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Datasheet for the decision of 24 April 2023

Case Number: T 0529/19 - 3.2.02

Application Number: 04257677.7

Publication Number: 1541084

IPC: A61B5/103, G01N21/64

Language of the proceedings: EN

Title of invention:
Method of assessing skin and overall health of an individual

Applicant:
Johnson & Johnson Consumer Inc.

Headword:

Relevant legal provisions:
EPC Art. 53(c), 111(1)
RPBA 2020 Art. 11

Keyword:
Exceptions to patentability - diagnostic method - (no)
Remittal to the department of first instance - (yes)

Decisions cited:
G 0001/04

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0529/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 April 2023

Appellant: (Applicant)	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 September 2018 refusing European patent application No. 04257677.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	Y. Podbielski

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division refusing European patent application No. 04 257 677.7. The examining division found that each claim of the two requests then on file defined a diagnostic method within the meaning of Article 53(c) EPC.

II. The appellant requested that the decision under appeal be set aside and that the case be remitted back to the examining division for further prosecution on the basis of the main request or, as an auxiliary measure, on the basis of the auxiliary request 1, both filed with the statement of grounds of appeal.

III. Claims 1, 11 and 12 of the main request read as follows:

1. "A method of determining skin health of an area of skin, said method comprising the steps of

(i) exposing said area of skin to a first exposure radiation to induce said area of skin to emit a first fluorescent emission, wherein said first exposure radiation comprises primarily of wavelengths of from about 290 nm to about 300 nm;
(ii) measuring the intensity of said first fluorescent emission having a wavelength of from about 320 nm to about 350 nm;
(iii) exposing said area of skin to a second exposure radiation to induce said area of skin to emit a second fluorescent emission, wherein said second exposure radiation comprises primarily of wavelengths of from about 330 nm to about 420 nm;

(iv) measuring the intensity of said second fluorescent emission having a wavelength of from about 380 nm to about 470 nm;
(v) calculating a ratio of said intensity measured in step (ii) to said intensity measured in step (iv); and
(vi) comparing said ratio to a control ratio."

11. "A method of assessing the overall health of an individual, including creating a standard curve for a plurality of healthy individuals by:
performing steps (i) to (v) of the method of claim 1 on each healthy individual;
plotting a standard curve for age of each healthy individual versus each ratio of step (v);
performing the measurements of steps (i) to (iv) for an individual;
calculating the ratio of step (v) for the individual; and
performing step (vi) of the method of claim 1, wherein said ratio is the ratio of step (v) for the individual and the control ratio is the standard curve."

12. "A method of assessing the overall health of an individual, including determining an average normalised fluorescence value by age for a plurality of healthy individuals by:
performing steps (i) to (iv) of the method of claim 1 on each healthy individual;
calculating the normalised fluorescence value for each of the plurality of individuals by calculating the ratio of step (v);
calculating the average normalised fluorescence value by age;

performing the measurements of steps (i) to (v) for an individual; and

performing step (vi) of the method of claim 1, wherein said ratio is the ratio of step (v) for the individual and the control ratio is the average normalised fluorescence value by age."

IV. The appellant's arguments, where relevant to the decision, can be summarised as follows.

Article 53(c) EPC

Determining "skin health" and assessing the "overall health" as defined in the claims of the main request did neither identify nor rule out any particular condition. The claims possibly revealed symptoms or provided intermediate findings of diagnostic relevance, but they did not provide a diagnosis for curative purposes *stricto sensu*. Hence, the main request did not define any diagnostic method precluded from patentability under Article 53(c) EPC.

Reasons for the Decision

1. The application

The native fluorescence of human skin and mouse skin varies with ageing and UV exposure. The application uses skin autofluorescence spectroscopy to evaluate skin health and the effects of ageing (e.g. chronological ageing and photoageing) on skin health.

In the method defined by claim 1, an area of the skin is exposed to a first radiation and the intensity of a first fluorescence emission is measured. The area of

the skin is exposed to a second radiation and the intensity of a second fluorescence emission is measured. A ratio of the intensity of the first fluorescence emission to the intensity of the second fluorescence emission is then calculated and compared to a control ratio so as to determine skin health of the area of the skin.

Claim 1 further specifies the wavelength ranges which are primarily comprised in the first and second exposure radiations and the wavelength ranges at which the intensities of the first and second fluorescence emissions are measured.

2. **Main request - Article 53(c) EPC**

2.1 In its Opinion G 1/04 (OJ EPO 2006, 334) the Enlarged Board came, among other things, to the following conclusion (see point 1):

"1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC [EPC 1973], the claim is to include the features relating to:
(i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
(ii) the preceding steps which are constitutive for making that diagnosis, and
(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature."

In point 5 of the Reasons for the Opinion, the Enlarged Board stated that the method steps to be carried out

when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include:
(i) the examination phase involving the collection of data,
(ii) the comparison of these data with standard values,
(iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

The interpretation of the scope of exclusion from patentability under Article 52(4) EPC 1973 elaborated in Opinion G 1/04 is still valid for Article 53(c) EPC (see G 1/04, Reasons 10-11).

2.2 Claim 1 of the main request defines a method "of determining skin health of an area of skin". The steps of this method include calculating a ratio between the intensities measured for two fluorescent emissions induced on the area of skin and comparing this ratio to a control ratio.

In the decision under appeal, the examining division found that the phases (i) to (iii) of G 1/04, Reasons 5, were present in the steps of the method recited by claim 1. The examining division further found that the phase (iv) of G 1/04, Reasons 5 was derivable from the wording "[a] method of determining skin health" at the beginning of claim 1. The appellant contests the latter finding and submits that the method of claim 1 does not include the attribution of the deviation to a particular clinical picture.

The Board observes that claim 1 leaves open what the determined "skin health" is. For example, it could refer to the quotient between the two ratios being compared in step (vi) of claim 1 or to some other parameter related to skin health, which may at most be an intermediate finding of diagnostic value.

Although the term suggests that some assessment of the skin health is made, neither the claim wording nor the relevant passages of the description indicate that the assessment would actually include the attribution to a particular clinical picture. Diabetes and its progression are mentioned in the description as having an impact on the obtained values (see page 19, lines 24-28), but the claimed method does not include attributing any finding to the presence or absence of diabetes. Instead, the description emphasises that the ratios obtained by the method are related to age and show the effects of ageing (see page 3, lines 15-18; page 8, line 19 to page 9, line 6; page 12, lines 19-21; and page 14, line 1 to page 15, line 18). Even if the method were construed as including some judgment of skin ageing for the assessed skin area, this would not represent the attribution to a particular clinical picture. Establishing that skin ageing is greater than expected for an individual would be, at most, an intermediate finding of diagnostic value.

Hence, the method of claim 1 does not include the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase. None of the dependent claims 2-10 includes this phase either.

2.3 Claims 11 and 12 relate to a "method of assessing the overall health of an individual". These methods include

on the one hand carrying out measurements on healthy individuals to determine a control ratio and, on the other hand, carrying out the method of claim 1 for an individual using the determined control ratio.

Similarly as explained for claim 1, claims 11 and 12 leave open what "assessing the overall health of an individual" means. The most relevant passages of the description teach that a ratio below the control ratio when assessing the overall health could be "an indication that there may be a health problem, such as diabetes" (see page 5, lines 21-28 and page 21, lines 1-4). Even if the assessment of method claims 11 and 12 were to be construed accordingly, an indication that there may be a health problem would, at most, represent an intermediate finding of diagnostic value. Hence, none of the methods defined by claims 11 and 12 includes the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

2.4 In summary, none of the methods defined by the claims of the main request include the deductive medical or veterinary decision phase. It follows that none of them defines a diagnostic method practised on the human or animal body within the meaning of Article 53(c) EPC.

3. Remittal

Pursuant to Article 111(1), second sentence, EPC the Board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

The refusal by the examining division was based on Article 53(c) EPC. It is not apparent from the appealed decision whether or not there were any other reasons which would prevent that a patent be granted on the basis of the main request. This situation constitutes in the Board's view special reasons within the meaning of Article 11 RPBA 2020 justifying remittal of the case.

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 Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated