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**Datasheet for the decision  
of 22 September 2009**

**Case Number:** T 1416/07 - 3.3.09

**Application Number:** 00974420.2

**Publication Number:** 1225810

**IPC:** A23L 1/30

**Language of the proceedings:** EN

**Title of invention:**

Method for treatment of chronic venous insufficiencies using  
an extract of red vine leaves

**Patentee:**

Boehringer Ingelheim International GmbH

**Opponent:**

Frutarom Schweiz AG

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 108, 114

EPC R. 99(2)

**Keyword:**

"Sufficiency of disclosure (yes)"

"Novelty (yes)"

"Inventive step (no - all requests)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1416/07 - 3.3.09

**DECISION**  
of the Technical Board of Appeal 3.3.09  
of 22 September 2009

**Appellant I:** Frutarom Schweiz AG  
(Opponent) Rütowisstrasse  
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**Representative:** Zink-Wild, Markus Peter  
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**Appellant II:** Boehringer Ingelheim International GmbH  
(Patent Proprietor) D-55216 Ingelheim am Rhein (DE)

**Representative:** Schreiber, Christoph  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
2 July 2007 concerning maintenance of European  
patent No. 1225810 in amended form.

**Composition of the Board:**

**Chairman:** P. Kitzmantel  
**Members:** J. Jardón Álvarez  
M.-B. Tardo-Dino

## Summary of Facts and Submissions

I. This decision concerns the appeals filed by the Opponent and the Patent Proprietor against the interlocutory decision of the Opposition Division which found that the European patent No. 1 225 810 in amended form satisfied the requirements of the EPC.

II. The patent was based on the European patent application No. 00974420.2 in the name of Boehringer Ingelheim International GmbH, which had been filed on 19 October 2000 as International application PCT/EP00/10292 (WO 01/28363). The grant was announced on 26 March 2003 (Bulletin 2003/13) on the basis of 12 claims. Claim 1 read as follows:

"1. The use of a composition in a form suitable for oral administration which consists of an active principle being capable of preventing or treating the discomfort associated with mild-to-moderate chronic venous insufficiency of the lower extremities and a pharmaceutically, cosmetically or dietetically acceptable carrier, wherein the active principle essentially consists of an aqueous extract of red vine leaves containing 2 to 20% flavonoids, wherein said aqueous extract of red vine leaves is obtainable by a method comprising the steps of:

(a) collecting red vine leaves at a point of time when the content in flavonoids has reached an optimum;

(b) drying and crushing the leaves;

(c) cutting the leaves to pieces;

(d) extracting the leaves with water at temperatures from 60 to 80 °C for 6 to 10 hours in an exhaustive percolation;

(e) optionally concentrating the obtained extract;

for the preparation of a dietary supplement for the prevention and/or treatment of the discomfort associated with mild-to-moderate chronic venous insufficiency of the lower extremities."

Claims 2 to 12 were dependent claims.

III. A Notice of Opposition, requesting revocation of the patent in its entirety on the grounds of Articles 100(a) and (b) EPC, as well as on the ground according to Article 52(4) EPC 1973 that Claims 7 to 12 of the patent concerned a method for the treatment of the human or animal body not susceptible to industrial application within the meaning of Article 52(1) EPC 1973, was filed against the patent by Frutarom Schweiz AG on 22 December 2003.

During the opposition proceedings, *inter alia*, the following documents were cited:

D4: Monographies de la 10<sup>e</sup> édition de la Pharmacopée Française, Extrait de vigne rouge (sec), janvier 1996;

D5: Rote Liste 1998, Venentherapeutika, 83048 and 83084; "Antistax®"

D7 "Rotes Weinlaub von A bis Z", Heidemarie Beck, PTA heute, Nr. 8, August 1997, pages 792-796;

IV. By its interlocutory decision announced orally on 22 May 2007 and issued in writing on 2 July 2007, the Opposition Division held that the grounds for opposition did not prejudice the maintenance of the patent in amended form on the basis of the claims according to auxiliary request 1.

Claim 1 of auxiliary request 1 maintained by the Opposition Division corresponds to Claim 1 of the main request (i.e. the granted version) with the deletion of the word "essentially" in the expression "the active principle essentially consists of" which was thus amended to read "the active principle consists of".

The Opposition Division in its decision accepted the industrial applicability of the subject-matter of Claims 7 to 12 and further considered that the invention satisfied the requirements of Article 83 EPC because the skilled person using common general knowledge would have had no difficulty in finding suitable carriers for oral administration.

The Opposition Division understood the expression "the active principle essentially consists of..." (Claim 1 as granted) as not excluding other components provided that the essential characteristics of the compositions were not affected by their presence.

The Opposition Division accepted that the granted subject-matter was novel, but held that it did not involve an inventive step in view of the combined teaching of documents D5 and/or D7 with D4. The Opposition Division, starting from the disclosure of

the product "Antistax®" disclosed in D5 and D7 as the closest prior art, saw the problem underlying the patent in suit as finding a suitable extract for use as an active principle in "Antistax®". The Opposition Division regarded it as obvious for the skilled person that the extract obtained according to D4 was suitable for use as an active principle in 'Antistax®', thus arriving at the claimed subject-matter. In this respect the Opposition Division held that the presence of esculin in the capsules and drops of D5/D7 was not a distinguishing feature because this ingredient would not affect the essential characteristics of the red vine leaves extract.

Finally, the Opposition Division held that the subject-matter of Claim 1 of auxiliary request 1 involved an inventive step, because the amendment to the claim excluded the possible presence of "other compounds as part of the active principle", i.e. its subject-matter was restricted to compositions wherein the extract was free of esculin. In arriving at this conclusion the Opposition Division considered that the omission of esculin from the capsules and drops of D5, and thus using the red vine leaves extract as the sole active principle, was non-obvious.

- V. On 23 August 2007 the Opponent (Appellant I) filed an appeal against the interlocutory decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 25 October 2007, Appellant I requested that the decision under appeal be set aside and the patent be

revoked in its entirety on the grounds of lack of novelty and inventive step, and insufficiency of disclosure.

Appellant I also filed with the Statement of Grounds of Appeal the following documents and experimental results:

D22: Handbook of Food Analysis, Volume 1, Physical characterization and nutrient analysis; edited by L.M.L. Nollet, Marcel Dekker, Inc, 1996, Chapter 21, "Phenolic Compounds" pages 821 - 894;

D23: M. Hmamouchi *et al.*, "Flavones and Flavonols in Leaves of Some Moroccan *Vitis vinifera* Cultivars", *Am. J. Enol. Vitic.*, Vol. 47, No. 2, 1996, pages 186 - 192;

D24: Frutarom Switzerland LTD. "HPLC determination of flavonoids in *Vitis vinifera* extr.a.sicc", document dated 16.08.05 (2 pages); and

D25: Frutarom Switzerland LTD, Versuchsprotokoll VENT, document dated 11 July 2005 (6 pages).

Appellant I filed further letters dated 7 March 2008 and 19 August 2009. It also filed the following fresh evidence:

D26: Advertising material concerning Flachsmann *Vitis vinifera* dated 18.10.1999 8:54;

- D27: "Spezifikation" 0085266 (Vitis vinif. fol extr.a.siccum), a document prepared on 28.04.1995 and lastly amended on 22 January 1999;
- D28: a non-dated delivery sheet concerning the product number 085266;
- D29: a production report from "Flachsmann Emil Flachsmann AG" concerning the product 085.266 dated 13.03.1998;
- D30: Flachsmann production scheme of the product number 85.266 (Vitis viniferae Fol extr.a.sicc. dated 28.07.98;
- D31: Flachsmann "Produkt-Strukturen" of the product 0085266 dated 16.12.99;
- D32: Internet page <http://www.antistax.at/at/Main/produkt/rotesweinlaub/standardisierung/index.htm> dated 02.04.2009;
- D33: Internet page <http://www.antistax.at/at/Main/produkt/rotesweinlaub/wirkstoffe/index.htm> dated 02.04.2009;
- D34: Internet page dated 5.8.2009 concerning the article "Effect of long-distance flights on oedema of the lower extremities" by D. Loew et al., Phlebology, 13(2) 1998, pages 64-67;
- D35: "Flavouring substances and natural sources of flavourings", 3rd edition. Council of Europe, Strasbourg 1981, pages 14 and 111;



- D36: List·Schmidt "Technologie pflanzlicher Arznei-  
zubereitungen, Stuttgart 1984, pages 19, 20, 31,  
32, 35, 36, 41 - 43, 68, 85, 92, 111, 114, 120,  
124, 139 - 142, 186, 196, 211 - 213 and 377;
- D37: The Medicinal Plant Industry, R.O.B. Wijesekera  
ed. 1991, pages 85 - 89, 93, 96 and 11;
- D38: "Interlocutory Decision in Opposition Proceedings"  
concerning EP 1 300 084 dated 14 July 2009 pages  
9-10 of; and
- D39: Internet page dated 18.08.2009 of the  
"Bundesministerium für Ernährung, Landwirtschaft  
und Verbraucherschutz concerning dietary  
supplements.

VI. On 3 September 2007 the Patent Proprietor (Appellant II)  
also filed an appeal against the decision and paid the  
appeal on the same day.

With the Statement setting out the Grounds of Appeal  
submitted on 8 November 2007, Appellant II requested  
that the decision be set aside and the patent be  
maintained as granted.

Appellant II filed further letters dated 17 March 2008  
and 21 August 2009. It also filed with the letter dated  
17 March 2008 the following fresh evidence:

Bil: Dr. E. Schneider "Gutachtliche Darstellung zur  
Aussagekraft von Leitsubstanzen als alleiniger  
Parameter zur Charakterisierung und zum Vergleich

von Pflanzenextrakten unter Betrachtung der Phytoäquivalenz", document dated 18 February 2008; and

Bi2: Dr. M. Veit "Stellungnahme zur Vergleichbarkeit pflanzlicher Extrakte *sui generis* und Gutachten zur Einordnung und Vergleichbarkeit von unterschiedlichen Weinlaubextrakten", document dated 18 February 2008.

VII. On 27 April 2009 the Board dispatched a summons to attend oral proceedings. In the attached Communication the Board drew the attention of the parties to the points to be discussed during the oral proceedings.

VIII. During the oral proceedings held on 22 September 2009, after discussion of the main request and auxiliary request 1 and the announcement that the Board was of the view that the requests were not allowable, Appellant II requested that the minutes of the oral hearing include the statement that "a refusal of the main request and the first auxiliary request was announced by the chairman prior to a decision on admissibility of documents Bi1 and Bi2 (filed by the patentee) into the proceedings and prior to a discussion of the relevance and content of Bi1 and Bi2."

The Board, after deliberation about this issue, re-opened the debate in order to hear the parties' comments on the relevance of these two documents and decided to admit them, as well as document D25 from Appellant I, into the proceedings. Appellant II pointed to the particular relevance of the figures on pages 9,

10 and 16 of Bil. Before closing the debate at the end of the oral proceedings the parties were asked to repeat their requests. Appellant II maintained its request regarding the content of the minutes. It was invited to draft the request in writing and it was then attached to the minutes. Finally the Board announced the decision.

Claim 1 of the main request is Claim 1 as granted (see above point I).

Compared to the main request the following amendments were made to the Claims 1 of the further requests:

- Auxiliary request 1. Claim 1 is identical to Claim 1 of the granted patent except that the word "essentially" has been deleted.
- Auxiliary request 3. Claim 1 of this request is based on Claim 1 of auxiliary request 1 with the additional features that (the) "dietary supplement is administered in dosages corresponding to 300-800 mg daily" and "the daily dose is administered at once".
- Auxiliary request 4. Claim 1 of this request is based on Claim 1 of auxiliary request 3 with the additional feature that "the daily dose is administered in the morning".

IX. The arguments presented by Appellant I (Opponent) in its written submissions and at the oral proceedings may be summarized as follows:

- Appellant I contested that the requirements of Article 83 EPC were fulfilled, essentially because the specification did not describe a method for analyzing the complete group of flavonoids and because there was no disclosure of only cosmetically acceptable carriers.
  
- Further, Appellant I maintained that the claimed subject-matter lacked novelty having regard to the disclosures of D4, D5, and D7. It argued that the extract according to Claim 1 of the patent in suit was not distinguishable from the known extract described in D4 and used in D5/D7. It noted in particular that the process disclosed in D4 aimed at obtaining an extract with a high content of flavonoids and therefore the skilled person when putting this information into practice would arrive at the same extract as the one obtained by the process specified on Claim 1.
  
- Concerning inventive step, it pointed out that the red vine leaves extract was already well known for treating venous insufficiency and that it was obvious to omit esculin from the composition of D5 and D7 as there was no disclosure in these documents that esculin had any activity for treating venous insufficiency. It also stated that it was scientifically known that the glucoside esculin was ineffective in this sense and that it was the saponine escin, another ingredient of horse chestnut, that had an effect on venous insufficiency. For that reason esculin was indeed a substance whose presence in minor amounts had no

influence on the activity of red vine leaves extract for the treatment of this disease.

- Concerning auxiliary requests 3 and 4 Appellant I noted that the dosage used in the claims of these requests was the same as used in D5/D7 and that the administration of a drug "once a day" or "in the morning" were well known alternatives for its administration. Moreover no unexpected effect for such administration had been shown. Accordingly, the subject-matter of the claims of the auxiliary requests also lacked inventive step.

X. The arguments of Appellant II may be summarised as follows:

- It argued that the appeal was admissible because the key point of the Opposition Division's decision was that the subject-matter of Claim 1 of the main request did not exclude the presence of esculin. By attacking this point of the decision, the Statement setting out the Grounds of Appeal dealt with the reasons of the Opposition Division for rejecting the main request of Appellant II, even if no reference was made to inventive step in the Statement of Grounds of Appeal.
- As to the expression "essentially consisting of" Appellant II maintained that it meant that a material was essentially pure, possible with minor traces of impurities but not including 1.6% of a further active principle, here esculin. It did not comment on Appellant I's statement concerning the ineffectiveness of esculin because it did not

consider itself in a position to respond appropriately to this new argument brought forward for the first time during the oral proceedings before the Board.

- Concerning novelty Appellant II pointed out that none of the documents cited was novelty destroying. In particular D4 did not disclose the claimed use and D5/D7 failed to disclose any details of the conditions of extraction.
  
- Regarding inventive step it argued that the subject-matter of Claim 1 differed from the closest prior art D5/D7 in that the extraction conditions defined a specific extract and in that the product did not contain esculin. None of these features was rendered obvious, because the extraction conditions would be critical and because there was no suggestion that in spite of the removal of esculin from the products of D5/D7 an effective composition would still be obtained.

Concerning the extraction conditions it noted that in order to obtain two extracts which are phytoequivalent, exact and reproducible extraction conditions should be used. In that respect it pointed in particular to the expert opinions in documents Bi1 and Bi2 concerning the comparability of red vine leaves extracts.

- Finally, the claims of auxiliary requests 3 and 4 were limited to the dosage conditions used in the working example; by single daily administration

these dosage regimes are more likely to be complied with by the patients.

XI. Appellant II (Patent Proprietor) requested that the decision under appeal be set aside or alternatively that the patent be maintained on the basis of one of the auxiliary requests 1, 3 or 4 filed with the letter of 16 April 2007 before the Opposition Division, having withdrawn its auxiliary request 2.

It also requested that documents Bi1 and Bi2 be admitted into the proceedings and that the following statement be included in the minutes of the oral proceedings: "A refusal of the main request and the first auxiliary request was announced by the chairman prior to a decision on admissibility of documents Bi1 and Bi2 (filed by the patentee) into the proceedings and prior to a discussion of the relevance and content of Bi1 and Bi2".

Appellant I (Opponent) requested that the decision under appeal be set aside and that the European patent No. 1 225 810 be revoked. It further requested that document D25 be admitted into the proceedings.

## **Reasons for the Decision**

1. *Admissibility of the appeals (Article 108 EPC).*
  - 1.1 The Appeal of Appellant I is admissible.
  - 1.2 The Opposition Division rejected the main request of Appellant II because Claim 1 as granted lacked

inventive step. In its Statement setting out the Grounds of Appeal, Appellant II did not address the issue of inventive step; it only presented arguments under the title "novelty", although this was a matter which had been accepted in the decision. It is therefore to be decided if the Grounds of Appeal of Appellant II state the legal and factual reasons why the decision under appeal should be set aside and the appeal allowed (Article 108 EPC, in conjunction with Rule 99(2) EPC).

1.3 The Board is indeed satisfied that this is the case for the following reasons:

1.3.1 As stated above (see point IV) the Opposition Division interpreted the wording "the active principle essentially consists of..." as not excluding other components provided that the essential characteristics of the composition were not affected by their presence. The Opposition Division held that the subject-matter of Claim 1 of the main request lacked an inventive step because it would have been obvious for the skilled person to use the extract obtained in D4 for use as an active principle in "Antistax". By proceeding in this way the Opposition Division started from the assumption that the presence of esculin in "Antistax" was inessential, i.e. did not affect the essential characteristics of the composition. On the other hand the Opposition Division accepted that the subject-matter of Claim 1 of the auxiliary request 1 lacked an inventive step because in this request the word "essentially" had been deleted and the subject-matter of the claims was thus limited to compositions wherein the presence of other active principles (here esculin)



was excluded. In its opinion it was not obvious in that case to combine the teaching of D5 with D4.

- 1.3.2 Appellant II in its Statement setting out the Grounds of Appeal disputed the interpretation by the Opposition Division of the expression "essentially consisting of". It argued that this expression only allowed the presence of minor traces of other materials/impurities/residues but not the presence of an active principle such as esculin. No reasoning was given in relation to inventive step. Bearing in mind that the extent to which Appellant II had been adversely affected by the decision was the refusal of its main request based on a specific interpretation of "essentially", its statement of grounds, although confusingly drafted, deals with the relevant issue and addresses the corresponding arguments. In this respect its appeal fulfils the requirement of Rule 99 EPC according to which "the appellant shall indicate the reasons for setting aside the decision impugned or the extent to which it is to be amended".
- 1.3.3 In addition, the Board notes that if the interpretation of Appellant II of the expression "the principle active essentially consists of" were accepted the subject-matter of Claim 1 of the main request would correspond to the subject-matter of Claim 1 of auxiliary request 1, which the Opposition Division had already accepted as involving an inventive step. Thus, although the Grounds of Appeal do not explicitly deal with the reason for which the main request should be allowed, it is implicit that Appellant II agrees with the grounds of the decision of the Opposition Division regarding inventive step of the auxiliary request, whose only

difference with the main request is the disputed term "essentially". In other words its submissions regarding the extent to which the decision should be amended are that the word "essentially" should be reintroduced into Claim 1 for the reasons it gave and that the reasoning of the impugned decision supporting the validity the claim without "essentially" should be applied as regards the claim containing essentially.

1.3.4 Under these circumstances the Board holds that the appeal of Appellant II is admissible.

## 2. *Procedural matters*

2.1 During the appeal proceedings both Appellants filed several documents and expert's reports in order to support their arguments (see above points V and VI). During the oral proceedings Appellant II requested the admission of documents Bi1 and Bi2 into the proceedings and Appellant I the admission of D25.

2.2 Document D25 was filed by Appellant I with its Statement setting out the Grounds of Appeal to stress its argument, already presented before the Opposition Division, that the method of extraction of the red vine leaves had no influence on the nature of the obtained extract. Documents Bi1 and Bi2 were filed by Appellant II in direct response to D25 in order to show how two extracts can be compared and to underscore the significance of the extraction conditions as specified in Claim 1 of the patent.

- 2.3 Both Parties filed the reports at an early stage of the proceedings and in support of arguments already present on file.

At a particular point in the course of the hearing the Board announced that it did not consider the main and first auxiliary requests of Appellant II to be allowable, without there having been any debate regarding the above documents. Appellant II raised an objection against this conclusion having been reached without separate discussion of documents Bi1 and Bi2. It requested that this objection be recorded in the minutes. At this stage of the discussion, the debate on the main and auxiliary request 1 was re-opened in order to give, in compliance with Article 113(1) EPC, an opportunity, on the one hand to the Appellant II/Patentee to expand in detail on the relevant contents of these two documents and on the other hand to the Appellant I/Opponent to fully respond. For this purpose, exercising its discretion under Article 114(2) EPC, the Board admitted D25, Bi1 and Bi2 into the proceedings.

3. *Sufficiency of disclosure (Article 83 EPC).*

- 3.1 The Board agrees with the finding in the appealed decision that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- 3.2 Appellant I has neither disputed that at least one example enabling the skilled person to carry out the invention is clearly indicated in the patent

specification nor shown that a reworking is not possible in this respect.

- 3.3 Appellant I argued however that the requirements of Article 83 EPC were not fulfilled because the patent did not disclose carriers which were only cosmetically acceptable, because it was not clear how the complete flavonoid content of the composition was to be measured and because it was not clear how the dosage specified in Claims 7 to 9 was to be understood.
- 3.4 The objections of Appellant I under Article 83 EPC in fact concern the question whether the claims clearly define the subject-matter for which protection is sought, that is to say in relation to Article 84 EPC, which is not itself a ground for opposition.
- 3.5 Insofar as Appellant I contests the absence of a method for analyzing the complete group of flavonoids in the specification of the patent in suit, it is noted that it is well known which flavonoids are present in red vine leaves (see e.g. D7, page 793, right column, lines 26 - 35) and that methods for analysing them, for instance high pressure liquid chromatography, are also well known and available to the skilled person without undue burden. This was not contested by Appellant I. In these circumstances, the fact that it may be difficult and time consuming to identify and quantify all of the flavonoid species contained in the red vine leaves extract is not a matter to be criticised under the aspect of sufficiency.

MAIN REQUEST

4. *Interpretation of Claim 1*

4.1 Claim 1 is drafted in the form of a second medical use claim and it is directed to the use of a composition in a form suitable for oral administration which consists of an active principle and an acceptable carrier for the prevention and/or treatment of the discomfort associated with mild-to-moderate chronic venous insufficiency of the lower extremities. The active principle essentially consists of an aqueous extract of red vine leaves containing 2 to 20% flavonoids, this aqueous extract being further defined by its method of preparation (extraction).

4.2 The expression "the active principle essentially consists of" was interpreted by the Opposition Division as not excluding other components provided that the essential characteristics of the composition were not affected by their presence. Following this interpretation of the above expression the Opposition Division concluded that the subject-matter of claim 1 included the possible presence of esculin (as in the orally administered Antistax® compositions of D5).

4.3 The Board agrees that this expression should be interpreted as "not excluding other components provided that the essential characteristics of the composition are not affected by their presence" but disagrees with the conclusion of the Opposition Division that this expression would not exclude the presence of esculin. The reason for that is that esculin is regarded in the composition of D5/D7 as an active principle and

therefore deemed to affect the properties of the composition. While neither D5 nor D7 explains the reasons for the presence of a small amount of esculin (1.6%) in the product, its very presence and the way its presence is indicated (in the same font as the red vine leaves extract, differently from the "further ingredients") suggests that it is considered to be an active ingredient and thus does indeed affect the essential characteristics of the composition.

Consequently the compositions according to Claim 1 are to be understood as not embracing the presence of esculin.

In arriving at this conclusion the Board has not taken into account the argument of Appellant I, which was put forward for the first time in the oral proceedings, that esculin by its very constitution could not have any influence on the sanitary/medical properties of the red vine leaves extract. Rather the Board started from the assumption implicit in D5/D7 that, for the reasons given above, esculin was an active ingredient.

The Board also did not consider the speculative argument of Appellant I that D5/D7 erroneously misspelled esculin and should refer to escin, which in Appellant I's view was the "real" active compound of horse chestnuts. Fresh evidence relating to this late argument, the correctness of which was in dispute, was not considered admissible at that stage of the proceedings as it would have meant that a final decision could not be made without adjournment of the oral proceedings, contrary to Article 13(3) RPBA.

5. *Novelty (Article 54 EPC).*

5.1 The novelty of Claim 1 was contested by Appellant I having regard to the disclosures of D4, D5 and D7.

5.1.1 Document D4 discloses a method of preparation of an extract of red vine leaves. The disclosure of D4 does not mention any use for this extract. Consequently the subject-matter of Claim 1 of the main request is novel in relation to D4 irrespective of the fact whether the extract disclosed therein is different from the one used according to the claimed invention.

5.1.2 Document D5 provides product information about Antistax® capsules and drops (cf. 83 048) which are intended for oral administration and which include in addition to an aqueous extract of red vine leaves the further substance esculin and a cream without esculin (cf. 83 084).

As explained above the subject-matter of Claim 1 does not include the presence of esculin. The capsules and drops are therefore not novelty-destroying. Concerning the cream, it is intended for external application only and therefore also does not anticipate the claimed oral administration. The disclosure of D5 is therefore not novelty-destroying for the claimed subject-matter.

5.2 D7 relates to the treatment of venous insufficiency essentially with the product Antistax® (cf. D7, abstract and pages 795 - 796 under the heading "*Klinische und therapeutische Erfahrungen*"). The reasons given above for the novelty with respect to D5 apply equally for the disclosure of D7.

5.3 For these reasons the subject-matter of Claim 1 of the main request is novel.

6. *Inventive step (Article 56 EPC).*

6.1 Closest prior art.

6.1.1 The Board considers in agreement with the decision under appeal and the parties that the closest prior art is represented by the orally administered Antistax® products disclosed in D5 and D7. They contain as active principle a mixture of an extract of red vine leaves (98,4%) and esculin (1,6%) and are used for the treatment of venous insufficiency of the lower extremities (cf. D5, product 83 048 and D7, Abstract and pages 795 - 796, last section of the article).

6.1.2 Document D5 is completely silent about the exact nature of the red vine leaves extract used. In D7 it is stated that the main components of the extract are flavonoids (page 793, right column, first full paragraph) and that the properties of the flavonoids are significant for its use in the treatment of venous insufficiency (page 794 section "*Venenleiden und Bioflavonoide*", in particular last paragraph).

Neither D5 nor D7 disclose the method of preparation of the red vine leaves extract therein used.

6.1.3 The subject-matter of Claim 1 differs from the disclosure of D5/D7 in that:

- the composition does not include esculin,



- the red vine leaves extract is specified to contain 2 to 20% flavonoids, and
- the method of preparation of the aqueous extract is specified.

6.2 Problem to be solved and its solution.

6.2.1 The compositions of Claim 1 have the same use as the product Antistax®. There is no evidence on file of any improved properties of these compositions compared with the properties of Antistax®.

6.2.2 Thus, in the absence of any unexpected effect over the prior art, the technical problem to be solved by the patent in suit can be formulated as the provision of alternative compositions which are also useful for the treatment of venous insufficiency of the lower extremities.

6.2.3 This problem is solved by using the compositions defined in Claim 1, wherein the active principle essentially consists of an aqueous extract of red vine leaves containing 2 to 20% flavonoids and obtainable under specific extraction conditions.

6.2.4 In the light of the results described in paragraphs [0025] to [0027] of the patent in suit, the Board is satisfied that the above-defined problem has been credibly solved. This finding was not challenged by Appellant I.

6.3 Obviousness.

6.3.1 It remains to be decided whether or not the claimed solution is obvious over the cited prior art. In this case the relevant questions are:

a) whether the skilled person would expect that the extract of red vine alone, that is to say without esculin, would be active for the treatment of venous insufficiency; and

b) whether the extraction conditions specified on Claim 1 result in a different extract from the one present in Antistax®.

6.3.2 Concerning (a), it is to be noted that neither D5 nor D7 makes explicit reference to the activity of the small amount of esculin (1.6%) present in the product. In contrast, D7 emphasises the importance of the flavonoids present in the red vine leaves extract as the main active principle of the Antistax® product and as being essentially responsible for its activity in the treatment of venous insufficiency (cf. D7 page 792, last sentence of the Abstract and page 794 second and third columns). It would therefore be evident to the skilled person from studying these passages of D7 that a composition containing only the red vine leaves extract and which was free of esculin would also show the desired activity.

Consequently, in the Board's judgement the exclusion of esculin from the Antistax® product cannot justify the presence of an inventive step.

- 6.3.3 Contrary to the opinion of Appellant II the Board sees also no invention in the fact that by eliminating esculin a simplified product is obtained. This result is merely the logical consequence of the measure taken and cannot contribute to an inventive step.
- 6.3.4 Concerning (b), the question whether the extraction conditions result in a different extract was hotly disputed in the proceedings and during the appeal proceedings both parties filed experimental evidence in support of their respective arguments (D25, B11 and B12).
- 6.3.5 Appellant I maintained that the extract used in the patent in suit could not be distinguished from the extract used in documents D5 and D7. The reason for this is that the extract must be assumed to have been prepared according to standard methods like the one disclosed in D4 and such methods would inevitably lead to the same extract as the extract according to Claim 1 of the patent.

D4 discloses a general method for the preparation of an extract of red vine leaves. In this document a method of preparation of an aqueous extract of red vine leaves is disclosed without indicating the specific conditions used in every single preparation step. The extract is obtained by warm lixiviation of suitable cut red vine leaves with water to complete exhaustion. In the Board's judgment, "lixiviation to complete exhaustion" describes extraction conditions which are identical to "exhaustive percolation", the technique used according to present Claim 1. Any different explanation not implying full extraction of the polyphenols (which

comprise the flavonoids) mentioned there would be at variance with the normal understanding of a skilled person.

Although D4 does not specifically disclose the extraction parameters of Claim 1, Appellant I maintained that the skilled person, when putting the teaching of D4 into practice, would inevitably achieve an extract not distinguishable from the extract of Claim 1. In other words the process as defined in Claim 1 of the patent did not produce any "special extract", the extract obtained by the invention necessarily being similar to that of D4. To underpin this argument Appellant I submitted experimental evidence showing that the flavonoid content of the extract was similar when working either within the requirements of the claim or outside (cf. D25). According to this evidence and within reasonable limits, different temperatures, times and extraction conditions (percolation vs. macerative extraction) do not essentially influence the extract composition, which in any case meets the flavonoid concentration required by present Claim 1.

6.3.6 Appellant II on the contrary maintained that the extract preparation conditions specified in Claim 1 would inevitably result in a specific extract different from the one described in D4. This remains the case even if the total amount of flavonoids extracted remained the same because deviating preparation conditions, including different harvesting times of different leaves, must lead to different extract compositions, if only as regards unspecified by-products. In this respect Appellant II filed two

certificates Bi1 and Bi2 in order to demonstrate that the exact composition of an extract is dependent on the maintenance of exact and reproducible extraction conditions. The several extraction steps as defined in Claim 1 ensured that a 'non-interchangeable' extract was obtained, the nature of this extract being determined by the specific composition of the starting material (dried red vine leaves collected at a determined point of time which result in a specific flavonoid content), the cutting and crushing of the leaves as well as the extraction temperature of 60 to 80°C for 6 to 10 hours with water in an exhaustive percolation. Moreover, the extract did not contain only flavonoids but also other components whose nature would also depend on the extraction conditions. Appellant II put special emphasis on the fact that Bi1 showed that the flavonoid content of the extract depends on the starting material (i.e. the red vine leaves) and that depending on their origin and harvest year the content in polyphenols and within that group that of flavonoids changes considerably.

6.3.7 When assessing the question of "identity or not" of the extracts of D4 and of the claimed invention it has to be borne in mind that the preparation conditions according to present Claim 1 do not define a precise extract composition. The extraction process involves on the one hand features with blurred characteristics such as: type of red vine leaves, growth variations stemming from location, climate and time of harvesting, drying and cutting conditions, and on the other hand leaves room to manoeuvre within the specified temperature and time ranges. The subject-matter of Claim 1 covers these variations by defining a broad range of the amount of

flavonoids (see page 10 of Bil, third paragraph from the bottom).

- 6.3.8 This said and account being taken of the evidence submitted by both parties, the Board considers that a realistic assessment of how a skilled person would put the information in D4 into practice must lead to an extract whose composition - account being taken of the very considerable leeway given by the contested subject-matter - is not different from an extract prepared when following the instructions of Claim 1.
- 6.3.9 In arriving at this conclusion the Board agrees with the opinion of the experts of Appellant II in Bil and Bi2 that different red vine leaves and extraction conditions may lead to different extracts, even possibly to extracts not covered by Claim 1. However this fact cannot invalidate the conclusion of the Board because all the "selection" steps the skilled person has to make according to Claim 1 (leaves having a high content of flavonoids, drying and cutting the leaves, water extraction, extraction time and temperature and percolation) are either also not clearly defined in present Claim 1 (like the "quality" of the leaves and their flavonoid content) or are obvious options which the skilled person would consider as realistic concretisations of the preparation conditions set out in D4. The same applies to the combination of such steps, as they all are performed with the purpose of getting a good yield of flavonoids in the extract. The latter conclusion also applies to choice of the leaves to be used as starting material.

6.3.10 Also the possible presence of "unspecified" components in the extract used cannot justify an inventive step. The main active ingredients of the claimed extract, namely quercetin-3-O- $\beta$ -D-glucunoride and isoquercitrin according to paragraph [0010] of the patent, are exactly the same main components of the red vine leaves extract according to D7 (page 793, right column, lines 25 - 29). The skilled person when preparing a red vine leaves extract for treating venous insufficiency would ensure that the components which are said to be the main active components are present in the extract in good yield. In any case there is no information on file showing that the activity of the compositions could be due to other components of the extract which would not be extracted in the same way according to D4 and according to the method of the claimed invention.

6.3.11 The Board can also not accept the argument of Appellant II that as far as the extract preparation is concerned the claimed subject-matter is a selection invention within the teaching of D4, the unexpected effect being the use for treating venous insufficiency, not mentioned in D4. As explained above, the intended use of a red vine leave extract was clear for the skilled person from D5/D7, and the fact that D4 is silent about this use cannot justify an inventive step because this document is only relevant with regard to the extract preparation conditions the skilled person would choose.

6.3.12 To summarise, there are compelling arguments and evidence for the position of Appellant I that orally administered Antistax® preparations of D5/D7 comprise a red vine leave extract prepared according to the

information given in D4; reducing this information into practice in a reasonable way must, in the Board's judgment, lead to an extract meeting the essential characteristics of an extract prepared when following the preparation steps set out in present Claim 1.

This conclusion does not go against the information contained in B11 and B12 according to which many factors have to be taken into account for getting phytoequivalent extracts; however this is not an issue pertinent to the question of obviousness of the claimed subject-matter because neither D4 nor the alleged invention specifies the conditions which ultimately define the extracts obtained in a sufficiently concrete way to allow any comparison of phytospecificity.

- 6.4 For the reasons set out above the subject-matter of Claim 1 of the main request lacks inventive step.

AUXILIARY REQUEST 1.

7. *Inventive step (Article 56 EPC).*

7.1 The only amendment made to Claim 1 is the deletion of the word "essentially" in the definition of the active principle which now reads "the active principle consists of an aqueous...".

7.2 The reason for this amendment was the interpretation by the Opposition Division of the subject-matter of Claim 1 of the main request as allowing the presence of other active principles such as esculin.



- 7.3 As explained above in relation to the main request the Board interprets the subject-matter of Claim 1 of the main request as excluding the presence of esculin.
- 7.4 The subject-matter of Claim 1 of auxiliary request 1 is therefore in that respect identical to the subject-matter of Claim 1 of the main request and the reasoning in relation to the main request applies *mutatis mutandis* to the subject-matter of auxiliary request 1, which therefore does not involve an inventive step.

#### AUXILIARY REQUESTS 3 AND 4.

8. *Inventive step (Article 56 EPC).*
- 8.1 The subject-matter of Claim 1 of auxiliary request 3 corresponds to the subject-matter of Claim 1 of auxiliary request 1 and specifies further that the "dietary supplement is administered in a dosage corresponding to 300 - 800 mg daily and that the dose is administered at once"; the subject-matter of Claim 1 of auxiliary request 4 further specifies that "the daily dose is administered in the morning".
- 8.2 The following considerations of the Board are made on the assumption (beneficial to Appellant II) that the dosage regime specified in Claims 1 of these requests can be considered a characterising technical feature; on this premise the eventual outcome of the referral to the Enlarged Board of Appeal pending under G 02/08 related to this issue can be ignored.
- 8.3 The amount of active principle used in Claim 1 of these requests is the same as used in D7 (page 796, last

paragraph) and there is no evidence on file of any unexpected advantage by administering it daily at once (auxiliary request 3) or in the morning (auxiliary request 4).

These are well-known alternative regimes for the dosage of medicaments and the choice of one of them cannot justify an inventive step. Insofar as Appellant II relied on the fact that by changing the dosage regime from three times a day to only once a better adherence to the regime by the patients was to be expected, this advantage was also known and its exploitation in the present case cannot justify an inventive step.

- 8.4 The subject-matter of Claim 1 of auxiliary requests 3 and 4 therefore also lacks inventive step.
9. In summary, none of the requests of Appellant II relates to patentable subject-matter.

**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

G. Röhn

P. Kitzmantel