- 5.2 It is established case law that a prophylactic treatment, aimed at maintaining health by preventing ill effects that would otherwise arise, amounts to a method for treatment by therapy as referred to in Article 52(4) EPC, and that therapy is not limited to treatments which restore health by curing diseases which have already arisen (T 144/83, *loc.cit.*; T 81/84, OJ EPO 1988, 207; T 19/86, OJ EPO 1989, 25; G 5/83, OJ EPO 1985, 64).

In the present case while the treatment of the female mammal with the LHRH composition is carried out to produce the desired contraceptive effect, the concurrent treatment with the oestrogenic and progestational steroids is carried out **not** to produce any contraceptive effect **but** as a prophylactic treatment which avoids the ill consequences which would otherwise occur as a result of the use of the LHRH composition. This latter step is a treatment by therapy within the meaning of Article 52(4) EPC.

- 5.3 The Appellant sought to avoid this conclusion by arguing that the method as a whole is a contraceptive method and that this avoids the prohibition of Article 52(4) EPC applying to the claim. This argument is based on a misconception of the nature of the prohibition of Article 52(4) EPC. By providing that methods for treatment of the human or animal body by surgery or

therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application, the first sentence of Article 52(4) EPC creates an exclusion from patentability that has been consistently interpreted by the EPO Boards of Appeal as meaning that such a method cannot be the subject-matter or part of the subject matter covered by a claim.

5.4 The parallel drawn by the Appellant with case T 208/84 (VICOM) (*loc.cit.*) is not considered pertinent. Article 52(2) EPC provides that certain activities of an abstract and intellectual character shall not be regarded as inventions, but Article 52(3) EPC provides that this exclusion applies only to the activities **as such**. This has been interpreted as meaning only that a claim directed to such activities *per se* is not allowable but that a claim is allowable where the interaction of such an activity with something else can be regarded as an invention. This contrasts with the position under Article 52(4) EPC which prevents the methods specified from being patented, even though otherwise they might be considered as an invention susceptible of industrial application as required by Article 52(1) EPC. It is to be noted that no provision similar to Article 52(3) EPC limits the exclusion of Article 52(4) EPC.

5.5 The decided cases show that in considering whether a request for a particular set of claims is allowable under Article 52(4) EPC, the critical question is whether there is any disclosure of a method none of whose steps fall under the prohibition of Article 52(4) EPC, i.e. none of whose steps are either a method for the treatment of the human or animal by therapy or surgery, or a diagnostic method practised on the human or animal body. The question is not merely one of having

a suitably worded claim, but whether on the disclosure of the case such a method claim is allowable at all.

5.6 No method claim was considered allowable in case T 290/86 (*loc.cit.*) because the disclosed method of eliminating plaque inevitably had the therapeutic effect of prevention of caries and periodontal disease, and so fell under the prohibition of Article 52(4) EPC, irrespective of the fact that removal of plaque could also have the cosmetic effect of improving the appearance of the teeth.

Nor was a method claim considered allowable in case T 780/89 (OJ EPO 1993, 440) where the Appellants argued that immunostimulation was used to improve meat production and not as a therapeutic treatment. However the Board considered that this did not alter the legal position (see Reasons, point 7) since even if more meat was produced because fewer animals became sick or died, the method for which patent protection was claimed remained a therapeutic treatment.

In case T 116/85 (OJ EPO 1989, 13) the Board considered that the particular use disclosed of a pesticidal composition to treat pigs to remove ectoparasites (mange mites) amounted to a therapeutic treatment, so that claims to this use fell under the prohibition of Article 52(4) EPC even though in general agricultural uses were patentable. It did not accept that merely because such a method carried out by a farmer could be considered industrial this would make the method lose its character of being treatment by therapy.

In each of these three cases the Appellant had failed to satisfy the Board that the method claims were not directed to a use prohibited by Article 52(4) EPC.

5.7 In case T 144/83 (*loc.cit.*), particularly relied on by the Appellant, the Board considered that the claimed use of an appetite suppressant was unrelated to the therapy of the human or animal body, and that the claims were formulated to clearly relate to a non-therapeutic use. The decision thus turns on the facts found by the Board in that particular case. It is also said there that exclusions from patentability such as Article 52(4) EPC must be construed narrowly and should not apply to treatments which are not therapeutic in character, and that the difficulty in distinguishing between a therapeutic and a cosmetic effect should not be allowed to work to the disadvantage of the Applicant who, according to the wording of his claims, seeks patent protection for cosmetic treatment but not for the therapeutic treatment as such. This must be seen in the context of the view of the Board that a non-therapeutic use of this particular treatment clearly existed. The case is no authority for the propositions that if there is any doubt as to whether the prohibition of Article 52(4) EPC applies it must be resolved in the applicant's favour, or that something described as a cosmetic treatment can *ipso facto* be considered as non-therapeutic.

In T 36/83 (*loc.cit.*) the Board found that there was described both a novel non-medical use and a novel medical use of thenoyl peroxide, particularly as a comedolytic, and accordingly allowed both a claim to a cosmetic use, and a claim to the compound for use in a method of therapeutic treatment for the human or animal body under the provisions of Article 54(5) EPC. In reaching this conclusion the Board treated the use of the word "cosmetic" in the context of this application as sufficient to exclude therapeutic uses, without the need for a specific disclaimer of such uses.



In each of these cases the Board had thus satisfied itself that no method of treatment by therapy was covered by the claims it allowed.

- 5.8 In case T 182/90 of 30 July 1993 (Headnote published in OJ EPO, 1993, Vol. 11, page XVII), method claims were allowed even though one step of the method included a surgical step on a living animal. But they were allowed (see Reasons, point 2.5.2) on the basis that the method used in that case consciously ended in the laboratory animal's death, and this prevented the surgical step from being considered a prohibited treatment by surgery. The Board stated in Reasons, point 2.5.1, that normally the presence of a surgical step in a multi-step method for treatment on the human or animal body confers a surgical character on that method, which would bring it within the prohibition of Article 52(4) EPC.
- 5.9 In the case of a method involving administration of two or more substances, the question for the purposes of Article 52(4) EPC is not whether the main or even the only reason for carrying out the whole of the claimed method is non-therapeutic. Rather a method claim falls under the prohibition of Article 52(4) EPC already if the administration of one of the substances is a treatment by therapy, and the administration of this substance is a feature of the claim.
- 5.10 The Board considers that since the method for preventing pregnancy according to Claims 8 to 13 of the main request includes a treatment by therapy the said claims fall within the prohibition on patentability set out in Article 52(4) EPC.
- 5.11 Given this conclusion, there is no need to go further into the question whether, and if so, in what

circumstances a patent can be granted under the European Patent Convention for a method of contraception.

6. *First auxiliary request: Claims 8 to 14.*

6.1 Claim 8 is directed to the use of an LHRH composition, an oestrogenic steroid and a progestational steroid in the preparation of an agent for preventing pregnancy in a female mammal, the said agent comprising a first and a second delivery system as set out in Claim 1. The claim is permissible according to decision G 5/83 (*loc.cit.*). This Claim 8 and, consequently, Claims 9 to 14 dependant on it, are considered patentable under the provisions of Article 52(1) EPC for the reasons already given in point 4. above. Thus, the first auxiliary request is allowable.

## Order

**For these reasons, it has been decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order that a patent be granted on the basis of the claims of the first auxiliary request submitted during the oral proceedings on 11 January 1994 and a description composed of pages 1 to 5, 7 to 10 and 12 to 16 as originally filed and pages 6 and 11 as filed with the letter of 14 October 1991.

The Registrar:

The Chairwoman:

P. Martorana

U. Kinkeldey