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**Datasheet for the decision
of 21 April 2017**

Case Number: T 0299/12 - 3.3.01

Application Number: 04028426.7

Publication Number: 1510213

IPC: A61K31/56, A61K47/00,
A61K47/10, A61K47/12

Language of the proceedings: EN

Title of invention:

Penetration enhancing and irritation reducing systems
comprising testosterone

Patent Proprietor:

Strakan International Limited

Opponent:

Nederlandsch Octrooibureau N.V.

Headword:

Testosterone transdermal formulation/STRAKAN

Relevant legal provisions:

EPC Art. 76(1), 123(2)
RPBA Art. 13(1)
EPC R. 116(2)

Keyword:

Admission: main, auxiliary request 1 (yes)
auxiliary request 2 (no)
Added matter: main, auxiliary request 1 (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0299/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 21 April 2017

Appellant: Nederlandsch Octrooibureau N.V.
(Opponent) J.W. Frisolaan 13
2517 JS Den Haag (NL)

Representative: Nederlandsch Octrooibureau
P.O. Box 29720
2502 LS The Hague (NL)

Respondent: Strakan International Limited
(Patent Proprietor) Galabank Business Park
Galashiels
TD1 1QH (GB)

Representative: Nieuwenhuys, William Francis
Marks & Clerk LLP
90 Long Acre
London
WC2E 9RA (GB)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 December 2011 concerning maintenance of the
European Patent No. 1510213 in amended form.

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
L. Bühler

Summary of Facts and Submissions

I. The present appeal by the opponent (appellant) lies from the interlocutory decision of the opposition division concerning maintenance of European patent No. 1 510 213 in amended form, based on the auxiliary request filed during the oral proceedings held on 8 December 2011, with the following claim 1:

"1. A semi-solid pharmaceutical composition for direct layering or spreading on epidermal tissue which consists essentially of:

- (a) 0.1% to 5% of testosterone;
 - (b) 0.1% to 5% of oleic acid;
 - (c) 25% to 35% of ethanol and isopropanol;
 - (d) 30%-40% of propylene glycol;
 - (e) 0.1%-5% of carbomer;
- optionally preservatives and cross-linking agents;
and water to 100%;

wherein % are weight to weight of the composition."

II. In the decision under appeal, the opposition division considered that the composition claimed in the patent as granted lacked inventive step. In addition, it admitted into the proceedings the auxiliary request filed during oral proceedings and concluded that the claims of said auxiliary request met the requirements of the EPC.

III. With its statement of grounds of appeal and with letter dated 16 January 2013, the appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety. In particular, it contested the admission of the auxiliary

request filed during oral proceedings before the opposition division and the acknowledgement by the division that said auxiliary request complied with the requirements of the EPC.

- IV. In its response dated 6 September 2012, the respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as amended in the opposition proceedings (main request).
- V. In a communication sent as annex to the summons to oral proceedings, the board gave its preliminary opinion that the opposition division had not exercised its discretion to admit the auxiliary request filed at the oral proceedings of 8 December 2011 in an unreasonable manner, and that the claims of said request seemed to add subject-matter (Articles 76(1) and 123(2) EPC).
- VI. With letter dated 21 March 2017, the respondent filed auxiliary requests 1 and 2.

Claim 1 of **auxiliary request 1** differed from that of the main request (auxiliary request filed during oral proceedings before the opposition division) in that the feature "semi-solid pharmaceutical composition" had been replaced by "**gel composition**"; the concentration range of **testosterone** had been restricted to **1% to 2%**; and the **optional features** had been specified to be **butylated hydroxytoluene** and **triethanolamine**.

Claim 1 of **auxiliary request 2** differed from that of auxiliary request 1 in that the expression "consists essentially of" had been replaced by "**consists of**"; **ethanol** had been specified to be "**dehydrated**"; the previously optional ingredients had been replaced by the **compulsory ingredients butylated hydroxytoluene**,

triethanolamine, and extra triethanolamine or 1.0 N HCl if necessary to adjust the pH; and the expression "water to 100%" had been replaced by "purified water q.s. to the final weight".

VII. Oral proceedings were held before the board on 21 April 2017.

VIII. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

With regard to the admission of the present main request by the opposition division, the appellant argued that the request should not have been admitted because the date of oral proceedings was too late to file for the first time amendments intended to overcome objections that had been raised at the beginning of the opposition proceedings. In addition, the request contained amendments that could not have been envisaged by the appellant, putting it in a disadvantageous situation.

Turning to the board's admission of late-filed auxiliary requests 1 and 2, the appellant contended that, although the requests had been filed in response to the board's preliminary opinion in preparation of oral proceedings, they were intended to overcome an objection of added subject-matter that was outstanding from the very beginning of the appeal proceedings. Moreover, none of the requests was suitable to overcome the mentioned objection, and component (h) in auxiliary request 2 was unclear because it did not specify when a pH adjustment would be necessary and to what value it should then be adjusted.

Concerning the objection of added subject-matter (Articles 76(1) and 123(2) EPC) in the main request, the appellant based its arguments on three main aspects:

Firstly, the clauses on pages 20 to 24 of the application as filed, which corresponded to the claims of the parent application, had been arranged as a reservoir of features, and multiple selections had to be made in order to arrive at the claimed composition. In this context, the examples could not be used as guidance to make the required selections, because they did not provide a basis for generic ranges, and because the examples that contained testosterone, oleic acid, ethanol, isopropanol, propylene glycol and carbomer also included triethanolamine, which was not an essential feature in claim 1.

Secondly, the replacement in claim 1 of the expression "comprises" by "consists essentially of", which was not disclosed in the application as filed, added a criticality as to the presence in the claimed composition of only testosterone, oleic acid, ethanol, isopropanol, propylene glycol, carbomer, preservatives, cross-linking agents and water, for which there was no basis in the application as filed. On this issue, the appellant noted that the application as filed explicitly disclosed the presence of ingredients other than those recited in claim 1. In particular, attention was drawn to the passage on page 7, lines 15-24, of the application as filed, and to most of the examples, which taught not only cross-linking agents and preservatives as the optional ingredients, but also additional irritation-reducing agents, which had been excluded from claim 1.

And thirdly, the expression "water to 100%" in claim 1 had no explicit support in the application as filed, and the examples could not provide a valid basis because they contained specific amounts of water, rather than the unspecified amount "water to 100%". Moreover, the compositions of examples 2 and 3 did not even contain water.

In its discussion of added subject-matter in auxiliary request 1, the appellant referred to the arguments presented against the main request and, additionally, objected to the introduction of the features "butylated hydroxytoluene" and "1% to 2% testosterone", because the compound butylated hydroxytoluene was not supported by the passage cited by the respondent on page 7, lines 17-18, which disclosed a different compound, and because the concentration range 1-2% mentioned on page 5, lines 13-14, of the application as filed did not specifically refer to testosterone.

IX. The respondent's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

On the admission of the present main request, the respondent contended that the opposition division had exercised its discretion appropriately, because the request had been filed during oral proceedings as a reaction to the change of mind of the division, which had previously given a positive opinion on the patent as granted, and because until the oral proceedings there had been no clear indication as to what problems might arise. In addition, the amendments were not complex.

With regard to the admission of auxiliary requests 1 and 2, the respondent argued that they should be admitted into the appeal proceedings because they had been filed in reaction to the board's preliminary opinion sent with the summons to oral proceedings, and because they did not raise any complex issues. Additionally, in connection with the pH adjustment required by feature (h) of auxiliary request 2, the respondent argued that measurement and adjustment of pH belonged to the common general knowledge of the skilled person and did not involve any technical difficulty.

Concerning the issue of added subject-matter in the main request, the respondent drew attention to the structure of the set of clauses 1 to 31 on pages 20 to 22 of the application as filed, which corresponded to claims 1 to 31 of the parent application. Thus, clauses 1 and 2 constituted the main basis for the combination of features (a) to (e), with a selection of preferred components and concentration ranges disclosed in the subsequent blocks of clauses. In particular, the selection of testosterone (clause 6), ethanol/isopropanol (clause 16), propylene glycol (clause 23) and carbomer (clauses 28-29), and their corresponding concentrations (clauses 8, 19, 27 and 31) over other preferred embodiments listed in the clauses, was the necessary conclusion at which the skilled person would have arrived when reading the clauses in the light of the examples, since the latter presented the selected components as being the most preferred ones. Additional support for these selections was to be found in the description on page 6, lines 3-8 (ethanol/isopropanol and concentration), page 6, lines 12-16 (propylene glycol and concentration), and page 3, lines 2-4 (carbomer as gelling agent, where Carbopol[®] was a synonym of carbomer, as stated on page 6, lines 29-30).

Further, the preferred concentrations of testosterone and oleic acid were disclosed in clauses 8 and 11 and on page 5, lines 12-13 and 16-18.

In connection with the replacement of the expression "comprises" by "consists essentially of" and the indication of optional ingredients, the respondent cited the passage on page 7, lines 15-24, of the application as filed in combination with the formulations in table 2 and in examples 5, 8 and 9, as well as the typical manufacturing process on pages 18 and 19, which supported the presence of cross-linking agents, such as triethanolamine, and preservatives, such as butylated hydroxytoluene, as optional ingredients. In response to the appellant's argument that further irritation agents mentioned on page 7, lines 15-24, had been left out of the optional ingredients, the respondent submitted that the cited passage did not disclose further irritation agents as compulsory ingredients, a fact that was corroborated, for instance, by the formulations in table 4 of the application as filed, which showed formulations that contained further irritation agents and formulations that did not. In relation to the objection that all of the examples that fall under the scope of claim 1 contained triethanolamine, which should therefore be regarded as an essential feature, the respondent argued that the passage on page 7, lines 16-17, disclosed triethanolamine as being optional, and that the passage on page 16, lines 20-23, showed that the effect of the invention could be achieved in the absence of triethanolamine.

Finally, with regard to the addition of water to 100%, the respondent asserted that this was the normal way of proceeding and that the skilled person would have had

no doubts in this respect when looking at the examples and, in particular, at step (4) of the typical manufacturing procedure on pages 18 and 19 of the application as filed.

On the issue of added subject-matter in auxiliary request 1, the respondent noted that claim 1 resulted from the combination of claims 1 to 3 of the main request. The specification that the composition was a gel (see claim 2 of the main request) was supported by the passage on page 7, line 5, and by the fact that the composition comprised a gelling agent and that all specific examples were gels. Further, the new concentration range of testosterone (see claim 3 of the main request) was disclosed in clause 9 and on page 5, lines 12-14, of the application as filed, and the restriction of the preservative and the cross-linking agent to their corresponding preferred embodiments butylated hydroxytoluene and triethanolamine was disclosed on page 7, lines 17-18, and page 7, lines 16-17, respectively.

- X. The appellant (opponent) requested that the decision under appeal be set aside and that European patent No. 1 510 213 be revoked. It further requested that the auxiliary request as filed during the oral proceedings before the opposition division on 8 December 2011 not be admitted into the appeal proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed (main request), or alternatively that the patent be maintained on the basis of one of auxiliary requests 1 and 2 filed with letter dated 21 March 2017.

XI. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Admission by the opposition division (Rule 116(2) EPC)*

In the course of the oral proceedings before the opposition division, the present main request was admitted into the proceedings. Its submission was considered to constitute a legitimate reaction to the rejection of the main request. The opposition division reasoned that there had been "no earlier possibility or necessity for the proprietor to file an auxiliary request trying to overcome any objection with regard to inventive step" (see point 45 of the decision under appeal), which is corroborated by the fact that in the annex to the summons to oral proceedings, the opposition division had given a positive opinion regarding inventive step (see point 20). Of course, a patentee should present its full case in reply to a notice of opposition. However, the need for amendments arose in the present case when the respondent was faced with a shift of opinion on the part of the opposition division. Whereas such a departure from the preliminary opinion is legitimate, the need for an opportunity to amend the claims may arise (see Rule 81(3) EPC).

The board, therefore, concludes that the division did not exercise its discretion to admit the present main

request in an unreasonable way, and sees no reason to overrule this decision.

3. *Added subject-matter (Article 100(c) EPC in combination with Articles 76(1) and 123(2) EPC)*

3.1 The description of the application as originally filed essentially corresponds to the text of the parent application as filed, wherein the claims of the parent application were designated in the present application as clauses. The discussion below relating to the application as originally filed (Article 123(2) EPC) therefore applies *mutatis mutandis* to the parent application as filed (Article 76(1) EPC).

3.2 In its arguments on added subject-matter, the respondent started from the composition defined by the combination of clauses 1 and 2 in the application as filed, which would establish the essential components of present claim 1, i.e. components (a) to (e). Starting from that composition, the board observes that claim 1 of the main request contains restrictions on three main aspects: firstly, claim 1 restricts the **number of possible components** present in the composition by the expression "consists essentially of", which limits said components to (a) to (e), water and, optionally, preservatives and cross-linking agents; secondly, the claim restricts the **nature of the components** (a), (c), (d) and (e) to be specifically testosterone, ethanol/isopropanol, propylene glycol and carbomer, respectively; and thirdly, the claim introduces a restriction on the **concentration of the essential components** (a) to (e).

The board is of the opinion that the introduction in claim 1 of said first restriction, i.e. the expression

"consists essentially of", already results in the addition of subject-matter in the sense of Articles 76(1) and 123(2) EPC, for the reasons explained below.

- 3.3 The respondent submitted that the wording "consists essentially of", which was not explicitly mentioned in the application as filed, would be supported by the combination of clauses 1 and 2 with the passage on page 7, lines 15-24, of the application as filed, whereby the clauses would establish the essential components (a) to (e), and the passage would limit the optional ingredients to cross-linking agents and preservatives. In addition, in the light of formulation 545 in table 2, the formulations in examples 5, 8 and 9 and the typical manufacturing process detailed in the passage bridging pages 18 and 19 of the application as filed, the skilled person would necessarily understand that testosterone, ethanol, isopropanol, propylene glycol and carbomer would be essential components, while cross-linking agents, such as triethanolamine, and preservatives, such as butylated hydroxytoluene, would be merely optional.

The board cannot agree with the respondent's view in this respect and notes that the respondent's arguments rely on a preliminary selection of the examples that contain only testosterone, oleic acid, ethanol, isopropanol, propylene glycol, carbomer, water and, optionally, cross-linking agents and preservatives, a selection that would result in a very limited number of embodiments, namely formulation 545 of table 2, composition K of table 3, formulation DAA-97-601 of table 4, the formulations of example 8, and the formulation of example 9. The selection, however, would leave out of the scope of claim 1 typical compositions lacking any of the ingredients now considered essential

by claim 1 (e.g. formulations A and B of example 1 and the formulations of examples 3-4) and compositions containing ingredients excluded from present claim 1, such as further irritation-reducing agents (e.g. formulations J and L of table 3; and formulations DAA-97-602 and DAA-97-600 of table 4). But, more importantly, all of the selected examples on which claim 1 would be based appear to contain triethanolamine (i.e. a cross-linking agent), thereby suggesting that, for the particular combination of components (a) to (e) and water defined in present claim 1, triethanolamine would be an essential feature. Hence, even though the passage on page 7, lines 15-24, generally mentions cross-linking agents as being optional ingredients, the teaching of the application as filed for the particular combination of ingredients now in claim 1 (i.e. testosterone, oleic acid, ethanol, isopropanol, propylene glycol, carbomer and water) is that cross-linking agents, in particular triethanolamine, are essential.

- 3.4 In conclusion, at least for the reason that claim 1 defines triethanolamine as being optional rather than essential, it encompasses subject-matter which extends beyond the content of both the application and the parent application as originally filed.

Auxiliary request 1

4. *Admission (Article 13(1) RPBA)*

Auxiliary request 1 was filed in the appeal proceedings in reaction to the board's preliminary opinion sent with its summons to oral proceedings. The board considers the limitation introduced by this auxiliary

request to be a reasonable reaction and has therefore decided to admit it.

5. *Added subject-matter (Article 100(c) EPC in combination with Articles 76(1) and 123(2) EPC)*

The composition of claim 1 of auxiliary request 1 consists essentially of the same components (a) to (e) and water as in the main request, and it also defines triethanolamine as an optional ingredient. Thus, at least for the reason explained in the discussion of the main request, that the application as filed teaches triethanolamine as being an essential ingredient for compositions consisting essentially of testosterone, oleic acid, ethanol, isopropanol, propylene glycol, carbomer and water, auxiliary request 1 adds subject-matter.

Auxiliary request 2

6. *Admission (Article 13(1) RPBA)*

Auxiliary request 2 was also filed one month before oral proceedings in reaction to the board's preliminary opinion. However, unlike auxiliary request 1, this request *prima facie* raises new issues of clarity because its feature (h) requires the presence of "extra triethanolamine or 1.0 N HCl if necessary to adjust the pH", but fails to define when a pH adjustment would be necessary and, in that case, to what value the pH should be adjusted. Consequently, the board has exercised its discretion against the admission of this request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated