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**Datasheet for the decision
of 15 June 2021**

Case Number: T 1694/18 - 3.3.07

Application Number: 13804259.3

Publication Number: 2861215

IPC: A61K9/10, A61K9/14, A61K38/00,
A61P31/18

Language of the proceedings: EN

Title of invention:
COMPOSITIONS AND METHODS FOR ENHANCING THE EFFICACY OF
CONTRACEPTIVE MICROBICIDES

Applicant:
Evoform, Inc.

Headword:
Contraceptive microbicides/ EVOFORM

Relevant legal provisions:
EPC Art. 123(2), 84, 111(1)
RPBA 2020 Art. 13(1), 11, 12(2)

Keyword:
Auxiliary request 1 - Admissible (Yes)
Auxiliary request 1 - Amendments (Yes)
Remittal - (yes)



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1694/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 June 2021

Appellant: Evofem, Inc.
(Applicant) 8910 University Center Lane
Suite 120
San Diego, California 92122 (US)

Representative: Wichmann, Hendrik
Wuesthoff & Wuesthoff
Patentanwälte PartG mbB
Schweigerstraße 2
81541 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 25 January 2018
refusing European patent application No.
13804259.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: D. Boulois
A. Jimenez

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application n° 13 804 259.3. The decision was a decision on the state of the file based on two communications dated 27 October 2015 and 22 June 2017, both based on the claims filed with letter of 29 September 2015.

Claim 1 of the request filed on 29 September 2015 read as follows:

"1. A contraceptive microbicide composition comprising: about 1-10% of a matrix forming compound, 1-10% a bioadhesive compound, and 1-10% L-lactic acid, wherein the composition has a nonmatrix state when not in contact with ejaculate, and a matrix state when in contact with ejaculate."

II. According to the examining division's communication dated 27 October 2015, the subject-matter of claim 1 did not meet the requirements of Article 123(2) EPC, since claim 1 comprised features which had been isolated from the application as filed, in particular from paragraph [0013] and from the original claims, and in particular in view of the suppression of the features relating to the carrier and the antiviral agent tenofovir.

In its communication dated 22 June 2017, the examining division confirmed its former objection under Article 123(2) EPC against the subject-matter of claim 1. In particular, the deletion of the features "antiviral" and "1-(6-aminopurin-9-yl)propan-2-

ylloxymethylphosphonicacid" (tenofovir) from the wording of amended claim 1 constituted an undue extension of subject-matter. Moreover, the examining division considered that amended claim 1 contravened as well the requirement of Article 84 EPC, since the claimed subject-matter lacked an essential feature, which was the presence of said antiviral agent tenofovir. Moreover the feature "wherein the composition has a nonmatrix state when not in contact with ejaculate, and a matrix state when in contact with ejaculate" did neither meet the requirements of Article 84 EPC.

III. The patent applicant (hereinafter the appellant) appealed the decision. With the statement of grounds of appeal dated 25 May 2018, the appellant filed a new main request and amended pages of the description 1-14.

Claim 1 of the main request read as follows:

"1. A topical contraceptive microbicide composition comprising: 1-10% of a matrix forming compound, 1-10% of a bioadhesive compound, 1-10% of L-lactic acid, and a pharmaceutically acceptable carrier; wherein the composition is in matrix state when in contact with ejaculate; wherein the matrix-forming compound is selected from the group consisting of: alginic acid, chitosan, gellan gum, and poloxamer; and wherein the bioadhesive compound is selected from the group consisting of: xanthan gum, alginic acid, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, sodium carboxymethyl cellulose, chitosan, polycarbophil, and carbopol. "

IV. With a letter dated 4 December 2018, the appellant submitted auxiliary requests 1 and 2.

The unique claim of auxiliary request 1 read as follows:

"1. A contraceptive microbicide composition comprising:
- one matrix forming compound, which is alginic acid and which is present in an amount of 3-5%,
- one bioadhesive compound, which is xanthan gum and which is present in an amount of 2.5-6%, and
- lactic acid, wherein the lactic acid is L-lactic acid and is present in an amount of 1-7%."

- V. A communication expressing the board's preliminary opinion was sent to the appellant. The Board stated in particular that the subject-matter of *inter alia* claim 1 of the main request did not meet the requirements of Article 123(2) EPC.
- VI. Oral proceedings before the board of appeal took place on 15 June 2021 by videoconference. During oral proceedings, the appellant withdrew the main request.
- VII. The appellant's arguments can be summarised as follows:

Admission of auxiliary request 1 into the proceedings

This request did not constitute a fresh case since resulting from a combination of claim 1 as decided on by the examining division with dependent claims 2, 5 and 7. There was no need of an additional search since this subject-matter was already on file.

Auxiliary request 1 - Amendments

Claim 1 of auxiliary request 1 was based on paragraph [0036]-[0038] of the original application. The whole amount of lactic acid contained in the composition was

L-lactic acid as disclosed in paragraph [0036] of the application. This was further supported by paragraph [0044] which emphasized that it has been found that L-lactic acid was superior to D-lactic acid and that pure L-lactic acid could be used as disclosed in [0046]. In contrast, the former Amphora® product contained a racemic mixture of lactic acid in an amount of 1.8%.

The disclosure in paragraphs [0034]-[0036] of the "Acidform" gels which only comprised the ingredients recited in claim 1 of auxiliary request 1, but without tenofovir, represented a direct and unambiguous basis for claim 1. In particular, since claim 1 referred to a composition with lactic acid, the composition clearly had microbicide and antiviral efficacy (see paragraph [0044] of the application).

In view of the above claim amendments, the objections for lack of clarity were rendered moot. The present claims fulfilled the requirements of Article 84 EPC in full. In particular, the expression " wherein the composition has a nonmatrix state when not in contact with ejaculate, and a matrix state when in contact with ejaculate" had been deleted.

VIII. Requests

The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims filed as auxiliary request 1 with letter of 4 December 2018.

Reasons for the Decision

1. Admission of auxiliary request 1 into the proceedings

This request has been filed with appellant's letter of 4 December 2018 after it had filed its statement of grounds of appeal dated 25 May 2018. Consequently, Article 13(1) RPBA 2020 applies.

According to Article 13(1) RPBA 2020, any amendment to a party's case after it has filed its grounds of appeal or reply is subject to the party's justification for its amendment and may be admitted only at the discretion of the Board. Article 12, paragraphs 4 to 6 shall apply *mutatis mutandis*.

The Board notes that the subject-matter of the unique claim of auxiliary request 1 corresponds to the subject-matter of claim 1 of the set of claims filed on 29 September 2015, on which the decision on the state of the file was based, with amendments originating from dependent claims 2, 5 and 7 of the same set of claims, and with the suppression of a feature which was objected for lack of clarity by the examining division.

This request is therefore not a fresh case, and has been clearly filed to resolve the objections raised by the examining division in its decision. Moreover, the amendments brought to the claim appear to *prima facie* overcome all said objections, and are therefore beneficial to procedural economy.

Consequently, auxiliary request 1 is admitted in the appeal proceedings (Article 13(1) RPBA 2020).

2. Auxiliary request 1 - Amendments

2.1 Article 84 EPC

The feature "wherein the composition has a nonmatrix state when not in contact with ejaculate, and a matrix state when in contact with ejaculate", which was objected to by the examining division in its communication referred to in the decision on the state of the file, has been suppressed from claim 1 of auxiliary request 1. This objection has therefore been rendered moot.

Moreover, the subject-matter of claim 1 relates now to a specific sub-component of the composition as initially claimed, namely the "contraceptive microbicide". This sub-component is disclosed in paragraphs [0034] to [0039] of the application as filed, and said passage does not disclose or relate to the further presence of the antiviral agent tenofovir. Consequently, the point raised by the examining division under Article 84 EPC with regard to the lack of essential features in the claim is also rendered moot.

The Board notes that the amended pages of the description still needs to be adapted to the new subject-matter of auxiliary request 1 under Article 84 EPC. Since the remaining patentability requirements have not yet been examined, it is preferable to proceed to the adaptation of the description at the final stage of the examination proceedings, when and if a set of submitted claims will be found patentable.

Consequently, auxiliary request 1 meets the requirements of Article 84 EPC.

2.2 Article 123(2) EPC

As disclosed in paragraphs [0013], [0015] [0017] and in original independent claims 1 and 6, the application as originally filed related to a composition comprising:

- (a) a contraceptive microbicide, comprising a matrix-forming compound, a bioadhesive compound and lactic acid;
- (b) tenofovir as antiviral agent; and
- (c) a carrier.

Claim 1 of auxiliary request 1 has now been restricted to the specific contraceptive microbicide composition, which is the sub-component (a) of the composition as originally disclosed. The claimed subject-matter of said contraceptive microbicide composition finds an explicit and exclusive basis in paragraphs [0034] to [0039] of the application as filed. The claimed concentrations are disclosed in paragraphs [0035] and [0036], while the restriction to alginic acid and xanthan gum as preferred matrix forming compound and bioadhesive compound is disclosed explicitly in paragraphs [0037] and [0038].

Consequently, the subject-matter of claim 1 is derivable directly and unambiguously from the original application, and auxiliary request 1 meets the requirements of Article 123(2) EPC.

3. Remittal to the examining division

The only grounds for the refusal set out in the decision under appeal, namely objections under Article 123(2) EPC and 84 EPC, are no longer justified .

The examining division has not yet examined the patentability requirements and no reasons as to this regard are included in the communications forming the decision under appeal.

Under Article 111(1) EPC, the Board may either proceed further with the examination of the application, in particular with respect to Articles 54 and 56 EPC, or remit the case to the examining division for further prosecution. Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The Board holds that such special reasons are apparent because the examining division has not taken an appealable decision on essential outstanding issues. As recalled in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of the application.

Under these circumstances, the Board considers it appropriate to allow the appellant's request for remittal of the case to the examining division (Article 111(1) EPC).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the examining division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated