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Datasheet for the decision of 23 July 2008

Case Number: T 0096/06 - 3.3.01

Application Number: 96307219.4

Publication Number: 0834254

IPC: A01N 65/00

Language of the proceedings: EN

Title of invention:
Azadirachtin formulations and a process for preparing them from neem seed/kernel

Patentee:
COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH

Opponent:
Trifolio-M GmbH

Headword:
Azadirachtin formulations/COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH

Relevant legal provisions:
RPBA Art. 13(1)(3)
EPC Art. 56

Relevant legal provisions (EPC 1973):

Keyword:
"Late-filed data (not admitted)"
"Inventive step - all requests (no)"

Decisions cited:
T 0181/82; T 0990/96; T 0355/97

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0096/06 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 23 July 2008

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 17 November 2005 rejecting the opposition filed against European patent No. 0834254 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: P. Ranguis
Members: J.-B. Ousset
C.-P. Brandt

Summary of Facts and Submissions

I. This appeal lies from the decision of the opposition division to reject the opposition filed against the European patent No. 0 834 254.

II. Claim 1 of the patent in suit reads as follows:

"1. A process for the preparation of azadirachtin, in a dry solid powder form, a purity of 10-19% from neem seeds/kernels, which comprises;

(a) disintegrating the neem seeds/kernels into a powder; (b) subjecting the said powder to continuous extraction by percolation of a batch using methanol, aqueous methanol, ethanol (rectified spirit) or aqueous ethanol at ambient temperature; (c) concentrating the extract and stirring the concentrate with petroleum ether (b.p. 60-80°C) or hexane and phase separating by conventional methods; (d) stirring the denser phase containing major quantity of azadirachtin with a water immiscible organic solvent and water as required depending on the solvent used for extraction and phase separating by conventional methods; (e) concentrating the organic phase and gradually adding the concentrate to petroleum ether (b.p. 60-80°C) or hexane under stirring at ambient temperature (f), filtering and drying under vacuum at a temperature in the range of 25-65°C to obtain a neem seed/kernel extract as a powder having azadirachtin of 10-19% purity."

III. The appellant (opponent) sought revocation of the patent in suit in its entirety for lack of novelty or

lack of inventive step (Article 100a) EPC).

IV. The opposition division held that the subject-matter of the patent in suit was novel in view of the following documents

(1) DE-A-4 109 473
(2) EP-B-0 579 624 (European patent corresponding to document (1))

The opposition division also concluded that an inventive step was to be acknowledged in view of the documents (1) or (2) in combination *inter alia* with the following documents:

(3) H. Schmutterer (ed), The Neem Tree, VCH Verlag, Weinheim, 1995, pages 35 to 37, 58, 59, 375 to 384
(7) K. Feuerhake and H. Schmutterer, Ztschr. Pfl. Krankh. Pfl.schutz, vol 92(6), 643 to 649 (1985)
(8) EP-A-0 617 119

The opposition division held, in particular that, in view of document (1) or (2), the problem underlying the process of the patent in suit was to provide an economic and conveniently upscalable process for the preparation of dry, powdered azodirachtin in a yield that is at least comparable to the yields obtained by the process of the closest state of the art.

Document (1) or (2) neither disclosed the use of a first alcoholic extraction step instead of water nor did it disclose a continuous percolation of powdered neem seeds. In document (1) or (2), the milled neem

seed kernels were extracted with water at 30°C in a batch process for 10 hours.

The other documents did not suggest modifying the above mentioned steps of document (1) or (2) in such a way that the person skilled in the art would have arrived at the claimed process. In particular, document (8) in the "background of the invention" part disclosed a method comprising the extraction of neem seeds with a polar solvent and the subsequent extraction of the obtained hydrophilic residue with non-polar solvents to remove oils and fatty acids. Those solvents were however unspecified.

V. Oral proceedings took place on 23 July 2008 before the board.

VI. In the appeal proceedings, the appellant (opponent) sought only revocation of the patent in suit for lack of inventive step. Document (2) was considered as representing the closest state of the art. In view of document (2), the technical problem to be solved could only be seen in the provision of an alternative process for preparing azadirachtin. Indeed, the process described in document (2) was performed on the same scale as the claimed process and the yields were comparable, if not better, as shown in

(17) Comparative table of yields obtained in the patent in suit and document (2).

submitted with the statement of grounds of appeal. No economical advantage could, therefore, be acknowledged.

The sole difference between the process disclosed in document (2) and the claimed process was the extraction of the neem seeds/kernels powder by methanol, aqueous methanol, ethanol or aqueous methanol (step b) instead of water, followed by concentration and separation steps (step c). Indeed, the use of the whole neem seed instead of the kernel provided no technical effect since the coating was devoid of azadirachtin as shown in document

(18) Report: LP 06.11 IS of Trifolio-M GmbH

Furthermore, the percolation step was within the common general knowledge of the person skilled in the art as shown by documents

(6a) Römpp Chemie Encyclopedia, Version 1.0; Georg Thieme Verlag 1995; headword: Percolation.

(16) Bertelsmann Universal Encyclopedia, Verlagsgruppe Bertelsmann GmbH, Gütersloh 1989, Volume 13, Headword: Percolator.

submitted with the statement of grounds of appeal.

The person skilled in the art would combine the teaching of document (2) respectively with the teachings of document (3) or document (7) or document (8) to solve in an obvious manner the problem underlying the patent in suit.

Contrary to the finding of the opposition division, document (8), in the "background of the invention",

specified the polar and non polar solvents to be involved, so that document (8) disclosed the steps b) and c) of the instant patent (see point IV above).

VII. The respondent (patent proprietor) disputed these arguments:

In view of document (2) as the closest state of the art, the technical problem to be solved was to be seen in the provision of an alternative method for providing azadirachtin, from neem seeds/kernels, with an appropriate degree of purity and comparable yield of azadirachtin.

The claimed process included in addition the following advantages with respect to that disclosed in document (2): (i) an increased yield of Salannin; (ii) reduced yield of Nimbin; (iii) extraction of azadirachtin from whole seed; (iv) the provision of an emulsifiable concentrate; (v) the provision of an extract comprising no water in the end product, thus having improved stability; and (vi) the provision of a more conveniently up scalable process and a yield at least comparable with that of document (1) or (2). In that context, purity, in industrial processes, was not a critical requirement.

Moreover, the appellant's approach was to be regarded as an *ex post facto* analysis selecting different features from different prior art documents. The specific steps b) and c) of the process of Claim 1 were not mentioned in document (2) and the replacement of the first solvent was not the result of a routine experiment. This choice was not only in relation to the

yield or purity of the azadirachtin end product, but also in relation to the selection of further steps in the claimed process, as the choice thereof would be dependent upon the use of the first extracting solvent.

Furthermore, the experimental report submitted before the opposition division under cover of a letter dated 19 July 2004 and documents

(19) Figures 1 to 3.

(21) Experimental Procedure

submitted with the response to the statement of grounds of appeal, showed that although the amounts of azadirachtin (A and B) were comparable in both the method of the patent in suit and that of document (2), the claimed process provided an improved yield of azadirachtin, especially insecticidally active azadirachtin isomers, complete with furan rings, compared to the prior method taught in document (2). This might be explained by the fact that azadirachtin is unstable in the presence of moisture, the furan moieties of azadirachtin being likely to be cleaved on exposure to water, leading to a loss of insecticidal activity. Doubts could, therefore, be thrown on the reliability of the results presented in document (2). All the more since as shown by document

(20) Neemix 4.5 by the Pest Management Regulatory Agency of Canada.

azadirachtin was poorly soluble in water.

The experimental results provided by the appellant as document (18), aiming to show that the coat of the seed does not contain any significant amount of azadirachtin, contained deficiencies in the experimental method of HPLC analysis. The origin of the seed could lead to different results and the mode of elution used when purifying the crude of reaction gave misleading results.

It was also disputed by the respondent that an up scalable method was described in document (2) due to the use of chromatography techniques for purifying the product obtained. He finally refuted that the combinations of document (2) either with document (3) or document (7) or document (8) would lead the person skilled in the art to the claimed subject-matter. Document (8), in particular, taught away from the invention since it required a co-solvent and, furthermore, provided little guidance on why the skilled person should select one first solvent over another one, let alone how this would affect the choice of the remaining steps.

VIII. In a further letter, the appellant argued against the conclusions drawn by the respondent and submitted, in particular:

The alleged advantages regarding an increased yield of salanin, a lower yield of nimbin were not substantiated. Furthermore, those compounds were only cited once in the description (see paragraph [0028]) and could not be relied on to reformulate the technical problem to be solved. An emulsifiable concentrate could also be obtained from the powder obtained by the

process according to document (2). The alleged better stability of the powder obtained by the claimed process due to the absence of water was not credible since the powder obtained according to document (2) did not contain water. That the process of document (2) be not up scalable in contrast to the claimed process due to the presence of water after extraction was unsustainable since after the step b) of the claimed process with aqueous methanol or ethanol as solvent, the concentration led to an enrichment in water. It could not be understood how the furan cycles influenced the insecticidal activity since neither azadirachtin A nor B had a furan ring. The solubility set out in document (20) related to the technical and not pure azadirachtin. This document was, therefore, irrelevant. The solubility of azadirachtin in water is of the same order as that in methanol or ethanol.

IX. Under cover of a letter dated 23 June 2008 the respondent provided a new document:

(29) Experimental protocol conducted in respect of the appeal filed against CSIR's Neem Seed patent EP 0834254

These experimental/comparative data aimed at showing the alleged advantages of the claimed subject-matter over the cited prior art. In this letter, the respondent filed also three auxiliary requests.

Claim 1 of the first auxiliary request reads as follows:

"1. A process for the preparation of azadirachtin, in a dry solid powder form, having a purity of 10-19% from neem seeds/kernels, which comprises;

(a) disintegrating the neem seeds/kernels into a powder;
(b) subjecting the said powder to continuous extraction by percolation using methanol, aqueous methanol, ethanol (rectified spirit) or aqueous ethanol at ambient temperature;
(c) concentrating the extract and stirring the concentrate with petroleum ether (b.p. 60-80 degrees C) or hexane and phase separating by conventional methods;
(d) stirring the denser phase containing major quantity of azadirachtin with a water immiscible organic solvent and water as required depending on the solvent used for extraction, and phase separating by conventional methods;
(e) concentrating the organic phase and gradually adding the concentrate to petroleum ether (b.p. 60-80 degrees C) or hexane under stirring at ambient temperature; (f) filtering and drying under vacuum at a temperature in the range of 25-65 degrees C to obtain a neem seed/kernel extract as a powder having azadirachtin of 10-19% purity;
(g) redissolving the product obtained in step (f) in a solvent and adding the solution to petroleum ether (b.p. 60-80 degrees C) or hexane under stirring yielding a white powder, which after filtration and drying under vacuum at 65 degrees C results in azadirachtin having 15-26 % purity as a white powder."

Claim 1 of the second auxiliary request reads as follows:

"1. A process for the preparation of azadirachtin, in a dry solid powder form, having a purity of 10-19% from neem seeds/kernels, which comprises;

(a) disintegrating the neem seeds/kernels into a powder;
(b) subjecting the said powder to continuous extraction by percolation using methanol, aqueous methanol, ethanol (rectified spirit) or aqueous ethanol at ambient temperature;
(c) concentrating the extract and stirring the concentrate with petroleum ether (b.p. 60-80 degrees C) or hexane and phase separating by conventional methods;
(d) stirring the denser phase containing major quantity of azadirachtin with a water immiscible organic solvent and water as required depending on the solvent used for extraction, and phase separating by conventional methods;
(e) concentrating the organic phase and gradually adding the concentrate to petroleum ether (b.p. 60-80 degrees C) or hexane under stirring at ambient temperature (f) filtering and drying under vacuum at a temperature in the range of 25-65 degrees C to obtain a neem seed/kernel extract as a powder having azadirachtin of 10-19% purity;
(h), dissolving the azadirachtin from step (f) in an organic solvent and subjecting it to column chromatography (silica gel) by stepwise elution using different compositions of hexane or petroleum ether

(b.p. 60-80 degrees C) and ethyl acetate leading to solid azadirachtin powder up to 49% pure."

Claim 1 of the third auxiliary request reads as follows:

"1. A process for the preparation of azadirachtin, in a dry solid powder form, having a purity of 10-19% from neem seeds/kernels, which comprises;

(a) disintegrating the neem seeds/kernels into a powder;
(b) subjecting the said powder to continuous extraction by percolation using methanol, aqueous methanol, ethanol (rectified spirit) or aqueous ethanol at ambient temperature;
(c) concentrating the extract and stirring the concentrate with petroleum ether (b.p. 60-80 degrees C) or hexane and phase separating by conventional methods;
(d) stirring the denser phase containing major quantity of azadirachtin with a water immiscible organic solvent and water as required depending on the solvent used for extraction, and phase separating by conventional methods;
(e) concentrating the organic phase and gradually adding the concentrate to petroleum ether (b.p. 60-80 degrees C) or hexane under stirring at ambient temperature; (f) filtering and drying under vacuum at a temperature in the range of 25-65 degrees C to obtain a neem seed/kernel extract as a powder having azadirachtin of 10-19% purity;
(h), dissolving the azadirachtin from step (f) in an organic solvent and subjecting it to column chromatography (silica gel) by stepwise elution using

different compositions of hexane or petroleum ether (b.p. 60-80 degrees C) and ethyl acetate leading to solid azarachtin powder up to 49% pure;
(i) finally dissolving the azadirachtin obtained in step (h) in methanol, ethanol or acetonitrile and subjecting it to HPLC (C18 column) to produce azarachtin of purity up to 88% in a solid pure form."

X. In a further letter, the respondent requested corrections of minor errors which had occurred in document (29).

XI. The appellant requested that the decision under appeal be set aside and the patent in suit revoked. The appellant further requested that document (29), submitted by the respondent under cover of a letter of 23 June 2008, not be admitted into the proceedings. The appellant withdrew the objection of lack of novelty.

XII. The respondent requested that the appeal be dismissed, namely, that the patent be maintained as granted, or in the alternative, that the patent be maintained on the basis of one of the three sets of claims filed with the respondent's letter of 23 June 2008 as respectively auxiliary requests 1 to 3.

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

Reasons for the Decision

1. The appeal is admissible.

Admissibility of the late filed document (29)

2. Document (29) was provided by the respondent with a letter of 23 June 2008, namely one month before oral proceedings. Moreover, its content was corrected by the respondent according to his letter of 11 July 2008. Since document (29) has been filed after the parties were summoned to oral proceedings by the board, it cannot be admitted into the procedure if issues are raised which cannot be dealt with without adjournment of the oral proceedings (Article 13(3) RPBA).

2.1 To justify this late filing, the respondent argued that he had only received these data recently and sent them without delay to the board and the appellant. He supported the view that document (29) should be admitted into the procedure, because the experiments of document (29), although showing that the amounts of azadirachtin vary drastically depending upon the origin of the seeds/kernels, the quantitative results contained in document (29) showed that the claimed process was advantageous compared to the process of the closest state of the art, i.e. document (2).

2.1.1 The board notes that document (29) describes first two methods respectively relating to the preparation of azadirachtin according to the patent in suit using methanol as first extraction solvent, i.e. "CSIR (present EP) method", and according to document (1) or (2), i.e. "E1/E2 Method". Table 3 summarizes the results obtained for each method from neem seeds obtained from two distinct sources for the whole seed, the seed kernel and seed shell. However although the description of the method of preparation of

azadirachtin according to the patent in suit, i.e. "CSIR (present EP) method", involves methanol as first extraction solvent, the results set out in Table 3 and the comments related thereof involve ethanol as first extraction solvent (see page 4, second and third paragraphs). Furthermore, as noted by the board during the oral proceedings, the purity of azadirachtin in the powder obtained by extraction carried out on the whole seed according to the patent in suit is of 8.2% for the IICT variety-1, i.e. 0.021/0.256, and of 3% for the Hyderabad market variety-2, i.e. 0.003 /0.100 and (see Table 1, samples 1 and 7).

2.1.2 In relation to the experimental procedure carried out in document (29) according to the patent in suit, in presence of methanol as extracting solvent, i.e. "CSIR (present EP) method", whereas the samples of Table 3 according to the patent in suit were performed in presence of ethanol as extracting solvent, the respondent argued that such a discrepancy was to be seen as a clerical error.

In relation to the ratio of pure azadirachtin versus technical azadirachtin presented in Table 1, which were clearly outside the purity range of 10 to 19% recited in Claim 1 of the patent in suit, the respondent argued that the chromatography was made under isocratic conditions whereas the results of table 3 were obtained under gradient conditions, thus leading to results which are more relevant with said ratio of 12.7%.

2.1.3 The board however cannot share the respondent's view. That the discrepancy mentioned above is due to a clerical error is unsubstantiated, all the more because

it is not clear whether methanol must be replaced by ethanol or the contrary. Furthermore, since the yields, at least for the whole seeds and from both sources are outside the range defined in Claim 1, the relevance of this document is highly dubious. The said ratio of 12.7% was obtained by the extraction of a seed kernel, not the whole seed and it remains, therefore, that the purity ratios obtained with the whole seed are outside the range defined in Claim 1 (see point 2.1.1). In view thereof, it plays no role that the yields depend upon the chromatographic conditions of elution (isocratic vs. gradient). It remains true that the yields obtained can be outside or inside the purity range set out in Claim 1 of the patent in suit, which renders the content of this document irrelevant.

Furthermore, the appellant clearly did not have sufficient time to counter-evaluate the results set out in document (29) without the adjournment of the oral proceedings.

2.2 In view thereof, document (29) is not admitted into the appeal proceedings (Article 13(1)(3) RPBA).

Main request

3. Inventive step

3.1 The patent in suit proposes a process for the preparation of azadirachtin in a dry solid powder form from neem seeds/kernels, which is characterized by six specific steps as defined in Claim 1.

3.2 According to the established jurisprudence of the boards of appeal, it is necessary, in order to assess inventive step, to identify the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This problem-solution approach ensures the assessment of inventive step on an objective basis and avoids an ex post facto analysis.

3.3 The first step is thus to identify the closest state of the art. According to the established jurisprudence of the boards of appeal, the closest state of the art is a prior art document disclosing subject-matter aiming at the same objectives as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (see Case Law of the Boards of Appeal of the EPO, 5th edition 2006, Section I.D.3.1., "Determination of the closest prior art in general", page 121).

3.4 Document (2) discloses a process for producing a storable azadirachtin-rich insecticide from the seed kernels of the neem tree involving the grinding of the seed kernels in water, adding to the water extract containing azadirachtin an organic solvent which is not completely miscible with water and which has a greater solubility for the azadirachtin than the water, separating the organic solvent containing the azadirachtin from the water after the phase separation has taken place, concentrating the organic solution, adding hydrocarbon and separating the precipitate formed containing azadirachtin (see Claim 1 and col. 2,

lines 22 to 49). As organic solvent, ketones or esters or alcohols can be used (see col. 3, lines 45 to 49). As hydrocarbon, hexane or petroleum ether can be used (see col. 3, line 58). In example 1, from 1000 g of neem seed kernels extracted by water followed by the use of acetic acid ester as organic solvent and petroleum ether as hydrocarbon, 4.61g of powder containing 44% of azadirachtin (HPLC), i.e 2.0284 g, is obtained. The yield with respect to the starting neem seed is 0.203%.

3.5 The board concurs with the parties in considering document (2) as representing the closest state of the art, although it appears that document (1) from which document (2) stems could have been chosen too (see point IV above). The process of document (2) differs, in particular, in that steps b) and c) of the patent in suit were not disclosed in document (2) which discloses an extraction using water as solvent.

3.6 Therefore, starting from document (2), the technical effects or results successfully achieved by the claimed subject-matter are to be determined for defining the objective technical problem to be solved.

3.6.1 According to the patent in suit, vis-à-vis document (2), the claimed process is advantageous in that, due to the low solubility of azadirachtin in water, the expected yield should be higher (see page 8, paragraph [0049]).

3.6.2 First, the board notes that the neem seed/kernel extract obtained as a powder according to the patent in suit has azadirachtin of 10-19% purity, whereas the powder obtained according to document (2) has

azadirachtin of 44% purity. Even the yields with respect to the starting neem seed/kernel as summarized by the appellant do not allow a clear difference to appear (see document (17)). Indeed, in the patent in suit some yields are higher, i.e. 0.232% (example 3), 0.323% (example 4), 0.374% (example 5), other, i.e. 0.197% (example 1) and 0.137% (example 2) are lower than the yield obtained according to example 1 of document (2), i.e. 0.203%. As admitted by the respondent in the appeal proceedings the yields were comparable (see point VII above).

3.6.3 The respondent nevertheless put forward in the opposition/appeal proceedings several other improvements provided allegedly by the claimed process vis-à-vis document (2):

– The claimed process would be more conveniently up scalable due to the increased ease of removal of the first solvent. However, the claimed process may be performed in aqueous methanol or ethanol. In the concentration step c), methanol or ethanol is removed first, enriching, therefore, the phase in water. Thus, it cannot be seen why the claimed process would be more up scalable than that of document (2) since water must also be removed in the claimed process when aqueous methanol or ethanol is used as first solvent.

– The reliability of the results set out in document (2) could be put in doubt since azadirachtin was poorly soluble in water (see document (20)). However it was not contested, that the disclosure of document (2) was enabling. Non-enablement was still less proved. Furthermore, document (20), cited by the respondent, describes solubility in

water of Azatin 15% Technical containing 15% of azadirachtin (see paragraph 1.1, page 1). The solubility of azadirachtin in water was not provided.

– The powder obtained according to the patent in suit could be formulated in an emulsifiable concentrate. However since the end-product obtained according to document (2) is also a powder, it is not credible that it cannot be formulated in an emulsifiable concentrate, a trivial formulation in the agrochemical field.

– The extract obtained according to the patent in suit would be more stable due to the absence of water. However since the end-product obtained according to the process of document (2) is in the form of a powder, free of water, the respondent's contention is not credible.

– The process according to the patent in suit would enable the extraction of azadirachtin from the whole seed. However, this alleged advantage cannot be acknowledged for the whole scope of Claim 1 since the claimed process also comprises the treatment of neem kernels. Furthermore, document (18) submitted by the appellant shows that the coat of neem seeds from Mauritania contains no azadirachtin (see page 3). It is irrelevant that coats of neem seeds from India might contain azadirachtin since the claimed process is not limited to particular species of neem seeds.

– Finally, documents (19) and (21) submitted by the respondent showed that the extracts obtained by the claimed process contained insecticidally active azadirachtin isomers, complete with furan rings, an increased amount of salannin and a

reduced amount of toxic nimbin. However, firstly, it does not appear that azadirachtin as set out in the Fig. 1 of the patent in suit comprises a furan ring. Furthermore, assuming that salannin has a beneficial effect and nimbin a detrimental effect, which was not substantiated, those improvements could not be taken into account to reformulate the technical problem to be solved since the person skilled in the art could not deduce this problem from the application as filed considered in relation to the closest state of the art. In the patent in suit salannin and nimbin are only cited in relation to the discussion of the state of the art (see paragraph [0028]). Extracts enriched *inter alia* in nimbin as active compound are mentioned in that respect as yielding effective agents.

3.7 Since no improvement vis-à-vis document (2) as the closest state of the art can be shown (see T 181/82, OJ 1984, 401, point 5; T 355/97, not published in the OJ EPO, point 2.6), the technical problem to be solved must be reformulated in a less ambitious manner, that is to say, in the provision of a further process to produce azadirachtin as a powder from neem seeds/kernels having a purity comprised between 10 and 19%.

3.8 The examples of the description show that the process of Claim 1 of the patent in suit actually provides the claimed powder containing azadirachtin in the required purity.

3.9 It should now be investigated whether or not the proposed solution can be deduced in an obvious manner from the available prior art.

3.9.1 The respondent argued that according to the disclosure of document (2), water as first extracting solvent is an essential feature of the process described therein and the person skilled in the art would therefore not change this solvent. However, the description of document (2) mentions that using water as an extracting solvent appears to be advantageous, because oils, also present in the seeds/kernels, are not solubilised by water and therefore does not require a further step to discard them. Hence, the person skilled in the art would have noted that the use of polar solvent other than water for the extraction of ground neem kernels necessitated a further step to remove the oils. In that context, seeking to solve the less ambitious problem as defined in point 3.7, the person skilled in the art would look for other methods of extraction of the neem seeds/kernels in the prior art and would not have ignored the teaching of document (8).

Document (8) relates to an improved process for solvent extracting neem seeds comprising contacting neem seeds with a co-solvent mixture of a nonpolar, aliphatic hydrocarbon solvent and a polar solvent to simultaneously remove the hydrophilic, azadirachtin-containing fraction and the hydrophobic, neem oil-containing fraction of seeds (see Claim 1). In the description related to the background of the invention, a method is also disclosed wherein the neem seeds/kernels can first be extracted with a polar solvent to remove the hydrophilic azadirachtin-

containing fraction from the seeds and the hydrophilic residue was then extracted by a non polar solvent to remove residual hydrophobic fatty acids oils (see bridging paragraph of column 1 and column 2). Document (8) also provides a list of solvents to be used as extracting solvents, such as methanol or ethanol (see column 1, lines 42 to 47) and cites aliphatic hydrocarbon as nonpolar solvent (see column 3, lines 7 to 8).

The respondent argued in that respect that document (8) taught that two solvents (e.g. ethanol and hexane) had to be used together to perform the process described in this document and there was thus no hint for the person skilled in the art to use one solvent after the other. However the teaching of a published patent application is not limited to what is considered by the applicant as the invention but extends to any information contained therein. The method disclosed in the background of the invention of document (8), although not necessarily leading to an identical result, can be considered by the skilled person since the technical problem to be solved does not aim at having any kind of advantage compared to the prior art but merely seeks an alternative way to obtain a powder containing azadirachtin.

Therefore, the person skilled in the art, knowing from document (2) that using a polar solvent other than water for the extraction of ground neem kernels necessitated a further step for removing the oils and knowing from document (8) a method for extracting azadirachtin from neem seeds involving first the extraction of neem seeds with a polar solvent such as

methanol or ethanol, followed by extraction of the hydrophilic azadirachtin-containing fraction by a nonpolar solvent such as an aliphatic hydrocarbon would have used this latter method as an alternative to the extraction way disclosed in document (2) using water.

Furthermore, according to the common general knowledge of the person skilled in the art percolation is a kind of extraction from crushed drugs by slowly flowing there through a liquid such as water or alcohol (see document (6a), first paragraph or document (16), page 334).

An obvious alternative to the method disclosed in document (2) is, therefore, to replace the extraction of ground neem kernels using water disclosed in document (2), by the percolation using an organic polar solvent, such as methanol or ethanol, followed by a further extraction step with a non polar solvent, such as an aliphatic hydrocarbon to remove the undesirable oils as taught by document (8). This alternative is encompassed by the steps a) to c) of the claimed process. Since the steps d) to f) of the claimed process do not distinguish from the further steps disclosed in document (2), i.e.

- separation with a water immiscible solvent, such as ethyl acetate (see Claim 1 of the patent in suit and column 11, line 47 versus document (2), column 4, lines 38 to 40)
- addition of petroleum ether or hexane (see Claim 1 of the patent in suit versus document (2), column 4, lines 48 to 50)
- drying (see Claim 1 of the patent in suit versus document (2), column 4, lines 55 to 58),

the board comes to the conclusion that the person skilled in the art seeking to solve the objective problem underlying the patent would have arrived in view of documents (2), (8) and its common general knowledge without inventive ingenuity at a solution falling within the scope of Claim 1 and for this reason Claim 1 does not involve an inventive step. In that context, it is not necessary to examine the two other lines of argumentation, namely documents (2) and (3) or (2) and (7) submitted by the appellant.

Since the board can only decide on a request as a whole, the main request is to be rejected.

Auxiliary requests 1-3

4. Claim 1 of the first auxiliary request differs from Claim 1 as granted in that the feature of Claim 7 as granted was included therein.

Claim 1 of the second auxiliary request differs from Claim 1 as granted in that the feature of Claim 10 as granted was included therein.

Claim 1 of the third auxiliary request differs from Claim 1 as granted in that the features of Claim 10 and 12 as granted were included therein.

5. Inventive step

5.1 The respondent put forward that auxiliary request 1 is to be considered as inventive over the cited prior art, because after having carried out the further process

step g), the purity of the powder containing azadirachtin has been raised from the range 10 to 19% to a range of 15 to 26%. This higher purity is regarded as an advantage of the claimed process and could not be deduced by the person skilled in the art from the available prior art.

A similar argument was provided by the respondent for the second and the third auxiliary requests.

According to the jurisprudence of the boards of appeal, it is common practice for a person skilled in the art of preparative organic chemistry to (further) purify a compound obtained in a particular chemical manufacturing process according to the prevailing needs and requirements, e.g. in samples for analytical purposes (see T 990/96, OJ EPO 1998, 489, point 7). Conventional methods for the purification of low molecular organic reaction products such as **recrystallisation**, distillation, **chromatography** (emphasis added by the board), etc., which normally can be successfully applied in purification steps, are within the common general knowledge of those skilled in the art. In view of the above, the board considers the purification steps "g)" or "h)" or "h) and i)" added to the previous steps "a) to f)" in the three auxiliary requests do not confer any inventiveness to these requests, since the purification techniques mentioned in these requests (chromatography, HPLC and crystallisation) are within the common general knowledge of the person skilled in the art and the higher purity achieved is therefore to be expected by the said person skilled in the art when applying these techniques to low molecular organic compounds.

5.2 In consequence of this, the board concludes that Claim 1 of these three auxiliary requests lacks inventive step pursuant to Article 56 EPC.

5.3 Since the board can only decide on a request as a whole those requests are to be rejected.

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 P. Ranguis