

Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2015-02-24
Docket Number / Aktenzeichen:	X ZR 31/13
Name of Decision / Name der Entscheidung:	Coenzyme Q10



Arbeitskreis
Patentgerichtswesen
in Deutschland e.V.



SUPERIOR COURT
ON BEHALF OF THE PEOPLE
RULING

X ZR 31/13

Date announced:
24 February 2015
Hartmann
Court Clerk
as Documents Officer
of the Court

in the patent nullification case of

Kaneka Corporation, represented legally by their manager, Osaka-shi, Osaka (Japan),

Defendant and Appellant,

– Attorneys of Record: Patent Attorneys and Attorneys at Law Hoffmann • Eitle,
Arabellastrasse 4, Munich;

assisting: Attorneys-at-Law Preu Bohlig & Partners,
Georg-Glock-Strasse 14, Düsseldorf –

versus

1. Zhejiang Medicine Co., Ltd. (ZMC), represented legally by their director,
59 Huangcheng East Road, Xinchang, Zhejiang (China),

2. Kyowa Hakko Europe GmbH, represented legally by their manager,
Am Wehrhahn 50, Düsseldorf,

Plaintiff and Appellee,

– Attorneys of Record No. 1 Law Firm Boehmert & Boehmert,
Pettenkoferstrasse 20-22, Munich –

– Attorneys of Record No. 2 Patent Attorneys and Attorneys-at-Law Grünecker,
Leopoldstrasse 4, Munich –

In response to the oral hearing on 24 February 2015, with the Presiding Judge Prof. Dr. Meier-Beck as well as Judges Gröning, Dr. Bacher, Hoffmann and Dr. Kober-Dehm, the Tenth Civil Division of the Federal Supreme Court

has ruled as follows:

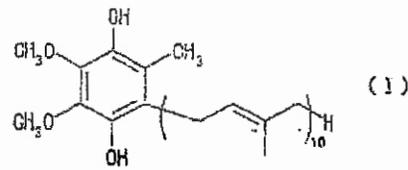
The appeal on the ruling by the Third Division (Nullification Division) of the Federal Patent Court, which was issued on 07 November 2012, is hereby rejected at the expense of the Defendant.

By law

Facts of the Case:

- 1 The Defendant is the holder of European Patent 1 466 983 (patent in suit) which was granted and in effect for the Federal Republic of Germany, with a filing date of 27 December 2002 and with a claim of a Japanese priority date of 27 December 2001 and relates to a process for producing reduced and oxidized coenzyme Q₁₀. The patent in suit includes 55 patent claims, of which Claims 1 and 31 are both independent claims and are worded as follows in the language of the proceeding:

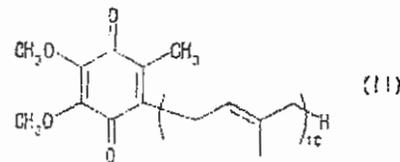
"1. A process for producing the reduced coenzyme Q₁₀ represented by the following formula (I):



which comprises

- (a) culturing reduced coenzyme Q₁₀-producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient to obtain microbial cells containing reduced coenzyme Q₁₀ at a ratio of not less than 70 mole % among the entire coenzymes Q₁₀,
- (b) optionally disrupting the microbial cells and
- (c) extracting thus-produced reduced coenzyme Q₁₀ by an organic solvent under the condition that the reduced coenzyme Q₁₀ is protected from an oxidation reaction, to thereby obtain an extract containing not less than 70 mole % of reduced coenzyme Q₁₀ among the entire coenzyme Q₁₀.

31. A process for producing the oxidized coenzyme Q₁₀ represented by the following formula (II):



which comprises

culturing reduced coenzyme Q₁₀-producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient to obtain microbial cells containing reduced coenzyme Q₁₀ at a ratio of not less than 70 mole % among the entire coenzymes Q₁₀,

optionally disrupting the microbial cells; and

either oxidizing thus-produced reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀ using an oxidizing agent and then extracting the resultant by an organic solvent,

or extracting thus-produced reduced coenzyme Q₁₀ by an organic solvent, purifying optionally and oxidizing the resultant to oxidized coenzyme Q₁₀ using an oxidizing agent."

2

The Plaintiffs have attacked the patent in suit to the extent of Patent Claim 31 as well as Patent Claims 32 to 35, which refer back to that claim. They have asserted that the subject

matter of the patent in suit is neither patentable nor disclosed so clearly and thoroughly that those skilled in the art could implement it. The Defendant has defended the patent in suit in the granted version and, alternatively, in two amended versions.

3 The Patent Court has declared the patent in suit to be null and void to the extent to which it has been attacked, effective for the Federal Republic of Germany. The Defendant's appeal is directed against this, also seeking rejection of the lawsuit and defending the patent in suit alternatively with its motions already filed in the first instance as well as with three new alternative motions. The Plaintiffs have opposed the legal redress.

Grounds for the Decision:

4 The appeal is admissible but is unfounded.

5 I. The patent in suit relates to a process for producing coenzyme Q₁₀ in the reduced form and in the oxidized form.

6 1. According to the elucidations in the patent in suit, both reduced coenzyme Q₁₀ and oxidized coenzyme Q₁₀ function as electron transport systems in the cells of the human body and are involved in the production of adenosine triphosphate (ATP). It is known that oxidized and reduced coenzyme Q₁₀ are in equilibrium in the human body, and they reciprocally reduce the absorbed oxidized coenzyme Q₁₀ and oxidize the absorbed reduced coenzyme Q₁₀.

The patent in suit also further explains that oxidized coenzyme Q₁₀ is a substance in pharmaceutical products that is pharmaceutically and physiologically effective against a number of diseases and is also widely used in food supplements and cosmetic products. On the other hand, reduced coenzyme Q₁₀ has hardly gained any attention so far, although it has been reported in recent years that reduced coenzyme Q₁₀ is more effective than oxidized coenzyme Q₁₀ in many applications.

8 With regard to possible production processes, the patent in suit states that reduced coenzyme Q₁₀ can be produced by chemical synthesis by a process similar to that used for oxidized coenzyme Q₁₀. However, this method is complicated, risky and expensive. It also has the disadvantage that the product may be contaminated due to the formation of (Z)-isomers,

which must be minimized because of regulations governing pharmaceutical drugs (description, paragraph 10).

9 Another method consists of using microorganisms, whose microbial cells produce reduced coenzyme Q₁₀. The disadvantage to this is that the reduced coenzyme Q₁₀ produced by the microbial cells contains a large amount of oxidized coenzyme Q₁₀ and separation and recovery of the reduced coenzyme Q₁₀ by a conventional process are associated with high costs (description, paragraph 11).

10 The presence of reduced coenzyme Q₁₀ in microbial cells is described in the Unexamined Japanese Patent Applications Sho-57-70834 (NK1) and Sho-60-75294 (NK3). However, the Unexamined Japanese Patent Application Sho-57-70834 relates to the use of photosynthesis bacteria, the culturing of which is complicated. Furthermore, it cannot be ascertained whether the ratio of reduced coenzyme Q₁₀ to the total coenzyme in the microbial cells of the microorganisms is sufficient, if the aim is to produce reduced coenzyme Q₁₀. The Unexamined Japanese Patent Application Sho-60-75294 relates to the production of reduced coenzyme Q₁₀ from bacteria of the *Pseudomonas* genus and describes a method for converting oxidized coenzyme Q₁₀ present in a hexane phase to reduced coenzyme Q₁₀ by using sodium hydrosulfite as the reducing agent. However, the ratio of reduced coenzyme Q₁₀ to the total coenzyme in the microbial cells is unclear (description, paragraphs 12, 14 and 15). Moreover, both publications are aimed at ultimately obtaining oxidized coenzyme Q₁₀ and therefore they describe the reduced coenzyme as being merely an intermediate product in the production of oxidized coenzyme Q₁₀. Finally, neither of the two documents describes the amount of coenzyme Q₁₀ produced in the culture (description, paragraphs 13 and 16).

11 In agreement with the statements in the patent specification in suit, the Patent Court has found the object of the patent in suit to be to provide a safe and simple process that is efficient in producing oxidized coenzyme Q₁₀ on an industrial scale by culturing microorganisms. With the reference to culturing microorganisms, however, the Patent Court has partially anticipated the approach according to the invention. The problem on which the patent in suit is based can be seen more generally as providing a process which is safe and efficient on an industrial scale for producing reduced coenzyme Q₁₀ as well as a simple and reliable process for producing oxidized coenzyme Q₁₀ (description, paragraphs 19 and 20).

12 2. To solve this problem, the patent in suit proposes in its Patent Claim 1 (not contested) a process for producing a reduced coenzyme Q₁₀, this process comprising the following steps:

- culturing microorganisms that produce reduced coenzyme Q₁₀ in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient to obtain microbial cells containing reduced coenzyme Q₁₀ in a ratio of no less than 70 mol% of the total coenzyme Q₁₀;
- optionally disrupting the microbial cells and
- extracting the reduced coenzyme Q₁₀ produced in this way using an organic solvent under the condition that the reduced coenzyme Q₁₀ is protected from an oxidation reaction to thereby obtain an extract containing no less than 70 mol% reduced coenzyme Q₁₀ in the total coenzyme Q₁₀.

13 3. However, the other independent Patent Claim 31, which has been attacked by the nullification action, relates to a process for producing oxidized coenzyme Q₁₀. According to that, as defined in Patent Claim 1, reduced coenzyme Q₁₀ is produced first, then is oxidized in another process step, wherein two alternatives are provided with regard to the sequence of extraction and oxidation. The process for producing oxidized coenzyme Q₁₀ thus consists of the following steps (different organization by the Patent Court shown in brackets):

1. Microorganisms, which produce reduced coenzyme Q₁₀, are cultured
 - 1.1 in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient [b],
 - 1.2 to obtain microbial cells containing reduced coenzyme Q₁₀ in an amount of at least 70 mol% of the total coenzyme Q₁₀ [c].
 2. The microbial cells are optionally disrupted [d].
 3. The reduced coenzyme Q₁₀ produced in this way is
 - 3.1 either oxidized using an oxidizing agent and then extracted with an organic solvent [e1] or
 - 3.2 extracted using an organic solvent, optionally purified and then oxidized using an oxidizing agent [e2].
-

14 4. The wording of Patent Claim 31 does not rule out *a priori* that certain requirements are made of the culturing conditions, so that the desired amount of at least 70 mol% of the total coenzyme Q₁₀ is obtained. Meanwhile, this is not derived from the description of the patent in suit, where it is stated only that culturing is generally performed aerobically (paragraph 47). Anaerobic culturing is therefore not ruled out in principle, and this is also confirmed by the fact that performing the culturing aerobically is not mentioned at all until Patent Claim 37. The appeal also cannot be successful when it asserts that, with the requirement for aerobic culturing, the patent in suit does not relate merely to a conventional supply of oxygen, accomplished in any manner, but instead it requires an oxygen supply, during which there cannot be any limitation on the oxygen in the form of an oxygen deficiency for the entire duration of the culturing, and a limited aeration is not sufficient for this. Apart from the fact that, even according to the general understanding, the term "aerobic" means only that oxygen must be present in a *sufficient* amount for the respective microorganism in question, the patent in suit also defines the term "aerobic" in this sense, when it is stated that this expression describes conditions under which oxygen is supplied, so that no oxygen limitation (oxygen deficiency) is caused during the culturing. More specifically, the patent in suit even specifies it as preferred that "sufficient" oxygen be supplied, so that no "substantial" oxygen limitation occurs (paragraph 47). To be sure, it is also stated in the description that the amount of reduced coenzyme Q₁₀ can be limited by a process for which a number of parameters are given, also including culturing while shaking (amplitude 2 cm, 310 pendulum movements per minute) (paragraph 26). However, this should serve only the purpose of standardization of the ratio specification for various microorganisms (paragraph 27). When the description also specifies suitable fermentation conditions (paragraph 40), this relates to the highest possible productivity, for example, with regard to the controlled concentration of the carbon source (paragraph 44 f.). Thus, nothing can be derived from the patent in suit to indicate that the process according to the invention – as asserted by the Defendant – presupposes a particularly strong aeration.

II. The Patent Court has come to the conclusion that the subject matter of the patent in suit is not novel to the extent contested and they substantiate this as follows:

The Unexamined Japanese Patent Application Sho-53-133687 (NK5) describes a process that can be used industrially for producing coenzyme Q₁₀. The conclusion to be drawn from Examples 1, 3 and 4 described there is that the proposed process is suitable in particular for producing oxidized coenzyme Q₁₀. Example 3 shows a way to produce reduced coenzyme Q₁₀ from microorganisms. From the fact that NK5 does not describe in greater detail the

conditions necessary for culturing the microorganisms, those skilled in the art, comprising a team of an organic chemist and a biologist, who is familiar with fermentation processes and has special knowledge in the field of microbiology, would conclude from this that culturing is possible under the standard conditions with which they are familiar. As proven by expert opinion based on US Patent 3,769,170 (NK2), the components mentioned in Patent Claim 31 for the culture medium are the conventional ingredients of a standard medium. Since the patent in suit does not describe the culturing conditions or the composition of the culture medium in detail, therefore feature 2 also includes standard conditions and media that those skilled in the art would infer as such in NK5. NK5 also discloses the disruption of the microbial cells, which is provided as an optional step according to feature 2 of the patent in suit. Those skilled in the art would recognize a conventional method for disruption of microbial cells in the measures mentioned in Example 3 of NK5 – namely, collecting the cells by centrifugation and extraction of the cell pellet thereby obtained with a solution of hexane and methanol, which is heated in the presence of sodium hydroxide and pyrogallol. This is also confirmed by NK2. Finally, NK5 discloses the concluding final step in the alternative option mentioned in feature 3.2 of the patent in suit. Example 3 of NK5 provides an extraction process for isolation of the intermediate stage containing the reduced coenzyme Q₁₀; in this process, a mixture of hexane and methanol first and then acetone is used. The oil, which is obtained after removal of the acetone and is enriched with reduced coenzyme Q₁₀, is purified by chromatography according to the specifications in Example 1 of NK5 and finally is converted into oxidized coenzyme Q₁₀ with the help of atmospheric oxygen.

17

Although NK5 does not include any specification concerning the amount of reduced coenzyme Q₁₀ in the cell culture, Example 3 of NK5 uses *Pseudomonas denitrificans*, which is also regarded in the patent in suit as a suitable microorganism for the process according to Patent Claim 31, because according to the data in Table 2 of the patent in suit, this microorganism contains 85 mol% reduced coenzyme Q₁₀. According to the patent in suit, based on the principle that the same procedures will regularly lead to identical products when using identical starting materials, culturing conditions that are customary in general are sufficient to obtain such a reduced coenzyme Q₁₀ content, so the percentage of reduced coenzyme Q₁₀ specified in feature 1.2 is also obtained with the bacteria of the genus *Pseudomonas denitrificans* used in Example 3 of NK5. This assumption is also consistent with the Defendant's argument in the infringement proceeding before the Düsseldorf Regional Court, where they (as the Plaintiff) asserted that a reduced coenzyme Q₁₀ content according to feature 3 does not

require any special culturing conditions, but instead those skilled in the art who select a microorganism mentioned in the patent in suit and culture it according to the state-of-the-art specifications will generally obtain an amount of reduced coenzyme Q₁₀ of no less than 70 mol%.

18 It may be true that the Defendant was not able to isolate reduced coenzyme Q₁₀ in reconstructing Example 3. However, in view of the repeated references to this intermediate product in NK5, there is no reason to doubt the achievement of Example 3. There is also no basis for Defendant's claim of the culturing under partially anaerobic conditions. Those skilled in the art are aware that *Pseudomonas denitrificans* is a microorganism that requires oxygen for its survival so that they would readily associate the culturing according to Example 3 of NK5 with purely aerobic culturing.

19 The feature whereby the culturing of the microorganisms is to be performed aerobically, which was additionally provided according to Alternative Motion I in comparison with the granted version, is thus also not suitable for substantiating the novelty of the subject matter of the patent in suit.

20 Nor is the restriction to the process alternative mentioned in feature 3.2, as provided according to Alternative Motion II, novel in comparison with NK5 because the same sequence for recovering the oxidized coenzyme Q₁₀ from the intermediate step enriched with reduced coenzyme Q₁₀ is provided there as in feature 3.2.

21 III. This evaluation has withstood the review in the appellate proceeding.

22 1. The Patent Court has correctly arrived at the conclusion that the subject matter of Patent Claim 31 is not novel. It is anticipated by the Unexamined Japanese Patent Application Sho-53-133687 (NK5), which describes a process for purifying coenzyme Q, in which reduced coenzyme Q is processed with a porous synthetic resin and then oxidized.

23 a) Feature group 1 is disclosed in NK5. According to the findings of the Patent Court, reproducing Exemplary Embodiment 3, in which the bacteria of the genus *Pseudomonas* (*Pseudomonas denitrificans*) are cultured, leads to a cell culture containing reduced coenzyme Q₁₀ in an amount of at least 70 mol% of the total coenzyme Q₁₀ produced.

24 This finding by the Patent Court is binding for the appellate proceeding (§ 117 PatG in combination with § 529 para. 1, no. 1 ZPO) and it withstands the appellate attack.

25 According to § 529, para. 1, no. 1 ZPO, the Appellate Court has based its hearing and its decision on the facts as found by the court in the first instance, inasmuch as no concrete points cast doubt on the validity and thoroughness of the findings relevant to the decision and therefore demand a new ruling. The latter is not the case here.

26 aa) Contrary to the assumption of the Patent Court that the ingredients of the culture medium listed in feature 1.1 are the usual ingredients that are essential for optimal growth of microorganisms and that this is proven by the corresponding explanations in NK2 (column 2, lines 2 through 17), it is equally not to be recalled as well as against its assumption that, in lieu of further details about the composition, the use of such a standard medium is also to be assumed for Exemplary Embodiment 3.

27 The complaint in the appeal that NK2 does not disclose that the culture medium contains a phosphorus source is unsubstantiated. The Defendant itself has presented a scientific expert opinion by Professor Turner in the infringement proceeding, which is still pending between the parties before the Düsseldorf Regional Court – as pointed out in the reply to the appeal. This expert opinion identifies the ingredients listed in feature 1.1 as being essential elements of any culture medium (NK23, margin nos. 17, 19). Moreover, NK2 lists ammonium phosphate as a possible ingredient (column 2, line 14) and this is also mentioned as a possible source of phosphorus in the patent in suit. Moreover, the patent in suit points out that phosphorus sources may be contained in the natural components of a culture medium, such as yeast extract, for example. However, yeast extract is also proposed as an ingredient by NK2 (column 2, line 16).

28 bb) The additional assumption by the Patent Court that *Pseudomonas denitrificans* is a microorganism with which those skilled in the art are familiar and which requires oxygen during its culturing for its survival and therefore requires aerobic culturing also does not meet with any objections.

29 To this extent, the Defendant cannot succeed with their objection that the presumed oxygen demand of the microorganisms used in NK5 is no proof that these microorganisms were cultured aerobically under the conditions specified in paragraph 47 of the description in the patent in suit. Inasmuch as the Defendant asserts that the use of *Pseudomonas denitrificans* as the microorganism says nothing about the amount of oxygen supplied and that a limited oxygen supply is considered to be adequate or even necessary for culturing a variety of microorganisms in the state of the art, it must be pointed out that the understanding of aerobic culturing in the

patent in suit, as explained above, conflicts with what those skilled in the art would usually understand by aerobic culturing. In particular, the patent in suit does not provide any information that the process according to the invention would require particularly strong aeration. There is therefore no objection to the conclusion by the Patent Court that the use of the bacteria of the genus *Pseudomonas denitrificans*, which are known as aerobic microorganisms by those skilled in the art, indicates that the culture conditions of NK5 do not differ from those of the patent in suit. The objection by the Defendant that, according to NK5, significant quantities of reduced coenzyme Q₁₀ are formed only by adding a reducing agent after culturing does not lead to any different evaluation. As already stated by the Patent Court, the reducing agents in Example 3 of NK5 are added only during digestion of the cells after the culturing of the microorganisms is concluded, so that no inferences about the conditions under which the culturing has taken place can be drawn from the use of the reducing agents in NK5. In particular, anaerobic culturing cannot be concluded from this.

30 cc) Nor can there be an objection to the finding by the Patent Court that the culturing of *Pseudomonas denitrificans* under the usual – aerobic – culture conditions results in a reduced coenzyme Q₁₀ content of at least 70 mol% of the coenzyme and that it can therefore be assumed that the amount of reduced coenzyme Q₁₀ obtained in recreating Example 3 from NK5 is also of this size.

31 As explained convincingly by the Patent Court, there is an indication that this finding is correct even from the description of the patent in suit itself. It is stated in Table 2, which is reproduced there, that a reduced coenzyme Q₁₀ content of 85 mol% can be achieved by using *Pseudomonas denitrificans*. Inasmuch as the Defendant wants to refute this through the appeal, the Patent Court has wrongly assumed that the cultures in NK5 and the patent in suit were prepared under corresponding – conventional – conditions, the Defendant cannot be successful in this because, as already explained, the culture conditions according to the patent in suit do not differ from the usual conditions that are known to those skilled in the art on the basis of their technical knowledge for culturing microorganisms. Furthermore, the Defendant's own arguments show the validity of the statement that the culturing of *Pseudomonas denitrificans* under the usual culture conditions results in obtaining microbial cells with a reduced coenzyme Q₁₀ content according to feature 1.2. Thus, in the infringement proceedings between the parties, the Defendant states in their brief of 25 October 2011 that they were wrong to assume in the infringement suit that very special culture conditions based on the respective microorganism in the patent in suit constitute a prerequisite for a 70 mol% amount of reduced coenzyme Q₁₀. The

reference to the culture conditions is to be understood merely as a reference to generally reasonable conditions (NK20, p. 2, para. 1 at the end). It is described in the patent in suit that certain microorganisms fundamentally produce a reduced coenzyme Q₁₀ content of more than 70 mol%. The results presented in the patent specification in suit (Tables 1 through 3, paragraph 115) are also not the result of extensive test series by the Plaintiff, in which they ascertained special culturing and fermentation conditions. Instead, a general experimental setup, such as that which those skilled in the art would usually select is described. Accordingly, the microorganisms mentioned there yielded a ratio of 70 mol% reduced coenzyme Q₁₀ even when the culture conditions had not been optimized or specially defined for the individual microorganism. Therefore, if those skilled in the art were to culture the corresponding microorganisms according to the state of the art, they would generally obtain a reduced coenzyme Q₁₀ content of 70 mol%. The conditions mentioned in the patent in suit need not be maintained obligatorily.

32 The Defendant cannot diminish the probative value of these indications, either through the Test Report submitted to the Patent Court or through the "Experimental Report" (Exhibit HE1) submitted in the appellate proceedings or the supplement thereto (Exhibit HE3). The Defendant's complaint that the Patent Court did not address the Test Report which they submitted is unfounded. The Patent Court did take the report into account and came to the conclusion that the fact that the Defendant did not succeed in isolating reduced coenzyme Q₁₀ in their reconstruction of Example 3 of NK5 does not give any reason to doubt that reduced coenzyme Q₁₀ can be obtained in isolated form using the process described in this example. The Patent Court based this assumption on the fact that obtaining reduced coenzyme Q₁₀ in Example 3 of NK5 is not merely mentioned peripherally but instead it is pointed out specifically, by using the chemically unambiguous designation 2,3-dimethoxy-5-methyl-6-decaprenylhydroquinone and by specifying the quantity obtained and the degree of purity, and on the fact that reduced coenzyme Q₁₀ is obtained and isolated as an intermediate product with this process. The "Experimental Report" (Exhibit HE1) submitted in the appellate proceedings confirms that the minimum amount of reduced coenzyme Q₁₀ according to feature 1.2 of the patent is at any rate exceeded with sufficient ventilation. Finally, it can also be concluded from the expert opinion by Prof. Turner that was submitted by the Defendant in the infringement proceeding that the values listed in Table 2 of the patent in suit, which even go beyond the value according to the patent as specified in feature 1.2, are achieved with the culturing of microorganisms that produce coenzyme Q₁₀ without necessitating special culture conditions to do so. Thus, the

expert opinion readily assumes, i.e., in particular without referring specifically to the necessary culture conditions with respect to the *Rhodopseudomonas palustris* microorganisms used by Plaintiff No. 1 in the contested embodiment, that this microorganism, as indicated in Table 2 of the patent in suit, produces the reduced form of coenzyme Q₁₀ in an amount of 90% of the total coenzyme (NK23, margin nos. 22 through 266).

33 b) The disruption of the microbial cells obtained by the culturing which is optionally provided according to feature 2 is also disclosed in NK5. It is thus provided in Example 3 of NK5 that the moist cell paste obtained from the culture after centrifugation is heated in the presence of sodium hydroxide and pyrogallol and extracted with a solution of hexane and methanol (p. 8, lines 23 through 28). The finding by the Patent Court that this is a conventional cell disruption process with which those skilled in the art are familiar and which can also be derived from US Patent Application 3,769,170 (NK2), for example, is not contested by the appeal and also does not reveal any legal errors. Moreover, the patent in suit, which does not stipulate a specific process for the optional process step of disruption of the microbial cells, includes this method as one of several possibilities that might be considered (description, para. 63).

34 c) Finally, the Patent Court has also correctly assumed that feature 3 is disclosed by NK5 in the variant of feature 3.2. The complaint of the appeal, i.e., that the Patent Court incorrectly inferred the oxidation step of Example 1 into Example 3 of NK5 is unfounded.

35 In Example 3 of NK5, after the disruption of the microbial cells, the intermediate stage containing the reduced coenzyme Q₁₀ is first extracted with a mixture of hexane and methanol and then with acetone. After removing the acetone – as further stated in NK5 – an oily substance containing reduced coenzyme Q₁₀ is obtained and then is subsequently to be treated in the same way as that described in Example 1. In Example 1, the fat, which contains the reduced coenzyme Q₁₀, is first purified by chromatography and then the solvents are distilled out of it and then the product treated in this way is oxidized by exposing it to air for 30 minutes at room temperature while stirring. Since the product obtained according to Example 3 corresponds to the starting material in Example 1, and according to the specifications in Example 3, it should be treated like that, the oxidation step described in Example 1 is also to be carried out in Example 3 and is thus also disclosed there. Therefore, we cannot speak of an unjustified inference of this process step as occurring in the process sequence disclosed in Example 3.

36 2. The Patent Court correctly found that the subject matter of Patent Claim 31 in the version of Alternative Motions I and II is not patentable for lack of novelty. The criterion of aerobic culturing, which was additionally included in the two alternative motions, is derived for those skilled in the art from NK5 because those skilled in the art know that the microorganisms used there will thrive only under aerobic conditions. The restriction of the concluding process step to the variant specified in feature 3.2, which has been included in Alternative Motion II, had also already been disclosed by NK5 – as explained above.

37 3. Whether the extent of the examination by the Appellant Court pursuant to § 117 PatG, in combination with the specifications of § 529 para. 1, no. 2, § 531 para. 2, clause 1, nos. 1 to 3 ZPO, which are to be applied accordingly, also extends to Alternative Motions III, IV and V, which were filed with the grounds for appeal, may remain moot. Even if the subject matter of Patent Claim 31 in the version of these alternative motions may be novel, its patentability must at any rate be denied because it was self-evident to those skilled in the art from the prior art. The Defendant has thus not presented anything in the appeal that could have allowed the finding of an inventive step.

38 a) Alternative Motion III limits the process according to the invention, starting from Alternative Motion I, to certain microorganisms, which are mentioned in addition to others in the granted Patent Claim 54, which should be omitted from the version defended with Alternative Motion III. This cannot substantiate the patentability of the subject matter of Patent Claim 31 because at least some of the aforementioned microorganisms were already known as coenzyme Q₁₀-producing microorganisms in the prior art. NK1 thus discloses the culturing of bacteria of the *Rhodopseudomonas* genus. NK2 describes the culturing of bacteria of the *Sporobolmyces* and *Trichosporon* genera. The bacterial strain *Rhodobacter sphaeroides* is listed as an excellent coenzyme Q₁₀ producer in the publication that was submitted as NK4 (Yoshida et al., Production of ubiquinone-10 using bacteria, J. Gen. Appl. Microbiol. 1998, vol. 44, pp. 19-26) (cf. introduction of NK4).

39 b) Alternative Motion IV corresponds to Alternative Motion III, except that only variant 3.2 should be claimed in feature 3. This version is to be regarded as unpatentable for the same reasons as the version according to Alternative Motions III and II.

40 c) Alternative Motion V is based on Alternative Motion IV, but it limits the microorganisms to yeasts. The possibility of culturing yeasts for production of coenzyme Q₁₀ was already disclosed in NK2 (column 1, line 31; column 5, line 55 to column 6, lines 1-19).

41 IV. The cost decision is based on § 121 para. 2 PatG in combination with § 97 para. 1 ZPO.

Meier-Beck

Gröning

Bacher

Hoffman

Kober-Dehm

Previous instance:

Federal Patent Court, decision of 07 November 2012 - 3 Ni 21/11 (EP) in combination with 3 Ni 39/11 (EP) –

Completed
[signature] (Hartmann)
Court Clerk
as the documents clerk of the
business office
