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D E C I S I O N
of 9 November 1994

Case Number: T 0074/93 - 3.3.1

Application Number: 88904588.6

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IPC: C07C 103/737

Language of the proceedings: EN

Title of invention:

Alicyclic compounds and their contraceptive use

Applicant:

BRITISH TECHNOLOGY GROUP LIMITED

Opponent:

-

Headword:

Contraceptive method/BRITISH TECHNOLOGY GROUP

Relevant legal provisions:

EPC Art. 52(1), (4), 57

Keyword:

"Patentability of a contraceptive method applied in the private and personal sphere (no)"

Decisions cited:

G 0005/83, T 0820/92

Headnote:

A method of contraception which is to be applied in the private and personal sphere of a human being is not susceptible of industrial application.

Case Number: T 0074/93 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 9 November 1994

Appellant: BRITISH TECHNOLOGY GROUP LIMITED
101 Newington Causeway
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Representative: Percy, Richard Keith
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Decision under appeal: Decision of the Examining Division of the European Patent Office dated 2 September 1992 refusing European patent application No. 88 904 588.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: A. Jahn
Members: R. E. Teschemacher
P. Krasa

Summary of Facts and Submissions

- I. European patent application No. 88 904 588.6 relating to alicyclic compounds and their contraceptive use was filed as an international application on 27 May 1988, claiming priority from an earlier application in the United Kingdom of 2 June 1987. The Examining Division refused the application on 2 September 1992 in a decision based on Claims 1 to 10 as filed by letter of 3 August 1992.
- II. The application was refused because Claim 5, which relates to the use of a compound for applying to the cervix of a female capable of conception, was not susceptible of industrial application as required by Article 57 EPC insofar as the compound was to be applied to the cervix of a human female. Such use was regarded as a purely personal use carried out in private by women themselves. There was no industry which offered women the service of applying the compounds for them.
- III. A notice of appeal was filed on 15 October 1992 accompanied by the appropriate fee. A statement of grounds received on 19 December 1992 contained an additional Claim 11 in response to the Examining Division's suggestion to submit a claim of the type normally used to protect a second medical indication.
- IV. During the oral proceedings held on 9 November 1994 the Board expressed doubts as to whether the way the additional claim had been drafted was appropriate in the present situation, since according to the Appellant's own submissions the contraceptive use in

the present case was not a medical one and the special type of use claim allowed by the Enlarged Board of Appeal for further medical indications in G 05/84 (OJ EPO 1985, 64) seemed in the present situation less clear than a normal claim for a process of manufacture.

V. In response to these objections the Appellant submitted the following claims as the main request:

"1. Compounds of the general formula

wherein n is from 1 to 6 and each of R₁ and R₂ represents an alkyl group of 1 to 4 carbon atoms, and their acid addition salts.

2. N-(2-dimethylaminoethyl)-1,3,8-trioxodecahydronaphthalene-2-carboxamide and its acid addition salts.

3. A composition comprising a compound claimed in Claim 1 or 2 and a non-toxic carrier.

4. A composition according to Claim 3 in the form of a cream or ointment.

5. Use of a composition claimed in Claim 3 or 4 for applying to the cervix of a female mammal capable of conception.

6. Compounds according to Claim 1 or 2, wherein the acid addition salts are pharmaceutically acceptable, for use in thickening gastro-intestinal mucus as an anti-ulcer agent.

7. Compounds according to Claim 6 wherein the gastro-intestinal mucus is oesophagal, stomach or duodenal mucus.

8. Compounds according to Claim 1 or 2, wherein the acid addition salts are pharmaceutically acceptable, for treating colitis or diverticulitis.

9. Compounds according to Claim 1 or 2, wherein the acid addition salts are pharmaceutically acceptable for application to the eyes, for treating "dry eye".

10. Process of preparation of a contraceptive composition by formulating a compound claimed in Claim 1 or 2 with a non-toxic carrier."

VI. In respect of the allowability of Claim 5 the Appellant argued essentially as follows:

The EPC was concerned with ensuring that applicants gave a proper technical teaching in return for the monopoly granted. It was common sense that if a contraceptive composition was put on the market and the novelty lay in the new use, there ought to be a claim allowed which would enable the Patentee to sue on it.

Provisions on contributory infringement in many of the Contracting States did allow the Patentee to exclude others from supplying means relating to an essential element for putting the invention into effect, even when the ultimate consumer was using the invention privately.

In respect of the only objection, which had been raised under Article 57 EPC, the use of a contraceptive was industrially applicable because the application of a contraceptive cream could be a paid-for service, for example when applied by a prostitute charging her client a price which included a contraceptive, or by a nurse applying a contraceptive to a woman who was disabled in a way which did not allow her to apply the contraceptive herself. It did not matter whether these uses were small-scale, since there was no requirement in Article 57 EPC for an industry to be of any particular size. Nor did it state that private use could not be commercial. "Private" did not mean "non-commercial". A nuclear reactor could, for example, be regarded as private. If a person could not be sued for private, non-commercial use, there was no problem anyway. The existence of private, non-commercial uses did not affect industrial applicability as long as industrial applications existed for the invention. Many inventions in the field of daily needs were used privately and their patentability should not be restricted. Finally, it was not required for an industrial use to be already known; industrial uses which might be created by the alleged invention in the future should also be taken in consideration.

VII. The Appellant requested that the impugned decision be set aside and a patent be granted on the basis of Claims 1 to 10 according to the main request submitted at the oral proceedings. Alternatively they requested that a patent be granted on the basis of the auxiliary request in which Claim 5 of the main request had been deleted.

VIII. At the conclusion of the oral proceedings, the Board pronounced its decision allowing the auxiliary request.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Main request*

2.1 The subject-matter of present Claim 6, in which the medical indication has been specified, is based on page 7, lines 25 to 27 of the description as originally filed. The additional claim for the preparation of a contraceptive composition (now Claim 10) is based on the paragraph bridging pages 6 and 7 of the description as originally filed, which also provides support for present Claims 3 and 4, which were submitted in proceedings before the first instance. The claims therefore comply with the requirement of Article 123(2) EPC.

2.2 The primary issue to be dealt with is whether the subject-matter of Claim 5 is susceptible of industrial application according to Article 57 EPC.

The objection raised by the Examining Division that the application of a contraceptive to the cervix of a human female is a purely personal use which does not meet the requirement of Article 57 EPC has not been dispelled by the Appellant.

2.2.1 The Board agrees with the Appellant's submission that the principle can be derived from the EPC that appropriate protection should be given to technical inventions. The latter must however fulfil the general criteria in Article 52(1) EPC, i.e. novelty, inventive step and industrial application, as was stated in particular by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64). This means that the general principle of patentability can apply only if the alleged invention is susceptible of industrial application.

2.2.2 The Appellant referred to provisions in the infringement law in many of the Contracting States, which in conformity with Article 26 of the Community Patent Convention give protection against contributory infringement. It is true that a third party who supplies means relating to an essential element of an invention for putting the invention into effect is acting commercially and is not entitled to exploit the invention, even when the end-user acts privately and for non-commercial purposes (see Articles 26(3), 27(a) CPC). The exemption for the private end-user thus does not extend to the contributory user selling means for

using the invention. However, the fact that the contributory user is subject to the effects of a patent does not necessarily mean that the end-user acts commercially.

2.2.3 The Board also agrees with the Appellant that a method of contraception is not excluded per se from patentability under the aspects of industrial application as stipulated in Articles 57 and 52(4), first sentence, EPC. Pregnancy is not an illness and therefore its prevention is not in general therapy according to Article 52(4) EPC (for a specific case see T 820/92, to be published, Headnote in OJ EPO 8/1994). It seems to have been widely accepted in the Contracting States that such methods may be susceptible of industrial application (Schering AG's appl. (1971) R.P.C. 337 (P.A.T.); Bruchhausen in Benkard, 9. Aufl. 1993, § 5 PatG, Rdnr. 13; Cour d'appel de Paris, 24 septembre 1984, PIBD 1984 III, 251). It is, however, not sufficient for such methods to be susceptible of industrial application in general. Rather, the invention as claimed in the specific case must fulfil the requirement of Article 57 EPC.

2.2.4 The method as claimed in Claim 5 is intended for application by the woman herself. Even the Appellant has not contested the fact that such application is not normally part of an industry as required in Article 57 EPC. Nevertheless they are of the opinion that industrial applicability has been established by the two examples given by them, in which the method is alleged to be part of an industry.

2.2.5 These examples are not convincing.

2.2.5.1 In the case of the prostitute, the Appellant referred to the "oldest industry in the world". Since "industry" in the field of industrial property is widely understood in its broadest sense (Article 2(3) of the Paris Convention), such a liberal interpretation may also apply to Article 57 EPC. But the decisive question is not whether a prostitute's profession is an industry, but whether the application by a prostitute of a contraceptive composition to the cervix is part of an industry. This is not the case. The application of a contraceptive composition to the cervix as claimed is not part of the business relationship between a prostitute and her client, and the contract between them does not cover the question of which means of contraception she may apply to herself. She has the freedom and responsibility to decide which one to choose, taking into consideration factors such as tolerance or reliability. This holds true at least as long as the client is not affected; if the prostitute applied contraceptive means to her client, their use might become part of the business relationship. As long as she applies them to herself and protects herself outside her contact with the client, the client is in no way involved and the application remains in the private and personal sphere of the prostitute.

A prostitute may have a professional interest in not becoming pregnant, in order to remain able to pursue her profession. This is, however, neither her only nor her predominant interest in using a contraceptive. The prostitute has a serious interest in not becoming pregnant from a client for purely private and personal reasons, because this could affect her future life to a much higher degree than the temporary inability to

practice. Also, a pregnancy arising from a non-professional relationship could damage her professional perspectives. Nevertheless, the use of a contraceptive in a private relationship could hardly be regarded as being of an industrial character. This shows that the mere motive for using a contraceptive is of minor importance for the question of industrial application.

2.2.5.2 The example of the contraceptive cream being applied to a disabled person by a nurse is different insofar as another person is involved in the application. The fact that this person acts professionally is not sufficient to make the application of the contraceptive an industrial activity. The nurse does not offer contraception to the disabled person as an industry but to help her satisfy her strictly personal needs. It follows from this that the nature of the activity is not changed by the fact that it is not exercised by the disabled woman herself but by her assistant acting according to her instructions. That is the difference between the present case and cases of cosmetic treatment, in which the Board has regarded the requirements of Article 57 EPC as satisfied because there are enterprises whose object is to beautify the human body (T 144/83, OJ EPO 1986, 301).

2.2.6 In determining the borderline between industrial activities, in which the effects of patents have to be respected, and private and personal activities, which should not be adversely affected by the exercise of these rights, the Board has taken into consideration the fact that Article 57 EPC may be regarded as an expression of the general idea that any natural person has the right to have his or her privacy respected. The

core of this right must not be taken away from anybody. Therefore the fact that for some women contraception is connected with professional activities does not give an act, which is in essence private and personal, an industrial character. It has to be stressed that this does not apply to contraception in general, but to the specific type of application of a composition as claimed in Claim 5.

The fact that the rights conferred by the patent are intended to be used against contributory users only, is irrelevant here. The Board has been unable to ascertain any field of industrial application for the direct use defined in Claim 5, for which the requirement of Article 57 EPC must be met.

The question as to whether it would be sufficient for an industrial application to be expected in future may be left unanswered. Even if the Board were to accept the Appellant's position in this respect, it would not be sufficient simply to make an unsubstantiated allegation to this effect. Without any specific indication the Board is not in a position to accept that the requirement of Article 57 EPC is fulfilled.

A patent cannot therefore be granted on the basis of the main request.

3. *Auxiliary request*

3.1 Original Claims 1 to 8 were not objected to in the international preliminary examination report. The Examining Division stated in its communication of 24 July 1992 that a patent could be granted on the

basis of these claims if the use claim (original Claim 3) were redrafted. This claim is not part of the auxiliary request. In its decision the Examining Division did not object to Claims 3 and 4, as submitted by letter of 3 August 1992, which were directed to compositions containing the compounds claimed in Claims 1 and 2.

3.2 The Board has examined these claims as amended in the appeal proceedings. Claim 5 of the main request having been deleted from this request, the Board has not found any reason for an objection. Nor does any objection exist to the only new claim submitted in the appeal proceedings, which relates to the preparation of a contraceptive composition (Claim 5 of the auxiliary request), which is to be assessed in respect of substantive requirements in the same way as the product claims for the compositions. With regard to Claims 6 and 7, page 7 of the description has been amended in order to give formal support to a feature originally disclosed in the claims.

3.3 In conclusion the Board finds that the application according to the auxiliary request and the invention to which it relates meet the requirements of the Convention.

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 with the order to grant a patent in the following version:

Description:

Pages 1 to 6, 8 to 17 as originally filed

Page 7 as submitted during oral proceedings

Claims 1 to 9 as submitted during oral proceedings as auxiliary request.

The Registrar:

The Chairman:

P. Martorana

A. Jahn