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Datasheet for the decision of 19 May 2020

Case Number: T 1916/19 - 3.3.10

Application Number: 11719581.8

Publication Number: 2575744

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A61K8/86, A61Q17/00

Language of the proceedings: EN

Title of invention:

SKIN TREATMENT COMPOSITION

Applicants:

Unilever N.V. Unilever PLC

Headword:

Relevant legal provisions:

EPC Art. 53(c), 123(2), 84, 111 RPBA 2020 Art. 11

Keyword:

Exceptions to patentability - method for treatment by therapy
- (no)
Amendments - undisclosed disclaimer - allowable (yes)
Claims - clarity (yes)

Decisions cited:

G 0001/03, G 0001/07, G 0001/16, T 0036/83, T 0144/83, T 0290/86, T 0385/09, T 1635/09, T 0767/12

Catchword:



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Case Number: T 1916/19 - 3.3.10

DECISION
of Technical Board of Appeal 3.3.10
of 19 May 2020

Appellant: Unilever N.V. Weena 455

(Applicant 1) Weena 433 3013 AL Rotterdam (NL)

Appellant: Unilever PLC

(Applicant 2) A Company Registered In England And Wales

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 9 January 2019

refusing European patent application No. 11719581.8 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman P. Gryczka

Members: M. Kollmannsberger

F. Blumer

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Summary of Facts and Submissions

- I. The appeal lies from the decision of the Examining Division to refuse European patent application No. 11 719 581.8.
- II. The application relates to methods of providing an anti-microbial effect to skin by applying a specific composition to it.

In the course of the examination proceedings the appellants split the claim set into claims directed to a non-therapeutic method of providing an anti-microbial effect to skin on the one hand, and a composition for use in therapeutically providing an anti-microbial effect to skin on the other hand.

III. The appellants were summoned to oral proceedings before the Examining Division. In the accompanying communication the appellants were informed that claims directed to a non-therapeutic method of providing an anti-microbial effect to skin contravened Article 53(c) EPC and could not be granted.

After issuing the summons the appellants filed three sets of claims as auxiliary requests, withdrew the request for oral proceedings and requested continuation of the proceedings in writing.

In a communication under Rule 71(3) EPC the appellants were informed that a patent could be granted on the basis of auxiliary request 3 then on file which only contained claims directed to a *composition for use in*

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therapeutically providing an anti-microbial effect to skin.

IV. With the reply to the communication under Rule 71(3) EPC the appellants stated their disapproval of the text specified in the communication and stated, pursuant to Rule 71(6) EPC, that they maintained the main, first and second auxiliary request, all of which contained claims directed to a non-therapeutic method of providing an anti-microbial effect to skin. The third auxiliary request, on which the communication under Rule 71(3) EPC was based, was withdrawn. Furthermore, they requested the Examining Division to issue a decision according to the state of the file.

Following this request the Examining Division refused the application for non-compliance of all pending requests with Article 53(c) EPC.

V. The independent claims of the main request underlying the impugned decision, as well as the present appeal proceedings, read as follows:

Claim 1 reads:

A non-therapeutic method of providing an anti-microbial effect to skin comprising the steps of

- (i) applying a composition to the skin comprising (a) a polymer A selected from the group of polyacrylic acid or a copolymer thereof or a polyalkylene oxide having a molecular mass greater than $2x10^4$ D, and
 - (b) at least two essential oils selected from eugenol, thymol, and terpineol; and
- (ii) waiting for at least 15 seconds.

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Claim 5 reads:

Non-therapeutic use of a composition comprising

- (a) polymer A selected from the group of polyacrylic acid and a copolymer thereof or a polyalkylene oxide having a molecular mass greater than $2x10^4$ D, and
- (b) at least two essential oils selected from eugenol, thymol, terpineol, and , [sic!] for providing an anti-microbial effect on skin.

Claim 6 reads:

A composition for use in therapeutically providing an antimicrobial effect to skin, wherein the composition comprises

- (a) a polymer A selected from the group of polyacrylic acid or a copolymer thereof or a polyalkylene oxide having a molecular mass greater than $2x10^4$ D, and
- (b) at least two essential oils selected from eugenol, thymol, and terpineol.

Claim 7 reads:

A composition according to claim 6, for use in a therapeutic method of providing an antimicrobial effect to skin, wherein the method comprises the steps of

- (i) applying the composition to the skin;
- (ii) waiting for at least 15 seconds.

The claims of the auxiliary requests add the requirements that the composition is a *skin care or cleansing product* (auxiliary request 1), a *hand soap*, hand hygiene, deodorant, face wash, body wash, shampoo or hair conditioner product (auxiliary request 2) or

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that the composition is a *deodorant* (auxiliary request 3).

VI. In the statement setting out the grounds of appeal the appellants argued why the claims on file did not contravene Article 53(c) EPC.

They requested:

That a patent be granted based on the claims of the main request as filed during examination proceedings with letter dated 24 January 2017 or based on auxiliary requests 1 to 3, all filed with the statement of grounds of appeal.

Oral Proceedings in case the main request cannot be granted.

That questions be referred to the Enlarged Board of Appeal under Article 112(1)(a) EPC in case the Board upheld the Examining Division's decision with respect to Article 53(c) EPC.

VII. The Board summoned for oral proceedings and issued a Communication under Article 15(1) RPBA 2020 setting out its preliminary opinion. Referring to this preliminary opinion the appellants withdrew their request for oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

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Main Request

2. Reasoning of the Examining Division

The Examining Division held that independent claims 1 and 5 related to a method of treatment of the human or animal body by therapy and contravened thus Article 53(c) EPC.

In particular it held that antimicrobial activity of a composition is inherent to a therapeutic prophylactic treatment to several diseases. Thus, a method providing antimicrobial activity could only be considered a therapeutic treatment even if the method could also be used in a non-therapeutic (e. g. cosmetic) way.

In the view of the Examining Division the subjectmatter of these claims related to a method having both therapeutic and non-therapeutic effects which are inextricably linked. Since the method thus inevitably encompassed a therapeutic effect the method as a whole fell under the provisions of Article 53(c) EPC. In this respect it was referred to T 290/86 (OJ 1992, 414).

3. The appellants' argumentation on the objection under Article 53(c) EPC

The appellants provided various lines of reasoning why the method claimed in claim 1 and the use defined in claim 5 would not be covered by the exclusion provision of Article 53(c) EPC. Inter alia, the following arguments were submitted:

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The appellants argued that by virtue of the disclaimer "non-therapeutic" the claimed method could not, by definition, cover any therapeutic treatment.

Furthermore they argued that there were clearly nontherapeutic realisations of the claimed method. There was thus a clear distinction between therapeutic and non-therapeutic methods and the corresponding effects were not inextricably linked.

They furthermore referred to G 01/07 (points 3.3.8.6 of the reasons) and argued that the methods were not therapeutic in *character*.

- 4. Inextricable link of therapeutic and non-therapeutic effects
- In the present case the compliance of the claims with the EPC depends on whether the claimed non-therapeutic methods/uses can be separated from the ones which exclusively or additionally have a therapeutic effect. Thus, this question will be treated first.
- 4.2 The reasoning of the Examining Division is based on its finding that in the present case non-therapeutic methods or uses are not separable from therapeutic ones. Following long standing jurisprudence (referred to in more detail below), this leads to the conclusion that a claim being directed to non-therapeutic uses or non-therapeutic methods does not comply with the EPC.
- According to T 290/86 (OJ 1992, 414) a claim directed to a method having both cosmetic and therapeutic effects is excluded from patentability under Article 52(4) EPC 1973, now Article 53(c) EPC. Such a method

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can, on the other hand, be claimed in an appropriate format as first or further medical use claim according to G 5/83, now codified in Articles 54(4)(5) EPC. T 290/86 related to a method of plaque removal which was held to have cosmetic as well as prophylactic effects which cannot be separated.

This line of argumentation has been followed in later decisions.

T 1635/09 (OJ 2011, 542) related to a method of contraception which was found to have intrinsically linked therapeutic effects. A claim to such a method was found to contravene Article 53(c) EPC. The introduction of a disclaimer to define the claimed method as "non-therapeutic" was considered not to change this situation since the method as such was still encompassing a method for therapy excluded under Article 53(c) EPC. Moreover the claim was considered to be unclear under Article 84 EPC since the disclaimer required a "non-therapeutic" method, whereas the method defined in the claim was in fact therapeutic.

In T 767/12 non-therapeutic and therapeutic methods for normalizing infradian rhythm were considered indistinguishable. A disclaimer intended to restrict the claim to "non-therapeutic" methods was considered unallowable for lack of clarity under Article 84 EPC since it rendered the scope of the claim void.

Reference was made to G 1/03 (OJ EPO 2004, 413), headnotes II.1 and II.4 according to which a disclaimer may be allowable in order to exclude subject-matter falling under Article 53(c) EPC, but the claim must meet the requirements of clarity and conciseness of Article 84 EPC.

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4.4 On the other hand, in case therapeutic and non-therapeutic (e. g. cosmetic) methods can be separated, claims directed to non-therapeutic methods may be allowed.

This was the case e. g. in T 144/83 (OJ 1986, 301; curing of obesity vs. reduction of body weight) or in T 36/83 (OJ 1986, 295) where antimicrobial acne treatment (therapeutic) was considered separable from comedo removal (cosmetic). In such cases also disclaimers to define "non-therapeutic" applications were considered allowable (e. g. in T 385/09).

4.5 In the present case, the claimed methods and uses relate to providing an anti-microbial effect to skin.

In the view of the Examining Division this inherently implies a prophylactic treatment of several diseases. Reference was made to the description page 1, lines 14-25. In this passage it is described that many microorganisms on skin are are harmless, but there are some which may be pathogenic. According to the Examining Division skin disinfection will always remove pathogenic bacteria and will provide a prophylactic effect to various diseases. A claim to such a method is thus excluded from patentability under Article 53(c) EPC.

- 4.6 The Board does not concur with this view.
- 4.6.1 Undoubtedly, at least some realisations of the claimed method of providing an anti-microbial effect on skin are therapeutic in nature, e. g. in case the composition is applied to individuals suffering from a bacterial skin infection or a wound. There may be also realisations of the method which, depending on the

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circumstances, may be of a therapeutic/prophylactic nature or not, e. g. applying the composition to the hands.

4.6.2 On the other hand the Board follows the arguments of the appellants in that there are at least some realisations of the method which are clearly nontherapeutic.

Removing non-pathogenic bacteria responsible for unpleasant body odour (page 1 lines 14-18 of the originally filed patent application), e. g. by applying a deodorant composition, is not a therapeutic/prophylactic, but a cosmetic application.

The argument that in such cases inevitably also pathogenic bacteria are removed, thus implying prophylactic treatment, is not convincing. Removal of bacteria from healthy skin is not necessarily prophylactic. Even in case potentially pathogenic bacteria are present on its skin a healthy individual is not likely to develop a pathological state only because of the presence of such bacteria. Not disinfecting one's armpits or feet may have unpleasant consequences, but will not, as such, lead to a pathological condition.

4.6.3 Thus, the Board does not share the reasoning of the Examining Division that the claims only define methods in which non-therapeutic and therapeutic effects are inextricably linked.

The Board comes to the conclusion that there are realisations of the claimed methods that are of a non-therapeutic nature, others that are of a therapeutic nature, and others that may be mixed.

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5. Allowability of the disclaimer under Articles 123(2) and 84 EPC

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Independent claims 1 and 5 contain the feature "non-therapeutic". This feature was not present in the original application documents and is an undisclosed disclaimer in the sense of G 01/03. Its allowability under Articles 123(2) and 84 EPC is thus subject to the conditions set out in this decision (confirmed in G 01/16, OJ EPO 2018, A70, headnote).

According to point II.1 of the headnote of G 01/03 a disclaimer may remove subject-matter that is excluded from patentability under Articles 52-57 EPC for non-technical reasons. The exclusion of therapeutic treatments under Article 53(c) EPC falls under this provision.

According to point II.4 of the headnote, the disclaimer must also comply with the requirements of clarity and conciseness of Article 84 EPC. In the present case the claim is clear since such non-therapeutic methods exist and can be identified. In particular the claims are not self-contradictory and the claimed scope is not rendered void by the disclaimer, unlike in the cases of T 1635/09 or T 767/12 (discussed above). Conciseness of the claims is not an issue here.

The Board is satisfied that also the requirements of headnotes II.2 and II.3 are fulfilled. The disclaimer does not remove more than necessary and is not relevant for the assessment of inventive step or sufficiency of disclosure.

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Thus, the disclaimer is allowable.

6. Exclusion from patentability under Article 53(c) EPC

Independent claims 1 and 5 are directed to non-therapeutic methods/uses of providing an anti-microbial effect to skin. As discussed above, such methods exist and can be identified.

Independent claims 1 and 5 thus do not cover therapeutic or prophylactic treatment of the human or animal body.

Compositions for use in therapeutic methods are covered by independent claim 6, correctly drafted according to Article 54(5) EPC.

Thus, none of the claims is directed to subject-matter excluded from patentability under Article 53(c) EPC.

7. Remittal (Article 111 EPC)

The Board notes that the Examining Division considered present claims 6-10 as compliant with the provisions of the EPC.

However, it is not clear from the file whether the subject-matter of present claims 1-5 has been examined for compliance with the EPC other than for questions of Article 53(c) EPC.

The Board considers this to be a special reason under Article 11 RPBA 2020 and decides thus to remit the case to the Examining Division for further prosecution.

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8. In view of the above, neither the further arguments brought forward by the appellants nor the claim sets filed as auxiliary requests need to be discussed.

The appellants' request for a referral to the Enlarged Board of Appeal is conditional on the Board maintaining the Examining Division's decision on Article 53(c) EPC. Since this is not the case, the appellants' request is moot.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated