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**Datasheet for the decision
of 18 March 2008**

Case Number: T 0298/06 - 3.3.04

Application Number: 96906750.3

Publication Number: 0814823

IPC: A61K 35/78

Language of the proceedings: EN

Title of invention:

Polyphenol fractions of tea, the use thereof and formulations containing them

Patentee:

INDENA S.p.A.

Opponent:

MediGene Aktiengesellschaft

Headword:

Teafractions/INDENA

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request - inventive step (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0298/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 18 March 2008

Appellant:
(Patent Proprietor)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 28 December 2005
revoking European patent No. 0814823 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chair: U. Kinkeldey
Members: B. Claes
D. S. Rogers

Summary of Facts and Submissions

- I. The patent proprietor lodged an appeal against the decision of the opposition division to revoke European patent No. 0 814 823 with the title "Polyphenol fractions of tea, the use thereof and formulations containing them" which was based on international application PCT/EP96/00973 (published as WO 96/28178).
- II. Claim 14 of the patent as granted read:

"14. Green tea polyphenol fractions containing 50-65% epigallocatechin-3-O-gallate, 13-20% epicatechin-3-O-gallate, 2-4% epicatechin and 1.5-3% epigallocatechin and no more than 0.2% of caffeine."
- III. The opposition division revoked the patent as they found that claim 1 of the main request before them infringed the requirements of Article 123(3) EPC whereas claim 1 of the auxiliary request infringed Article 123(2),(3) EPC and Rule 57a EPC 1973. Claim 13 of the main request and claim 9 of the auxiliary request before the opposition division were identical to claim 14 as granted.
- IV. With the statement of the grounds of appeal dated 24 April 2006, the appellant filed a new main request comprising 11 claims. Claim 4 of this request was identical to claim 14 of the patent as granted.
- V. The respondent (opponent) responded to the appeal with letter dated 14 September 2006.

- VI. The board summoned the parties to oral proceedings to take place on 18 March 2008.
- VII. In a communication pursuant to Article 17(2) of the Rules of Procedure of the Boards of Appeal, dated 19 February 2008, the board expressed its preliminary opinion that the claims of the main request filed with the statement of grounds of appeal complied with the requirements of Articles 84, 123(2),(3) EPC and Rule 80 EPC and noted that during the oral proceedings before the board the parties might be required to express their opinion on whether or not the case should be remitted to the department of first instance for further prosecution.
- VIII. With letter dated 11 March 2008, the appellant announced that he would not attend the oral proceedings and responded to the submissions of the respondent.
- IX. Oral proceedings were held on 18 March 2008 in the absence of the appellant who had been duly summoned.
- X. The following documents is cited in the present decision:
- D7: US 4,673,530
- XI. The arguments of the appellant as far as they are relevant for the present decision may be summarised as follows:
- The closest prior art was represented by document (D7). The problem to be solved was the provision of

polyphenol-enriched and standardized tea extracts with a reduced caffeine content.

- The standardized polyphenol-enriched extract of the invention was particularly effective in terms of antioxidant activity, had an antimutagenic effect and was characterized by differential cytotoxicity (paragraphs [0019] and [0020]). All these beneficial effects could be attributed to the polyphenol-balanced composition of the extracts obtained with the claimed process.

- Although each single step of the extraction process described in the patent in suit might be generically mentioned in document (D7), their sequential combination as per the claimed process was neither disclosed nor suggested. There was no suggestion to combine the extraction steps in the manner provided by the invention, in order to prepare a standardized and polyphenol-enriched composition.

- The products obtained from the processes disclosed in document (D7) were very different from those obtained by the process of the invention. In particular, the compounds which mainly contributed to the antioxidative effect, i.e. epigallocatechin-3-O-gallate and epicatechin-3-O-gallate, were contained in higher proportions in the extract according to the invention as compared to those obtained by the processes as disclosed in document (D7).

- The amount of tannin in the extracts as disclosed in document (D7) were variable and depended on the

solvent used for the extraction process. The products of document (D7) were therefore not standardized in polyphenol content.

XII. The arguments of the respondent as far as they are relevant for the present decision may be summarised as follows:

- In accordance with paragraph [0002] of the patent the problem to be solved by the subject-matter of claim 4 was to provide decaffeinated tea extracts mainly containing polyphenols derived from epigallocatechin in their natural ratio.
- The process of the invention in the patent in suit was a combination of steps which were all disclosed in document (D7).
- The tannin extract of the invention had comparable antioxidant activity as that of example 1 in document (D7).

XIII. The appellant requested to set aside the decision under appeal and to maintain the patent on the basis of a new main request (claims 1 to 11) filed with the statement of the grounds of appeal dated 24 April 2006. The appellant further requested that "if the board is not in a position to decide the case on the basis of the written submissions and considers that the issues under Article 56 and 83 EPC require further examination" the case be remitted to the first instance for further prosecution. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Article 15(3) RPBA

1. According to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA) the board is not obliged to delay any step in the proceedings, including its decision, by reasons only of the absence at oral proceedings of any party duly summoned who may then be treated as relying only on its written case. In the present case the board could therefore take a decision at oral proceedings, notwithstanding the announced absence of the duly summoned appellant.

Remission of the case to the department of first instance

2. Under Article 111(1) EPC a board of appeal may either decide on the appeal or remit the case to the department which was responsible for the decision appealed. In the present case the board considers that it is in a position to decide the case on the basis of the written submissions of the appellant and the submissions of the respondent.

Formal requirements of Articles 84, 123(2),(3) EPC and Rule 80 EPC

3. In view of the decision of the board under Article 56 EPC (see below, point 5 ff.) the board deems a decision on the formal requirements of the claims not necessary.

Novelty

4. The respondent has not argued against novelty of the subject-matter of claim 4. Also the board is satisfied that this subject-matter is novel.

Inventive step

5. In accordance with its paragraph [0002], the patent relates to polyphenol fractions of decaffeinated tea, mainly containing polyphenols derived from epigallocatechin in their natural ratio. The invention as subject-matter of claim 4 expresses this ratio in particular percentage ranges for the compounds epigallocatechin gallate, epigallocatechin, epicatechin gallate and epicatechin. The amount of caffeine is limited to no more than 0,2%. As can be seen from the table on page 3 of the patent in suit, the antioxidant activity of the fraction is comparable to that of epigallocatechin-3-O-gallate alone when applied in the same concentrations.
6. For assessing whether or not a claimed invention meets the requirements of Article 56 EPC the boards of appeal apply the "problem and solution" approach, which requires as a first step the identification of the closest prior art. In accordance with the established case law of the boards of appeal, the closest prior art is a teaching in a document conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications to arrive at the claimed invention.

7. The board agrees with the appellant that document (D7) represents the closest prior art. Document (D7) discloses a process for producing a natural tannin extract from tea leaves having excellent antioxidant properties (column 2, lines 65 to 66). Typically the tannin content of the extract is about 70% (column 2, lines 45 to 49) and is composed primarily of epigallocatechin gallate, epigallocatechin, epicatechin gallate and epicatechin (see column 2, lines 51 to 55). In example 1 of document (D7) a tea extract is disclosed in which the tannin content of the solids was 72% by weight (column 3, lines 23 to 24) and from which caffeine was removed (column 3, lines 10 to 14). From 12 grams of the obtained powder 4,87 grams of epigallocatechin gallate, 1,44 grams of epigallocatechin, 1,24 grams of epicatechin gallate and 0,85 grams of epicatechin were obtained (column 3, lines 23 to 28). The board notes that, when converted to percentages, these amounts correspond to 40,58% epigallocatechin gallate, 12,00% epigallocatechin, 10,33% epicatechin gallate and 7,08% epicatechin. The four ingredients represented accordingly 70% of the powder (column 3, lines 28 to 29). The antioxidant activity of the product (column 3, lines 30 to 49, Figures 1 and 2) was comparable with the antioxidant activity of epigallocatechin-3-O-gallate as displayed in Figure 3 (compare Figure 3, EGCg (20 ppm) with Figure 1, natural antioxidant of the invention B: 20 ppm; both tested on lard).
8. The appellant argued that the invention was particularly effective in terms of antioxidant activity, antimutagenic effect and that it was characterized by

- differential cytotoxicity, whereby all these beneficial effects could be attributed to the polyphenol-balanced composition of the extracts of the invention. The antioxidative effect was furthered in particular by the fact that epigallocatechin-3-O-gallate and epicatechin-3-O-gallate were contained in higher proportions in the extract according to the invention as compared to those obtained by the processes disclosed in document (D7).
9. In the context of the antioxidative activity of the extract of the invention the board notes that from the data in the patent in suit and the data in document (D7) it can be concluded that both the subject-matter of claim 4 and the extract of example 1 in document (D7) have similar activities. The facts of the case therefore appear not to provide evidence for an enhanced antioxidative activity of the fraction as subject-matter of claim 4 over the fractions as disclosed in the prior art.
10. The appellant argued that the extracts of the invention have an antimutagenic effect and referred to paragraph [0019] of the patent in suit as support for this. The paragraph states: "*Surprisingly, the polyphenols obtained from green tea (though having a high antioxidant activity), at the same concentrations as those antimutagenic for the products extracted from grape-seeds were antimutagenic, turned out to be devoid of said activity; on the other hand, they are characterized by a differential cytotoxicity (higher in cell lines in which a mitochondrial mutation is lethal) considered of great interest.*". The board finds that this passage of the patent in suit does not support the

- allegation of the appellant. In fact this passage states the contrary of what the appellant alleges.
11. Finally, in the context of alleged differential cytotoxicity of the extracts of the invention, the board notes that according to the case law of the boards of appeal, alleged advantages to which a patent proprietor merely refers, without offering sufficient evidence to support a comparison with the closest prior art, cannot be taken into consideration in determining the problem underlying the invention and therefore in assessing inventive step (Case Law of the Boards of Appeal of the European Patent Office, 2006, 4.2). In the present case no such comparative evidence has been provided by the appellant. Thus the alleged advantage of differential cytotoxicity cannot be taken into consideration for the assessment of inventive step.
 12. In view of the above considerations the technical problem to be solved by the invention as subject-matter of claim 4 is therefore the provision of an alternative tannin tea extract to the extract disclosed in document (D7) having a similar antioxidant activity. In view of the results displayed in the table at page 3 of the patent in suit the board is satisfied that this problem is solved by the claimed subject-matter.
 13. When assessing whether or not the subject-matter of claim 4 was rendered obvious by the prior art to the skilled person, it is worth noting that this claim concerns a product, as opposed to claim 1 which concerns an extraction process. Indeed, it is evident and established in the case law of the boards of appeal that although a process for the production of a product

may involve an inventive step, a claim to the product itself need not necessarily be novel or inventive. In the present case the board deems it not necessary to decide whether or not the subject-matter of claim 1 involves an inventive step in view of the position it takes below on the question of claim 4 and inventive step.

14. As earlier established, the subject-matter of claim 4 differs from the tea extract disclosed in example 1 of document (D7) in that the percentages of epigallocatechin-3-O-gallate and epicatechin-3-O-gallate are slightly higher (50-65 % as compared to 40,58 % vs. and 13-20 % vs. 10,33 %, respectively) whereas the percentages of epicatechin and epigallocatechin are slightly lower (2-4 % vs. 7,08 % and 1,5-3 % vs. 12 %, respectively). The appellant has argued that depending on the solvents used in the extraction process different tannin compound concentrations are obtained. The board therefore concludes that at the relevant date it was known to the skilled person that use of different solvents in a tannin extraction processes for green tea resulted in alternative tannin compositions. Accordingly, in the absence of any advantageous and/or surprising effects resulting from the choice of the fraction in claim 4, this fraction is to be considered as a mere arbitrary selection, the variation of the concentration of the compounds in the in the fraction being such as the skilled person would expect to result from the application of an extraction procedure that used a different solvent than that disclosed in the closest prior art.

15. In view of the above considerations the subject-matter of claim 4 was obvious to the skilled person and therefore lacks an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chair

P. Cremona

U. Kinkeldey