

Regional Court of Düsseldorf

IN THE NAME OF THE PEOPLE

Judgment

In the lawsuit involving

Kaneka Corporation, 3-2-4, Nakanoshima, Kita-ku, Osaka 530-8288, Japan

- Plaintiff -

- represented by counsel: Attorney Dr. Augenstein and all other attorneys admitted to the local or regional bars of the law offices of Preu Bohlig & Partner, Preiligrathstraße 27, 40479 Düsseldorf -

v.

1. **Zhejiang Medicine Co., Ltd.**, No. 268, Dengyun Rd., Gonshu Dist., 3₁₀01 Hangzhou, China, represented by its director, Xiaioyne Jiang, same address,
2. **Zhejiang Medicine Co., Ltd., Xinchang Pharmaceutical Factory**, No. 59 East Huancheng Road, Chengguan, Town, Xinchang County, 312500 Zhejiang, China, represented by its legal representative, Li Chumbo, same address

- Defendant -

- represented by counsel: Attorney Dr. Haarmann and all other attorneys of the law offices of Boehmer[t] & Boehmert, Pettenkoferstraße 20-22, 80336 Munich who are admitted to the local or regional bars -

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Civil Division 4a of the Regional Court of Düsseldorf
after hearing oral arguments on 14 February 2012
has ruled, through the Presiding Regional Court Judge, Dr. Crummenerl
and the Regional Court Judges Dr. Voß and Dr. Thomas,

as follows:

The action is dismissed.

The costs of the litigation are to be borne by Plaintiff.

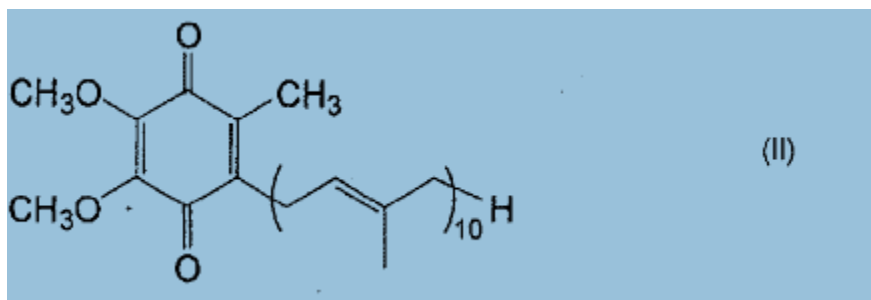
The judgment is provisionally enforceable against provision of security in the amount of 1₁₀% of the respective sum to be enforced. The provision of security may be also be effected by means of an irrevocable, unconditional and directly enforceable guarantee that is unlimited as to time, from a bank in the European Union licensed as a customs or tax guarantor.

Statement of facts

Plaintiff is the registered owner of the European Patent 1 466 982 B1 (patent in suit), which was applied for on 27 December 2002, claiming a Japanese priority date of 27 December 2001. The reference to the granting of the patent in suit was published on 05 March 2008 with the EPO. The patent remains in force. Defendant 1, by its brief dated 30 May 2011, filed an action for nullity with the Federal Patent Court, asking that the patent be declared null. No decision has yet been pronounced in the action for nullity.

The patent in suit relates to a method for the manufacture of the coenzyme Q₁₀. Claim 31 of the patent in suit, asserted by Plaintiff, in the English language, reads as follows in German:

Method for the manufacture of the oxidized coenzyme Q₁₀, represented by the following formula (II):



where the method includes the following steps:

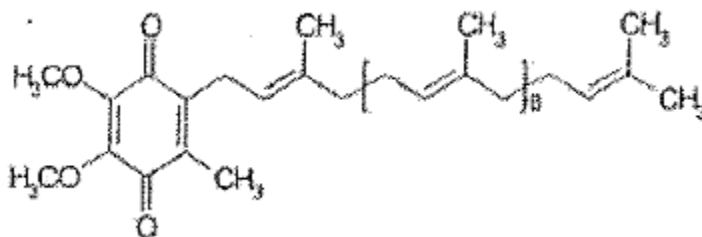
the cultivation of microorganisms that produce the reduced coenzyme Q₁₀ in a culture medium that contains a carbon source, a nitrogen source, a phosphorus source and a micro-nutrient, in order to produce microbial cells that contain reduced coenzyme Q₁₀ in a proportion of no less than 70mol% of the total coenzyme Q₁₀,

if applicable, the destruction of the microbial cells, and

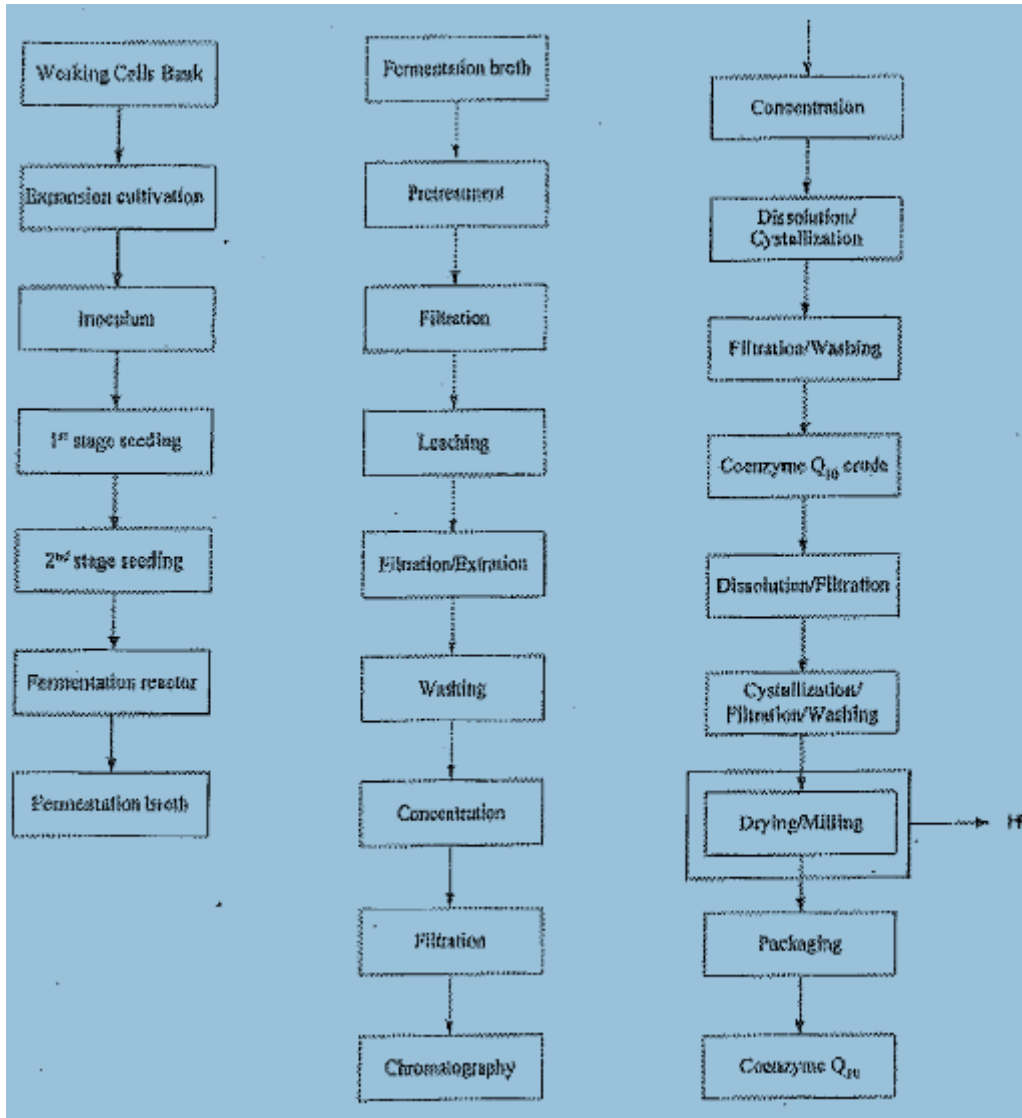
either the oxidizing of the reduced coenzyme Q₁₀ so produced using an oxidizing agent, followed by extraction of the result with an organic solvent or the extraction of the reduced coenzyme Q₁₀ so produced with an organic solvent,

if applicable, cleaning and oxidizing of the result to oxidized coenzyme Q₁₀ through the use of an oxidizing agent.

Defendants produce oxidized coenzyme Q₁₀ which they supply to, among others, Kyowa Hakko Europe GmbH, Düsseldorf. In the product information sheet from this company, the oxidized coenzyme Q₁₀ is shown with the following structural formula:



The production process used by Defendants is shown in the flow chart submitted as Exhibit PBP 18, and reproduced below, the origin of which has not been further specified.



This product will hereinafter be identified as the contested embodiment. Furthermore, in the product information sheet, submitted as Exhibit PBP 17, the Zhejiang Medicine Company Ltd., China, is named as the manufacturer of the contested embodiment. On the aforementioned flow chart the Zhejiang Medicine Company Ltd. Xinchang Pharmaceutical Factory is listed in the header.

Plaintiff is of the opinion that Defendant 2 is capable of being a party to the lawsuit; although under Chinese law it is not legally independent, it is organized as a “Ltd.” and thus constitutes a legal entity of its own. In this respect it also appears on the Internet and vis-à-vis the European Medicines Agency as a holder of rights and obligations.

Moreover, Plaintiff presents the view that the contested embodiment is a product that is directly produced by means of the method protected by the patent in suit. It argues that the Defendant uses the microorganism *rhodopseudomonas sphaeroides* in the production of the coenzyme Q₁₀. This, Plaintiff says, has been confirmed, upon request, by an employee of the British sales representative of Kyowa Hakko Europe GmbH via email. The fact that this microorganism is cultivated in a culture medium under the conditions cited in the patent claim in suit is indispensable and results as well from the flow chart cited, which describes fermentation of the organisms. Plaintiff is further of the opinion that the microorganisms cultivated by Defendants produce coenzyme Q₁₀ with a share of reduced coenzyme Q₁₀ that is no less than 70 mol%. Microorganisms of the *rhodopseudomonas sphaeroides* species have similar genes and closely related biosynthetic pathways. The share of reduced and oxidized coenzyme Q₁₀ thus did not deviate greatly from one another in representatives of the same species. Plaintiff asserts that in the specification for the patent in suit, for the *rhodopseudomonas palustris* strain, a portion of reduced coenzyme Q₁₀ of 90% is described, so that the *rhodopseudomonas sphaeroides* organism, which belongs to the same species would contain a portion of at least 70%. This has been confirmed in a private expert opinion commissioned by it (Exhibits PBP 19 and 20). Experiments are also said to have shown that when using the standard conditions a portion of over 70mol% of the reduced coenzyme Q₁₀ is always obtained (Exhibits PBP 30-32). It is undisputed that Defendants sell the contested embodiment, with a purity of 97%. Plaintiff is of the opinion that such a result can be achieved only if an oxidizing agent converts the reduced coenzyme Q₁₀ to an almost pure oxidized coenzyme. As a solvent, in order to extract the coenzyme, Defendants – also indisputably – use ethanol.

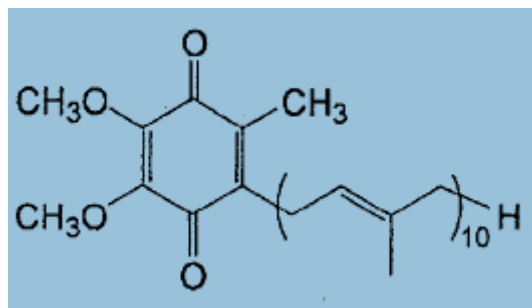
Plaintiff asks the Court

- I. to order Defendants
 1. under penalty of an administrative fine to be imposed by the Court of up to EUR 250,000.00 – or alternatively, administrative detention – for each

instance of contravention, or administrative detention of up to six months; in the case of repeated instances of contravention, up to a total of two years, where the administrative detention is to be enforced against Defendants' legal representatives,

to cease offering, marketing or using or introducing for the purposes cited or possessing

oxidized coenzyme Q₁₀ with the following formula



as the product of a method

in the Federal Republic of Germany, where the method includes the following steps:

The cultivation of microorganisms that produce the reduced coenzyme Q₁₀ in a culture medium that contains a carbon source, a nitrogen source, a phosphorus source and a micro-nutrient, in order to produce microbial cells that contain reduced coenzyme Q₁₀ in a proportion of no less than 70mol% of the total coenzyme Q₁₀; if applicable, the destruction of the microbial cells, and

either the oxidizing of the reduced coenzyme Q₁₀ so produced to oxidized coenzyme Q₁₀ using an oxidizing agent, followed by extraction of the result with an organic solvent or the extraction of the reduced coenzyme Q₁₀ so produced with an organic solvent; if applicable, cleaning and oxidizing of the result to oxidized coenzyme Q₁₀ through the use of an oxidizing agent;

2. to give Plaintiff an accounting, by means of a complete and orderly list, of the extent to which it has carried out the actions in 1 since 05 April 2008, providing

- a) the names and addresses of the manufacturers, suppliers and other previous owners, as well as commercial customers and sales offices for which the products were intended,
- b) the quantity of the products manufactured, delivered, received or ordered, as well as the prices paid for the products in question,
- c) the individual offers, broken down by the quantities, times and prices of the offers, as well as names and addresses of the recipients of the offers,
- d) the advertising carried out, broken down by advertising media, expenditures, period of dissemination and area of dissemination,
- e) the production costs and the profit achieved, broken down by individual cost factors,

and also provide the associated proof of purchase and sales (delivery slips or invoices) with the exception that data not related to the information and accounting owed and concerning which Defendants have a justified interest in confidentiality, may be covered or blacked out,

Defendants may reserve the right to give the names and addresses of their non-commercial customers as well as the recipients of offers not to Plaintiff, but to a sworn auditor who is pledged to confidentiality, with registered office in the Federal Republic of Germany, to be named by Plaintiff, if Defendants bear the costs for such auditor and authorize and oblige him to inform Plaintiff, in response to specific questions, whether a particular non-commercial customer or recipient of an offer is included;

- II. to find that Defendants are obliged to compensate Plaintiff for all losses incurred by it and that may yet be incurred by it through the actions cited in I.1 and carried out since 05 April 2008;

Defendants ask the Court

to dismiss the action,

alternatively, to suspend the litigation pending a final and legally binding decision on the action for nullity filed against the German part DE 602 25 478 T2 of the European Patent EP 1 466 983 B1.

Defendants are of the opinion that Defendant 2 is not capable of being a party to the lawsuit. It is said to be merely a factory of Defendant 1. It is not a legal entity under Chinese law.

Moreover, Defendants argue that the contested embodiment is not manufactured according to the patent-protected method. Defendants dispute the use of *rhodopseudomonas sphaeroides* saying that the email correspondence from which Plaintiff learned this information may not be accepted as evidence, since it constitutes Defendants' trade secrets. Furthermore, they argue, it has no knowledge of what proportions of the microorganisms used by them contained reduced or oxidized coenzyme Q₁₀. Plaintiff also has not shown that the method used by Defendant leads to a share of reduced coenzyme Q₁₀ of no less than 70mol%. The statements by Defendants are said to be based solely on unfounded and unproven assumptions. Even the prior art shows that one type of microorganism produces reduced coenzyme Q₁₀, while another type from the same species produces no coenzyme Q₁₀ at all. The ratio of reduced and oxidized coenzyme Q₁₀, however, does not depend solely on the choice of microorganisms, but rather also on the respective culture conditions under which each were grown. Tests commissioned by Defendants showed this (Exhibits B 5-7 and NK₁₀-12). Irrespective of this, it is necessary according to the teaching of the patent claim in suit that the oxidation and extraction be carried out in two separate, sequential process steps. However, in the method used by the Defendants this is not the case, because the extraction takes place in a one-stage process under non-protective conditions. The oxidation occurs without any specific oxidizing agent, rather through the presence of air.

Defendants are further of the opinion that the patent in suit will be found invalid in the action for nullity, because the technical teaching is not novel, but in any case is suggested by the prior art. In addition, it is not practicably disclosed.

Plaintiff has withdrawn the originally filed motions for destruction and recall and removal from distribution.

Reasoning

The action is admissible, but unsubstantiated.

A

The action is admissible.

Defendant 2 is capable of acting as a party to court proceedings. Pursuant to § 50 Para. 1 ZPO (German Code of Civil Procedure), any entity that has legal capacity, i.e. has rights and obligations, is capable of acting as a party to court proceedings. Pursuant to Art. 7 Para. 1 sentence 1 EGBGB (Introductory Act to the German Civil Code), the legal capacity and capacity of acting as a party to court proceedings vis-à-vis foreign parties is governed by the law of the state to which the person belongs. Defendants have asserted that Defendant 2 is merely the factory of Defendant 1, and under Chinese law is not a legal person. The court does not agree. Defendant 2 is structured as a “Ltd.” company. It is not identical to Defendant 1 as it has a different name, namely “Zhejiang Medicine Co. Ltd. Xinchang Pharmaceutical Factory”. The company acts independently in legal transactions under this name. In addition to its own website, to which Defendant 2 reserves of all rights (“All Rights Reserved” - Exhibit PBP 28), it acted as a responsible party, represented by its director, when it submitted a declaration on solvent residues in pharmaceutical active ingredients and non-active ingredients pursuant to Directive CPMP/ICH/283/95 of the European Medicines Agency (Exhibit PBP 23). It thereby presented itself as an independent entity having rights and also sees itself as such. Accordingly, it refers to itself on its website as the most important company or “main enterprise” of Defendant 1. After Plaintiff made reference to this state of affairs, Defendants did nothing to contest it. The fact that Defendant 2 may be dependent on Defendant 1 under company law is of no consequence to the question of its being capable of acting as a party to court proceedings.

B

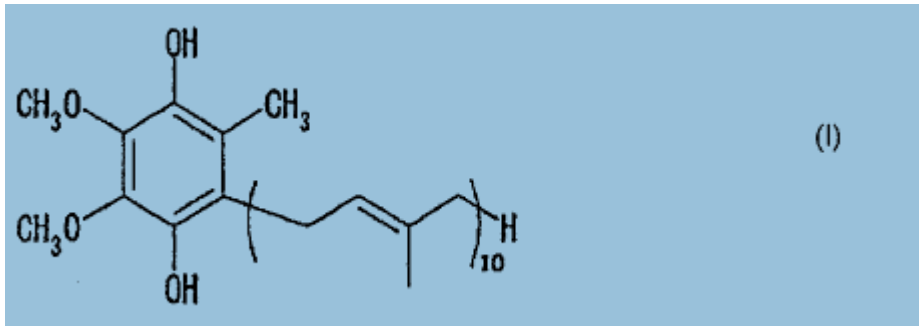
The action is unsubstantiated.

Plaintiff has no claims against Defendant for a prohibitory injunction, disclosure of information or accounting, or to determine liability for damages pursuant to Art. 64 Para. 1 EPC in connection with Sect. 139 Para. 1 and 2, 140b Para. 1 PatG (German Patent Act), Sect. 242, 259 BGB. It is

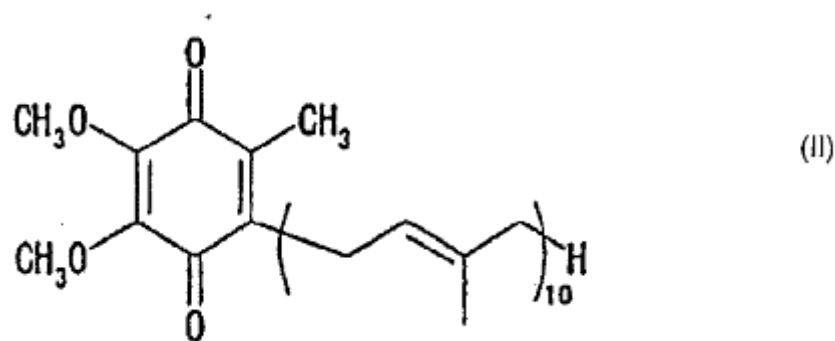
not evident that the contested embodiment is a product that has been directly produced using the patent-protected method within the meaning of Sect. 9 sentence 2 No. 3 PatG.

I.

The patent in suit concerns a method for producing reduced coenzyme Q₁₀, represented by the following formula (I)



and also a method for producing oxidized coenzyme Q₁₀, represented by the following formula(II):



The patent in suit states that the reduced coenzyme Q₁₀ (I) and the oxidized coenzyme Q₁₀ (II) are mitochondrial factors that represent an electron transport system present in the cells of the body of a living person and are involved in ATP production in that they act as electron carriers in oxidative phosphorylation reactions (Para. [0004]; text passages without references are from the patent specification of the patent in suit). [It states that] in addition to being used in pharmaceutical products employed to treat a range of illnesses as a pharmaceutically and physiologically active substance, oxidized coenzyme Q₁₀ is widely used in nutrition supplements and cosmetic products (Para. [0005]). Moreover, [the specification states] the reduced coenzyme Q₁₀ has hardly garnered any attention; however in recent years, it has been reported that reduced coenzyme Q₁₀ is more effective than oxidized coenzyme Q₁₀ for various applications (Para. [0006]).

It is further stated in the specification of the patent in suit that, for example, the Japanese publication Kokai Hei-10-330251 describes an anti-hypercholesterolemic substance that has excellent cholesterol-reducing properties; an anti-hyperlipidemic substance; and a substance to treat and prevent arteriosclerosis, which contains reduced coenzyme Q₁₀ as an active ingredient. In addition [the text states], Japanese publication Kokai Hei-10-109933 discloses a pharmaceutical compound with excellent oral absorption properties, including coenzyme Q₁₀, which contains reduced coenzyme Q₁₀ as an active ingredient (Para. [0007]).

Furthermore [according to the specification of the patent in suit], reduced coenzyme Q is effective as an antioxidant and free-radical scavenger. [The specification states that] R. Stocker et al. reported that reduced coenzyme Q more efficiently suppresses peroxidation of human LDL than α -tocopherol, lycopene and 3-carotene (Proceedings of the National Academy of Science of the United States of America, Volume 88, pages 1646-1650, 1991). (Para. [0008]). [According to the text] it is also known that oxidized coenzyme Q₁₀ and reduced coenzyme Q₁₀ are present in living bodies in a certain proportion to one another and that in living bodies absorbed oxidized coenzyme Q₁₀/reduced coenzyme Q₁₀ are mutually reduced/oxidized (Para. [0009]). [The text states that] it is suspected that reduced coenzyme Q₁₀ is produced by way of a chemical synthesis process that is similar to the process by which oxidized coenzyme Q₁₀ is produced. [The text further states] however, that it is assumed that the synthesis process is complicated, risky and costly. [The text continues] that in the case of chemical synthesis processes, it is necessary to suppress the formation of and contamination with a (Z) isomer that is suspected of being unsafe (Biomedical and Clinical Aspects of Coenzyme Q, Volume 3, pages 19-30, 1981). [The text states] that the European Pharmacopoeia prescribes that the content of (Z) isomer in oxidized coenzyme Q must not be higher than 0.1% (Para. [0010]).

The specification of the patent in suit further states that it can be assumed that there is an additional method to produce reduced coenzyme Q₁₀ that uses microbial cells, i.e. a method to separate and extract reduced coenzyme Q₁₀ from microorganisms that produce coenzyme Q₁₀. [The text states that] the reduced coenzyme Q₁₀ produced by the aforementioned microbial cells, however, contains a large amount of oxidized coenzyme Q₁₀ and that traditional methods to separate and extract the reduced coenzyme Q₁₀ are very costly (Para. [0011]).

[The text states that] The following documents describe the presence of reduced coenzyme Q₁₀ in microbial cells and the following examples of bacteria are known:

- (1) An example that describes how at least 5 to 10 mass% up to a maximum of 30 to 60 mass% of reduced coenzyme Q₁₀ is present among the total amount of coenzyme Q₁₀ in cultured cells of photosynthetic bacteria (Japanese publication Kokai Sho-57-70837).
- (2) An example that describes how the *pseudomonas* species was subjected to thermal extraction using an organic solvent in the presence of sodium hydroxide and pyrogallol, and in which the product was treated with a 5% sodium hydrosulfite solution and was then dried and concentrated in order to produce an acetone-soluble component, and in which oil-containing reduced coenzyme Q₁₀ is produced (Japanese publication Sho-60-75294) (Para. [0012]).

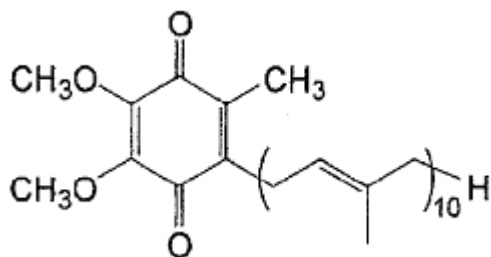
According to the specification of the patent in suit, both Example (1) and Example (2) aim at transforming a mixture of the reduced coenzyme Q₁₀ and oxidized coenzyme Q₁₀ that was produced or the reduced coenzyme Q that was produced, into oxidized coenzyme Q₁₀. However [the text states], reduced coenzyme Q₁₀ is described merely as a byproduct in the production of oxidized coenzyme Q (Para. [0013]). The specification of the patent in suit regards it as a disadvantage that in the above example (1) photosynthetic bacteria used that are difficult to cultivate. [It states further that] it is not clear whether the proportion of reduced coenzyme Q₁₀ to the total amount of coenzyme Q₁₀ in the microbial cells or the aforementioned microorganisms is sufficient if the goal is to produce reduced coenzyme Q₁₀ (Para. [0014]).

The specification of the patent in suit states with regard to Example (2), above, that it comprises a method to convert oxidized coenzyme Q₁₀ contained in a hexane phase into reduced coenzyme Q₁₀ using sodium hydrosulfite, a reducing agent. But in this case too [the text states], the proportion of reduced coenzyme Q₁₀ among the total amount of coenzyme Q₁₀ in the microbial cells is not clear (Para. [0015]). The specification of the patent in suit regards it as a disadvantage that the amount of coenzyme Q₁₀ produced in the culture is not described in either of the above Example (1) or Example (2) (Para. [0016]). [The text states that] to present, the prior art does not include reports about microbial cells that exhibit a high proportion of reduced coenzyme Q₁₀. [The text states that] the prior art contains even less reference to a fermentation method to produce reduced coenzyme Q on an industrial scale, i.e. a method that includes the cultivation of microorganisms in order to produce microbial cells that contain a high proportion of reduced coenzyme Q₁₀ compared to the total amount of coenzyme Q₁₀, and to the extraction of the reduced coenzyme Q₁₀ in order to produce highly purified reduced coenzyme Q₁₀ (Para. [0017]).

In light of this, the patent in suit sets its task (the technical problem) as being to supply a method that is safe and efficient at an industrial scale to produce coenzyme Q₁₀ by cultivating microorganisms that themselves produce reduced coenzyme Q₁₀, in order to produce microbial cells that contain a high proportion of reduced coenzyme Q₁₀, and to make them available for obtaining reduced coenzyme Q₁₀ from the microbial cells. Furthermore, it intends to provide a method to produce oxidized coenzyme Q₁₀ using a simple method by cultivating microorganisms that produce reduced coenzyme Q₁₀, in order to obtain microbial cells with a high proportion of reduced coenzyme Q₁₀, and to oxidize the reduced coenzyme Q₁₀ that was obtained from the microbial cells as a byproduct of producing oxidized coenzyme Q₁₀.

The second part of the task - production of oxidized coenzyme Q₁₀ - is supposed to be solved by Claim 31 of the patent in suit asserted by Plaintiff, whose features can be broken down as follows:

1. Method to produce oxidized coenzyme Q₁₀, represented by the following formula



where the method comprises the following steps:

2. The cultivation of microorganisms;
 - 2.1 the microorganisms produce reduced coenzyme Q₁₀;
 - 2.2 the microorganisms are cultivated in a culture medium that contains
 - 2.2.1 a carbon source
 - 2.2.2 a nitrogen source
 - 2.2.3 a phosphorus source

- 2.2.4 a micro-nutrient source;
- 2.3 the cultivation serves the purpose of producing microbial cells that contain reduced coenzyme Q₁₀ in a proportion of not less than 70 mol% among the total coenzyme Q₁₀;
- 3. if applicable, the microbial cells may be destroyed;
- 4. either
 - 4.1 oxidation of the reduced coenzyme Q₁₀ thus produced into oxidized coenzyme Q₁₀ using an oxidation agent and
 - 4.2 subsequent extraction of the product using an organic solvent
- 5. or
 - 5.1 extraction of the reduced coenzyme Q₁₀ thus produced using an organic solvent,
 - 5.2 if applicable, purification and
 - 5.3 oxidization of the product into oxidized coenzyme Q₁₀ using an oxidation agent.

II.

The method to produce oxidized coenzyme Q₁₀ protected by Claim 31 of the patent in suit essentially consists of four steps. In the first step, microorganisms that produce reduced coenzyme Q₁₀ are cultivated in a culture medium (Feature Group 2). The intent is to obtain microbial cells that contain reduced coenzyme Q₁₀ in a proportion of not less than 70 mol% among the total coenzyme Q₁₀ (i.e. including oxidized coenzyme Q₁₀) (Feature 2.3). The second step is optional and may provide for the destruction of the microbial cells thus obtained (Feature 3). The sequence of the third and fourth steps can be reversed. They provide for the oxidation of the reduced coenzyme Q₁₀ thus produced and the extraction of the product (Feature Group 4), or the extraction of the reduced coenzyme Q₁₀ and – potentially after purification – subsequent oxidation of the product into oxidized coenzyme Q₁₀ (Feature Group 5).

It is evident from the wording of the patent in suit that the extraction and oxidation are two separate, subsequent steps, Steps 3 and 4. In both cases, the “product” in Features 4.2 and 5.3 refers to the result of the preceding step, namely the oxidized and the extracted coenzyme Q₁₀, respectively. This is even more evident in Feature 4.2 in which the extraction is to take place

“subsequently”, i.e. after the oxidation. The description of the patent in suit also states that “either the extraction of the oxidized coenzyme Q₁₀ after oxidation of the (...) microbial cells or the destroyed product thereof, or the extraction of the reduced coenzyme Q₁₀ from the (...) microbial cells or the destroyed product thereof, in order to afterwards oxidize the reduced coenzyme Q₁₀ obtained” (Para. [0003]). According to the teaching of the patent in suit, the sequence of the oxidation and extraction steps is reversible. It is possible to first extract the reduced coenzyme Q₁₀ and then to oxidize it, and it is also permissible to first oxidize the reduced coenzyme Q₁₀ and then to extract it.

However, it is excluded that both steps should coincide. This is evident not only from the choice of terms such as “resulting” and “subsequent extraction”, but also from the use of the “either - or” combination for both steps. Consequently, either oxidation comes first and then extraction, or extraction first and then oxidation. The claim in the patent in suit does not allow any other possibility. Therefore, for claiming that the method according to the invention is used it is not sufficient that the coenzyme Q₁₀ is extracted (or cultivated) in ambient air and the oxidation of the coenzyme Q₁₀ occurs simultaneously with the extraction (or cultivation) solely due to the ambient air. The description of the patent in suit is also predicated on this.

The description of the patent in suit differentiates between intentional oxidation of the coenzyme Q₁₀ by addition of an oxidizing agent and a random oxidation reaction (cf. Para. [0111]). The patent in suit is fundamentally concerned with the method to produce reduced coenzyme Q₁₀. This requires that the reduced coenzyme Q₁₀ not be decomposed, and definitely not be oxidized (Para. [0₁₀5]). For example, the patent in suit cites “condition[s] that the reduced coenzyme Q₁₀ be protected from an oxidation reaction” (Para. [0₁₀7]), such as extraction in a deoxygenated atmosphere, a high salt concentration in the culture medium, the presence of a strong acid or presence of an antioxidant. To extract oxidized coenzyme Q₁₀, the specification of the patent in suit merely says that such conditions to protect against an oxidation reaction are not required. This means the reduced coenzyme Q₁₀ is not required to be extracted in a deoxygenated atmosphere, for example. However, the patent in suit differentiates between the absence of conditions preventing oxidation and the use of an oxidizing agent to produce the oxidized coenzyme Q₁₀, for example by mixing the reduced coenzyme Q₁₀ with manganese dioxide (Para. [0111]).

It is true that the aforementioned text passage (Para. [0111]) only mentions mixing the coenzyme Q₁₀ with an oxidizing agent - in this case, manganese dioxide - and oxidizing the

mixture for not less than 30 minutes only as an example (“can” and “e.g.”). Nevertheless, the mention of an example evidently refers only to the mixing process, the duration of mixing, and the specific use of manganese dioxide and not to the use of a separate oxidizing agent per se. This is evident because the oxidizing agent is described as “e.g. manganese dioxide or something comparable”. Therefore, the only oxidizing agents that can be considered are those that, like manganese dioxide, can be separately added to the reduced coenzyme Q₁₀. Ambient air, whose oxidizing effect is not prevented during cultivation or extraction, is not such a separately added oxidizing agent. This is also evident from the further description of the patent in suit where it states “moreover it is not necessary for the extraction of the oxidized coenzyme Q₁₀ to occur under ‘such a condition, that the reduced coenzyme Q₁₀ is protected from an oxidation reaction’, which is recommended for the extraction of reduced coenzyme Q₁₀” (Para. [0111]; emphasis added by the Division). To this extent, the patent in suit differentiates between adding an oxidizing agent, on one hand, and the mere absence of conditions that would prevent oxidation. The latter does not represent use of an oxidizing agent within the meaning of the teaching of the claim of the patent in suit.

III.

In light of this interpretation, the contested embodiment does not represent a product that was directly produced using the method protected by Claim 31 of the patent in suit. It is not evident that Defendants are using the patent-protected method to produce the contested embodiment. It is irrelevant whether the production method used by Defendant actually produces microbial cells that contain reduced coenzyme Q₁₀ in a proportion of not less than 70 mol% of the total coenzyme Q₁₀ (Feature 2.3). At any rate, it cannot be ascertained that reduced or extracted coenzyme Q₁₀ is oxidized using an oxidizing agent and this constitutes a separate step in the method that is distinct from the extraction process.

The method used by Defendant is unknown to Plaintiff. It is clear that its assertion that Defendants were using an oxidizing agent consistent with the teaching of the claim of the patent in suit – other than air – has no basis and rests solely on the assumption that an oxidizing agent must be used to achieve the desired purity in any production of oxidized coenzyme Q₁₀ on an industrial scale. Defendants have denied adding an oxidizing agent. [According to them] the oxidation occurs instead solely by way of ambient air. In the oral proceedings, they further stated that the microorganisms are cultivated on an industrial scale in fermenters, where the

nutrient solution with the microorganisms is stirred continuously in the presence of ambient air. There is therefore no realization of Feature 4.1 and Feature 5.3.

This reasoning also serves to deny any realization of Feature Groups 4 and 5 with regard to a two-step method – extraction and oxidation. It is not evident that Defendants perform oxidation as a separate step from extraction. According to Defendants' supplementary statements on the production process in the oral proceedings, it cannot even be assumed that oxidation occurs separately from cultivation of the microorganisms.

IV.

The decision on costs is based on Sect. 91, 269 Para. 3 sentence 2 ZPO.

The decision on provisional enforceability derives from Sect. 709 sentences 1 and 2 ZPO.

Disputed value: EUR 1,000,000.00; EUR 200,000 is the portion of the amount determined to be owing as joint and several liability.

Dr. Cummenerl

Dr. Voß

Thomas

Chief Justice at

Justice at the

Justice at the

the Regional Court

Regional Court

Regional Court