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Datasheet for the decision of 8 July 2009

Case Number: T 0525/07 - 3.3.02

Application Number: 98401535.4

Publication Number: 0887074

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Intravaginal drug delivery device

Patentee:
Aventis Pharma S.A.

Opponent:
Akzo Nobel N.V.

Headword:
Intravaginal drug delivery device/AVENTIS PHARMA S.A.

Relevant legal provisions:
EPC Art. 54, 56, 83, 84

Keyword:
"Main request: Clarity - (yes): unclarity removed by amendment"
"Sufficiency - (yes)"
"Novelty - (yes): no specific disclosure in the prior art of an intravaginal device comprising a removable polymer membrane for absorbing excess active agent"
"Inventive step - (yes) - removable polymer membrane for absorbing excess active agent not obvious"

Decisions cited:
G 0009/92

Catchword:
-

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Case Number: T 0525/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 8 July 2009

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 30 January 2007 concerning maintenance of European patent No. 0887074 in amended form.

Composition of the Board:

Chairman: J. Riolo
Members: A. Lindner
C. Vallet

Summary of Facts and Submissions

I. European patent No. 0 887 074 based on application No. 98 401 535.4 was granted on the basis of a set of 28 claims.

The independent claims read as follows:

"1. An intravaginal drug delivery system having a first intravaginal part comprising at least one active agent in a polymer matrix, said first part being provided in association with a second part comprising a removable polymer membrane arranged to absorb excess active agent.

21. A method for the manufacture of an intravaginal drug delivery system as claimed in any preceding claim, said method comprising the step of providing a polymer matrix containing at least one active agent with a removable polymer membrane arranged to absorb excess active agent.

22. A method for the manufacture of an intravaginal drug delivery system as claimed in any one of claims 1 to 20, said method comprising the following steps:

(a) dispersing at least one active agent in a polymer matrix whereby to form a core;

(b) optionally surrounding said core with a rate-controlling sheath; and

(c) providing the resulting device with a removable polymer membrane capable of absorbing excess activeagent.

23. An intravaginal drug delivery device comprising at least one active agent dispersed in a polymer matrix, wherein the concentration of active agent at the outer surface of the device at the time of use is not substantially higher than the concentration of the active agent in the remainder of the device.

26. Use of a device as claimed in claim 25 as a contraceptive.

28. A process for preparing a ready-to-use intravaginal drug delivery device, said process comprising removal of a polymer wrapping from an intravaginal part or device as defined in any one of claims 1 to 20 and claims 23 to 25."

II. An opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) EPC for insufficient disclosure of the invention.

III. The documents cited during the opposition and appeal proceedings included the following:

(1) EP-A-0 876 815
(2) US-A-3 923 939
(3) US-A-4 822 616
(6) US-A-3 920 805
(9b) South African Electronic Package Insert of Estring™
(14) Declaration of Mr Wouter de Graaff

IV. In the decision pronounced on 16 November 2006, the opposition division found that, account being taken of the amendments made by the patentee during the opposition proceedings, the patent and the invention to which it related in the form of auxiliary request 3 met the requirements of the EPC. Its principal findings were as follows:

The subject-matter of the main request met the requirements of Article 83 EPC. However, the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 lacked novelty over document (9b). Regarding auxiliary request 3, the opposition division came to the conclusion that the subject-matter claimed therein met the requirements of Articles 123(2), 123(3), 84, 54 and 56 EPC. In connection with inventive step, it was reasoned that document (2), which related to the same technical problem as the contested patent, i.e. the reduction of the initial burst of the active agent from intravaginal delivery devices, constituted the closest prior art. In document (2) the problem was solved by removal of the excess active agent by washing the device before use in an appropriate solvent. Document (9b) was the only document disclosing a kind of wrapping around the intravaginal device. However, this document was silent as regards the reduction of the initial burst. On the contrary, it was mentioned in document (9b) that the active agent was released with a brief initial peak. As a consequence, the skilled person would not combine the teachings of documents (2) and (9b), and therefore the requirements of Article 56 EPC were met.

V. The appellant (opponent) lodged an appeal against that decision.

VI. With his reply to the statement of the grounds of appeal dated 19 October 2007, the respondent (patentee) filed a new main request. The independent claims read as follows:

"1. An intravaginal drug delivery system having a first intravaginal part comprising at least one active agent in a polymer matrix, said first part being provided in association with a second part comprising a removable polymer membrane arranged to absorb excess active agent, wherein said active agent is ethinyl estradiol.

17. A method for the manufacture of an intravaginal drug delivery system as claimed in any preceding claim, said method comprising the step of providing a polymer matrix containing ethinyl estradiol with a removable polymer membrane arranged to absorb excess active agent.

18. A method for the manufacture of an intravaginal drug delivery system as claimed in any one of claims 1 to 16, said method comprising the following steps:

(a) dispersing ethinyl estradiol in a polymer matrix whereby to form a core;

(b) optionally surrounding said core with a rate-controlling sheath; and

(c) providing the resulting device with a removable polymer membrane capable of absorbing excess active agent.

19. A process for preparing a ready-to-use intravaginal drug delivery device, said process comprising removal of a polymer wrapping from an intravaginal part or device as defined in any one of claims 1 to 16."

VII. With letter dated 6 May 2009, the appellant withdrew his request for oral proceedings.

VIII. With letter dated 19 May 2009, the respondent filed an auxiliary request (= auxiliary request 1).

IX. Oral proceedings took place on 8 July 2009.

X. The appellant's arguments presented in the written phase of the proceedings can be summarised as follows:

In connection with insufficiency, it was reasoned that

(a) the term "excess active agent" was not defined

(b) there was no disclosure in the contested patent of how the membrane should be arranged to absorb excess active agent

(c) the devices used in the examples were not tested for excess active agent

(d) the polymer membranes of the examples were not tested for absorbed active agent

(e) the patent did not contain any evidence that the absorption was not effected by silicone oil

(f) in case the examples fell within the scope of the claims, they were limited to devices that were stored with the polymer membrane for three weeks or less and from which the polymer membrane was removed just prior to the release test. Reference was made to document (14) which demonstrated that upon longer storage the initial burst effect

disappeared. Such embodiments were, however, encompassed by the claims.

As regards novelty, it was reasoned that the claims lacked novelty over documents (1) and (9b). In connection with inventive step, it was held that the claimed subject-matter lacked inventive step over document (9b).

XI. The respondent contested the arguments of the appellant. Moreover, he requested that all documents filed by the appellant after expiry of the opposition period defined in Article 99(1) EPC not be admitted.

XII. The appellant requested that the decision under appeal be set aside and that the European patent No. 0887074 be revoked.

The respondent requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request filed with letter dated 19 October 2007 or, alternatively, on the basis of the auxiliary request filed with letter dated 19 May 2009.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of documents:

2.1 Document (9b):

Document (9b) is a copy from the internet (htpp://www.intekom.com/pharm/pharmaca/estring.html) of a package insert concerning the product Estring®. The publication date of the package insert is October 1995, but the document was only made available in the internet on February 2005. There is no evidence that the content of the internet article literally corresponds to the content of the original package insert. In fact, as was correctly pointed out by the respondent, there are indication such as the missing logo that document (9b) is not a true copy of the original package insert of 1995. It therefore cannot be excluded that the internet article was subject to modifications. As a consequence, the package insert of 1995 is state of the art, but its exact content is unknown to the board. Document (9b) can therefore not be used for the evaluation of novelty and inventive step.

2.2 Document (14):

In the decision under appeal, document (14) was not admitted into the proceedings, as it had been late-filed and was not considered to be *prima facie* relevant. However, the filing of document (14) may be seen as a reaction of the appellant to the preliminary

opinion of the opposition division in connection with insufficiency, issued in the official communication annexed to the summons to attend oral proceedings dated 2 May 2006. As a consequence, document (14) is not late-filed and is therefore admitted into the proceedings. However, the board agrees with the opinion of the opposition division that document (14) is not pertinent, as it is based on a mathematical model for which numerous assumptions were made. Such a disclosure cannot be regarded as proof of insufficiency.

3. Main request:

3.1 Admissibility:

According to decision G 9/92 (OJ EPO 1194, 875), the patentee, by not filing an appeal, has indicated that he will not contest the maintenance of the patent in the version accepted by the opposition division in its decision. As a consequence, any amendments he proposes in the appeal proceedings may be rejected by the board if they do not arise from the appeal (see point 16 of the reasons). In the present case, the amendments made in claim 1 are a direct response to clarity objections raised by the appellant in the statement of the grounds of appeal. The amendments do not result in any extension of the scope of the claims. As a consequence, the main request is admissible.

3.2 Formal aspects:

3.2.1 Clarity:

By changing the wording of claim 1 from "wherein said oestrogen is ethinyl estradiol" to "wherein said active agent is ethinyl estradiol", the clarity objections raised by the appellant in the statement of the grounds of appeal have been overcome, as there is a previous reference to an active agent in claim 1. As a consequence, the subject-matter of the main request meets the requirements of Article 84 EPC.

3.2.2 Article 123(2) EPC:

The feature "wherein said active agent is ethinyl estradiol" is based on claim 19 of the application as originally filed. The requirements of Article 123(2) EPC are therefore met.

3.2.3 Article 123(3) EPC:

The introduction of ethinyl estradiol as active agent into claim 1 results in a restriction of the scope of the claims so that the requirements of Article 123(3) EPC are also met.

3.3 Sufficiency of disclosure:

The appellant raised a variety of objections in connection with sufficiency of disclosure (see point X above).

3.3.1 As regards the term "excess active agent", the board agrees with the opposition division that it is correlated with an amount which causes an initial burst of release of the active agent.

3.3.2 As for the objection that there is no disclosure in the contested patent of how the membrane should be arranged to absorb excess active agent, reference is made to examples 1, 2 and 3, which clearly indicate that the intravaginal rings are wrapped in the polymers forming the removable membrane.

3.3.3 Regarding the objections that the devices used in the examples were not tested for excess active agent, reference is made to figure 6, where the initial burst of the unwrapped device according to example 3 of the contested patent is demonstrated.

3.3.4 As regards the objections summarised in point X, paragraphs (d) and (e), the board agrees with the opposition division that the wrapping of the device according to example 3 of the contested patent was carried out in the absence of silicone oil. As a consequence, figure 6 shows that the polymer wrapping does indeed reduce the initial burst. An additional analysis of the polymer membrane for absorbed active agent is therefore not necessary.

3.3.5 In connection with the objection summarised in point X, paragraph (f), it is emphasised that claim 1 relates to a product. A product cannot be defined by its intended storage time. The board does not exclude the possibility that the initial burst does not occur over the entire period in which the claimed device may be

stored before use. However, it was plausibly shown that in times when the initial burst occurs, the removable polymer membrane effectively reduces it so that the device can be safely used over the whole period of its shelf life. Moreover, the examples of the contested patent enable the skilled person to reproduce the invention without having to use inventive skill.

3.3.6 As a consequence, the devices as claimed in the present main request are sufficiently disclosed.

No additional objections were raised with regard to the methods for the manufacture of the intravaginal drug delivery system as claimed in claims 17 and 18 and to preparation of the ready-to-use intravaginal drug delivery device as claimed in claim 19. As a consequence, the above reasoning applies *mutatis mutandis* to these claims.

3.3.7 It follows therefrom that the ground of opposition according to Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the main request.

3.4 Novelty:

3.4.1 Document (1) discloses ring-shaped vaginal drug delivery systems for the simultaneous release of two or more active agents. Ethinyl estradiol is among the preferred active agents (see page 1, lines 3-5 and page 3, lines 46-47). The systems are then packed in suitable sachets (see page 4, line 28).

Document (1) does not specifically disclose that said sachet is composed of a polymer matrix. The appellant reasoned that this feature was implicitly disclosed in document (1), as it was common general knowledge that suitable sachets would be made of heat-sealable laminates, in which the innermost layer was made of a polymer. The board does not contest that such sachets are common in the art, but it is equally possible that the sachets of document (1) are composed of a different material, including e.g. an aluminium foil or a polymer which is not capable of absorbing excess active agent. As a consequence, a polymer membrane capable of absorbing excess active agent is not implicitly disclosed in document (1). The subject-matter of claim 1 is therefore novel over document (1).

3.4.2 Document (9b):

The content of document (9b) cannot be used in the evaluation of novelty for the reasons outlined in point 2.1 above.

3.4.3 Further documents:

In the appeal procedure, the appellant did not cite any further documents in relation to lack of novelty. The board has no reason to deviate from the analysis of the opposition division in connection with novelty over documents (1) to (3) and (6) (see point 7.2 of the oppositions division's decision), as no further arguments have been submitted by the appellant.

3.4.4 The above evaluation of novelty applies *mutatis mutandis* to the subject-matter of independent claims 17,

18 and 19. As a consequence, the subject-matter of the main request meets the requirements of Article 54 EPC.

3.5 Inventive step:

3.5.1 The subject-matter of the main request concerns intravaginal drug delivery devices where the active agent is released at a constant rate over a prolonged period of time and where the initial high burst of active agent during the first 24 hours following vaginal administration is reduced (see paragraphs [0001] and [0012] of the patent specification).

3.5.2 In the statement of the grounds of appeal, the appellant based his argumentation exclusively on document (9b), which, however, for the reasons outlined in point 2.1 above, cannot be used for the evaluation of novelty or inventive step. The board agrees with the opposition division that document (2) constitutes the closest prior art. Document (2) is also concerned with reducing the initial burst of active agent from intravaginal devices. The problem was solved by washing the device with a suitable solvent prior to use (see column 2, lines 45-60). In the light of this prior art, the problem of the present invention can be defined as the provision of an intravaginal device which does not require a washing step prior to use in order to reduce the initial burst of active agent. The problem was solved by the addition of a removable polymer membrane arranged to absorb excess active agent. In view of the examples, in particular of example 3, and figures 5 and 6, the board is satisfied that the problem was plausibly solved.

3.5.3 The above solution is not obvious, as none of the available documents relates to the concept of applying removable layers, let alone removable polymer membranes, in order to absorb excess agent so that the initial burst observable with intravaginal devices is effectively reduced. As a consequence, the subject-matter as claimed in the main request involves an inventive step (Article 56 EPC).

4. In the light of this finding, examination of the auxiliary request is not necessary.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained on the basis of the main request filed with letter dated 19 October 2007.

The Registrar: The Chairman:

N. Maslin J. Riolo