Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2021-01-26
Docket Number / Aktenzeichen:	X ZR 24/19
Name of Decision / Name der Entscheidung:	Phytase

Arbeitskreis
Patentgerichtswesen
in Deutschland e.V.

FEDERAL COURT OF JUSTICE

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZR 24/19

Pronounced on:
26 January 2021
Anderer
Judicial Secretary as
Clerk of the court
registry

in the patent nullity proceedings

Phytase

Patent Act Sec. 81

An action for nullity is admissible despite the lapse of the patent in suit if the patent proprietor, after an unsuccessful court request to conduct inspection proceedings, declares upon request of the nullity plaintiff that he is still willing to defend all IP rights relating to the products concerned.

Federal Court of Justice, judgment of 26 January 2021 - X ZR 24/19 –
Federal Patent Court

ECLI:DE:BGH:2021:260121UXZR24.19.0

The X. Civil Senate of the Federal Court of Justice, following the oral hearing on 26 January 2021, attended by the presiding judge Dr. Bacher, the judge Dr. Deichfuß, the judges Dr. Kober-Dehm and Dr. Rombach as well as the judge Dr. Rensen

ruled that:

On appeal by the defendant, the judgment of the 3rd Senate (Nullity Senate) of the Federal Patent Court of 20 November 2018 is amended.

The European patent is declared partially null and void by deleting the wording "or 5 to 5.5" in patent claim 13.

In all other respects, the plaintiff is dismissed.

The plaintiff shall bear the costs of the legal dispute.

By operation of law

Facts of the case:

1 The defendant is the proprietor of European patent 1 090 129 (patent in suit), which was filed on 23 June 1999, claiming a U.S. priority of 25 June 1998, and which was granted with effect for the Federal Republic of Germany. The patent in suit relates to the overexpression of phytase in yeast systems. The patent in suit comprises 32 claims. Claims 1, 13, 18, 24 and 30 were amended in opposition proceedings as follows:

> 1. A method of producing phytase in yeast comprising: providing an appA gene isolated from bacterial cells, which appA gene encodes a protein or polypeptide with phytase activity, expressing said appA gene in a yeast strain, and isolating the expressed protein or polypeptide.
>
> 13. The protein or polypeptide obtainable by a method according to claim 1 having phytase activity with optimum activity in a temperature range of 57 - 65°C and at a pH of 2.5 to 3.5 or 5 to 5.5.
>
> 18. A yeast strain comprising: an appA gene isolated from bacterial cells, which appA gene encodes a protein or polypeptide with phytase activity and which is functionally linked to a promoter capable of expressing phytase in yeast, wherein said protein or polypeptide has increased thermostability when expressed in a yeast host cell as compared to that of said protein or polypeptide expressed in a non-yeast host cell.
>
> 24. A vector comprising: an appA gene isolated from bacterial cells, which gene encodes a protein or polypeptide with phytase activity; a promoter functionally linked to the appA gene, said promoter capable of initiating transcription in yeast; and an origin of replication capable of maintaining the vector in yeast, wherein said protein or polypeptide has increased thermostability when expressed in a yeast host

cell as compared to that of said protein or polypeptide expressed in a non-yeast host cell.

30. A method of converting phytate to inositol and inorganic phosphorus comprising: providing an appA gene isolated from bacterial cells; expressing a protein or polypeptide with phytase activity from said gene in a yeast host cell; and contacting the protein or polypeptide with phytate to catalyze the conversion of phytate to inositol and inorganic phosphorus.

2 The plaintiff challenged the patent in suit in its entirety, claiming lack of executability, inadmissible extension, and lack of patentability. The defendant defended the patent in suit primarily in a version in which the passage "or 5 to 5.5" was omitted from claim 13, and alternatively in sixteen further amended versions.

3 The Patent Court declared the patent in suit null and void. This is opposed by the defendant's appeal, which defends the patent in suit with its first-instance claims and three further auxiliary claims. The plaintiff opposes the appeal.

Grounds of the decision:

4 The appeal is not only admissible and otherwise admissible, but also well-founded. It leads to the amendment of the contested decision and dismissal of the action insofar as the defendant defends the patent in suit.

5 I. However, the action is still admissible despite the lapse of the patent in suit.

6 The plaintiff has a sufficient interest in legal protection, because it has reason to fear a legal claim due to acts during the term of the patent.

7 According to the established case law of the Senate, the interest in legal protection required for an action for nullity may arise from the fact that the plaintiff has reason to fear that he may be exposed to claims for past acts despite the expiry of the term of protection. In such cases, an interest in legal protection is only to be denied if a claim is seriously out of the question (Federal Court of Justice, order of 13 July 2020 - X ZR 90/18, GRUR 2020, 1074 marginal no. 28 - Signalübertragungssystem; judgment of 22 September 2020 - X ZR 172/18, GRUR 2021, 42 marginal no. 7 - Truvada).

8 Accordingly, the plaintiff's interest in legal protection in the dispute must be affirmed.

9 It can be left open whether the request for inspection proceedings filed by the licensee, which was unsuccessful for formal reasons, already gives rise to a sufficient concern of a judicial claim arising from the patent in suit. Such an apprehension results at any rate from the fact that the defendant, after conclusion of the said proceedings and expiry of the patent in suit, stated in response to an inquiry by the plaintiff that it was still willing to defend all IP rights relating to phytase products.

10 II. The patent in suit relates to the production of phytase in yeast.

11 1. According to the patent in suit, cereals for food and feed contain the element phosphate, which is necessary for nutrition, not freely but bound in phytic acid, which occurs naturally as an anion and in this form is called phytate. Certain enzymes called phytases break down phytate into inositol and

phosphate.

12 Phytases are found in a number of plants as well as in bacteria that live symbiotically with ruminants. Ruminants can therefore utilize phytate contained in the diet better than other animals. Animals with simple stomachs (monogastrics), especially pigs and poultry, do not have appropriate bacteria. They can therefore utilize the phosphate bound in phytate only to a lesser extent. Accordingly, feed for monogastrics is supplemented with inorganic phosphate. This leads to increased resource consumption and environmental problems because of the higher phytate content in the excreta. In addition, deficiency symptoms can occur because phytate binds certain trace elements contained in the feed (for example zinc), so that the body can no longer utilize them (para. 2).

13 According to the patent in suit, various methods for cloning and sequencing phytases were known at the time of priority. Different genes and organisms had been used for this purpose, including fungi such as Aspergillus niger, Aspergillus terreus, and Myceliophthora thermophila, as well as maize (para. 3), and also bacteria such as Enterobacter column 4, Klebsiella terrigena, and Bacillus column DS11 (para. 4).

14 The introduction of the phyA gene into Aspergillus niger had increased phytase activity tenfold compared to the naturally occurring form. However, an obstacle to its use in industrial animal husbandry is that the phytase produced in this way is expensive, available only in small quantities, and unstable when heated. In addition, phytase from Aspergillus niger is probably not suitable for the production of food for humans (para. 5).

15 2. Against this background, the patent in suit concerns the technical problem of providing a phytase that is as simple and inexpensive to produce as possible and suitable for use in industrial food and feed production (para. 8).

16 3. To solve this, claim 1 provides a process with the following features:

1.1	A method of producing phytase in yeast comprising:	Ein Verfahren zur Erzeugung einer Phytase in Hefe, umfassend:
1.2	providing an appA gene isolated from bacterial cells,	das Bereitstellen eines aus bakteriellen Zellen isolierten appA-Gens,
1.3	which appA gene encodes a protein or polypeptide with phytase activity,	das ein Protein oder ein Polypeptid mit Phytase-Aktivität kodiert,
1.4	expressing said appA gene in a yeast strain,	die Expression dieses appA-Gens in einem Hefestamm
1.5	and isolating the expressed protein or polypeptide.	und die Isolierung des exprimierten Proteins oder Polypeptids.

17 Claim 13 protects a protein or polypeptide to be produced, claims 18 and 24 protect a yeast strain or vector suitable for the process, and claim 30 protects a process for the conversion of phytate into inositol and phosphorus.

18 4. The Patent Court correctly regarded the skilled person as a scientifically active biologist or biochemist who has experience in the recombinant expression of enzymes.

19 5. Several features require further consideration.

20 a) Characteristic 1.1 specifies the phytase produced by the method only to the extent that it is produced in yeast.

21 This does not result in a specification of certain properties of the phytase nor a specification of a certain yeast.

22 b) The gene used for the production of phytase is specified in features 1.2 and 1.3 to the effect that it is an appA gene isolated from bacterial cells which encodes a protein or polypeptide with phytase activity.

23 aa) This does not specify a particular bacterium.

24 As a gene known in the state of the art with these properties and as a preferred embodiment, the appA gene of the bacterium Escherichia coli (E.coli)

is named in the description of the patent in suit, the structure of which is publicly deposited under accession number M58708 (paragraph 21).

25 From the explicit designation as an example and from the fact that patent claim 1 does not designate a specific bacterium, it follows that patent claim 1 also protects the use of appA genes of other bacteria.

26 In this context, it is irrelevant whether the patent specification or other sources available on the priority date indicate how other appA genes can be obtained. The formulations mentioned indicate that the patent claims such genes in principle irrespective of this question.

27 bb) Contrary to the opinion of the Patent Court, the designation as appA gene implies that the gene according to the invention must, in addition to the coding of a protein or polypeptide with phytase activity provided for in feature 1.3, have certain further properties which characterize the appA gene from E.coli.

28 (1) The patent in suit does not use the term "appA gene" as a synonym for any gene from E.coli or other bacteria encoding a protein or polypeptide with phytase activity.

29 It is already clear from the description of the state of the art that there may be different genes within the same organism that exhibit the latter property. Also for E.coli, referring to the publication by Greiner et al. (Purification and Characterization of Two Phytases from E.coli, Arch. of Biochemistry and Biophysics 303 (1993), 107-113, D8), two different phytases (P1, P2) are reported. Only one of them (P2) is associated with the phytase produced by the appA gene.

30 (2) Against this background, it cannot be assumed for other bacteria either that every gene producing a phytase is to be regarded as an appA gene within the meaning of the patent in suit. Rather, subsumption under this feature presupposes that, in addition to the coding of a protein or polypeptide with phytase activity, further properties are present that are characteristic of the appA gene from E.coli.

31 (3) In any case, these properties include activity as an acid histidine phosphatase and the presence in the active site of a motif designated RHGXRXP or RHG.

32 These two properties are described in the state of the art as specific properties of the appA gene from E. coli, as the parties essentially agree and as the Patent Court did not fail to recognize in its approach. The property as acid phosphoanhydride phosphohydrolase was even decisive for the naming in a publication by E. Dassa and Boquet from 1985 (Identification of the gene appA for the acid phosphatase (pH optimum 2.5) of E.coli, Molecular and General Genetics 200 (1985), 68, G12). From further publications it appears that the appA gene from E.coli contains the RHG motif (J. Dassa et al., The Complete Nucleotide Sequence of the E.coli Gene appA Reveals Significant Homology between pH 2.5 Acid Phosphatase and Glucose-1-Phosphatase, Journal of Bacteriology 172 (1990), 5497, 5498 Fig. 2, D3) and that this motif is characteristic of acid phosphatases (Ostanin et al., Overexpression, Site-directed Mutagenesis, and Mechanism of E.coli Acid Phosphatase, The Journal of Biological Chemistry 267 (1992), 22830, D12).

33 The patent in suit explicitly refers to the latter two publications in connection with the appA gene from E. coli (paragraph 21). It can be inferred from this that a gene is to be regarded as an appA gene within the meaning of the patent in suit which exhibits the properties mentioned therein - not only with regard to phytase activity, but at least also with regard to the characteristics cited in connection therewith, i.e. in any case concerning activity in the acidic range and the presence of an RHG group.

34 Contrary to the opinion of the Patent Court, the fact that no clear findings were available from the publications available in the state of the art as to whether genes from other bacteria exhibit the said characteristics does not lead to a different assessment. This circumstance could at most be of significance if subsumption under the term "appA gene" were already possible on the basis of other criteria and further research had led to the realization that not every gene defined in this way exhibits the above-mentioned characteristics. However, as the Patent Court correctly stated in its approach, the state of the art does not indicate that "appA" was an established generic term in the art. For this very

reason, the meaning attributed to this term by the patent in suit must be decisive for the interpretation. Also from this point of view, it can be inferred from the fact that the patent in suit refers to D3 and D12 in this respect that the features described therein as characteristic for the appA gene from E. coli are decisive for the subsumption under the term "appA gene".

35 (4) Whether there must be further structural similarities, as the plaintiff claims, is not relevant for the decision of the dispute and can therefore be left open.

36 III. The Patent Court substantiated its decision essentially as follows:

37 It could remain open whether the invention was disclosed in such a way that a skilled person could carry it out, as well as whether the subject matter of the patent went beyond the content of the originally filed documents and was new. In any case, based on the publication by Greiner et al. (D8), it was not based on inventive step.

38 The phytase described as P2 in D8, which was active at a pH of 4.5, was similar to the phosphatase described in a 1982 publication by E. Dassa et al. (The Acid Phosphatase with Optimum pH of 2.5 of E.coli, The Journal of Biological Chemistry 257 (1982), 6669-6676, D4), the optimum of which was at a pH of 2.5. In D8, the conclusion is drawn from this that it is the same phosphatase which is better classified as phytase. In view of this, it appears to the skilled person that an activity of this phytase is possible not only in a moderately acidic environment (pH 4.5), but also in an environment with a significantly lower pH. This, in turn, would make use in the acidic gastric milieu seem possible. In view of the reputation of the research institution from which D8 originated, the skilled person had had no reason to reject the findings published there as not credible without further ado. On the contrary, the skilled person had had reason to further investigate phytase P2.

39 The publication by J. Dassa et al. from 1990 (D3) showed that the appA gene from E. coli encoded the phosphatase described in D4. Since it was also known that phytases occur in almost all organisms and thus also in various bacterial species, it was obvious to the skilled person that not only E. coli but

also other bacteria contained a phytase-encoding appA gene. This was also evident from the publication of Sun (Cloning and Expression of Calpain and Phytase Genes for the Improvement of Animal Growth and Nutrition, Diss. Purdue University, December 1996, D17).

40 The teaching to use yeasts for the expression of the bacterial appA phytases could also not establish an inventive step. The skilled person had to make a selection from a large number of possibilities when determining the host cells. However, this selection does not go beyond general knowledge and skill. For example, it is clear from D8 and from a publication by Wodzinski and Ullah (Phytase, Advances in Ap-plied Microbiology 42 (1996), 263-302, D8a) that, for phytases used in feed, it is not only a matter of activity at the lowest possible pH values, but also of thermostability. It has long been known to the skilled person that glycosylation can make a decisive contribution to thermal stability. This is apparent, for example, from the publication by Vegarud and Christensen (Glycosylation of Proteins: A New Method of Enzyme Stabilization, Biotechnology and Bioengineering XVII (1975), 1391-1397, D14). It is also common knowledge that glycosylation does not occur in bacterial expression systems. The skilled person therefore concentrates on eukaryotic systems from the outset. Publications such as those by Curry et al. (Expression and Secretion of a Cellulomonas fimi Exoglucanase in Saccharomyces cerevisiae, Applied And Environmental Microbiology 54 (1988), 476-484, D15) and Olsen and Thomsen (Improvement of bacterial ß-glucanase thermostability by glycosylation, Journal of General Microbiology 137 (1991), 579-585, D16) focused attention on the use of yeast cells. Such an approach using the promising phytase P2 and known expression systems had been much closer for reasons of cost and time than a completely open-ended search for new, suitable phytase mutants.

41 The decision of the Opposition Division of the European Patent Office with regard to European patent 1 688 500, which arose from the same application as the patent in suit, concerned the use of bacterial appA and not a recombinant process for the production of bacterial appA phytases. In addition, a different problem definition had been taken as a basis there.

42 IV. These considerations do not stand up to scrutiny in the appeal

proceedings.

43 The Patent Court wrongly considered the subject matter of claim 1 to be obvious on the basis of D8. 1.

44 It is correct that the skilled person had reason to take note of and evaluate D8 in his search for new phytases suitable for the industrial production of feedstuffs in particular.

45 Thus, D8 highlights phytases as important enzymes for the feed industry and, against this background, certifies that the enzyme designated as P2 has excellent phytase activity under certain conditions (Table III). Also, the pH optimum of 4.5 mentioned in D8 with respect to phytase activity is within a range that had also been disclosed for other enzymes of importance in this context, for example in European patent application 699 762 (D9: 3.5 to 4.5) or international application 97/48812 (D11: 4.0 to 5.5). Furthermore, the temperature of 55°C given as optimum in D8 corresponds to the values given in D7 (55°C) and D11 (37 to 55°C). Moreover, the thermal optimum stated in D8 is not too far below the value of BASF's phytase already available on the market at the priority time (60°C).

46 2. Furthermore, the skilled person would have come to the conclusion, even without inventive step, that the phytase from E. coli discussed in D8 is encoded by the appA gene.

47 It can be left open whether the phytase designated as P2 is identical to the enzyme designated as "pH 2.5 acid phosphatase" in D4, as the authors of D8 considered likely. Nor does the Senate need to decide whether the skilled person would have arrived at the sequence of the coding gene disclosed in D3 on the basis of D4/D8. In any case, as confirmed by studies published after the priority date, he would have reached the appA gene of E.coli by further experiments with P2.

48 4. Finally, the Patent Court correctly assumed that the expression of bacterial genes in yeast was a procedure familiar to the skilled person.

49 As also the defendant does not doubt, D7 (p. 9: Pichia, Saccharomyces)

and D11 (inter alia p. 28: Pichia Pastoris) cite yeasts as a suitable host for the expression of bacterial genes encoding phytase, in addition to other fungi, plant substances such as soybeans, maize, rapeseed, cabbage and nightshade plants as well as substrates from poultry, pigs or fish.

50 Contrary to the opinion of the Patent Court, however, these circumstances did not give the skilled person sufficient reason to consider an expression of bacterial appA genes in yeast as primarily or particularly promising from the multitude of possible combinations (cf. only D8a p. 273-275 Tables II to V on possible phytases and corresponding microorganisms as well as D7 p. 9 para. 3 and 4 on host cells). In view of the large number of possibilities that could be considered, the uncertain prospects of success and the effort required for a comprehensive series of experiments, there was no sufficient expectation of success in this respect.

51 a) According to the case law of the Senate, the requirements for an adequate expectation of success, which gives the skilled person reason to pursue a possible solution despite the uncertain predictability of the results, cannot be formulated in a generally valid manner. They must be determined on a case-by-case basis, taking into account the field of expertise at issue, the size of the incentive for the skilled person, the effort required to take and pursue a particular approach and the alternatives that may be considered, as well as their respective advantages and disadvantages (Federal Court of Justice, judgment of 7 July 2020 - X ZR 150/18, GRUR 2020, 1178 marginal no. 108 - Pemetrexed II; judgment of 16 April 2019 - X ZR 59/17, GRUR 2019, 1032 marginal no. 31 - Fulvestrant).

52 b) In the case in dispute, given the high importance of using a phytase that is as active, acid-resistant and thermostable as possible for the industrial production of feed, there was indeed a high economic incentive to find an alternative to products already available on the market. In addition, there may be aspects of environmental protection as well as human and animal health. As the Patent Court correctly pointed out, it was also more suitable for the skilled person to investigate substances already identified as phytases instead of searching for new phytases, because the latter tended to involve even greater effort and uncertainty.

53 c) Regardless of this, the chances of success with regard to an expression of the phytase P2 known from D8 in yeast were not sufficiently high.

54 aa) As the plaintiff made clear at the oral hearing, the results disclosed in D8 (Tab. III) gave a certain incentive to consider phytase P2 because, with a value of 6209, it had an extremely high turnover (Tab. III) and thus exceeded the values of other phytases examined, as can be seen from D8a (Tab. V), by at least a factor of 2 and in some cases even by more than a factor of 20.

55 bb) Irrespective of this, the values disclosed in D8 for thermostability made a suitability of phytase P2 for the production of feedstuffs appear unlikely.

56 The skilled person knew on the priority date, for example, from D9 that feedstuffs in industrial production are formed at temperatures between 75°C and 85°C (D9 p. 2 lines 36 f.). This gave him reason to attach great weight to thermostability in the search for suitable candidates.

57 In this context, the skilled person could see from D8 that the activity of phytase P2 decreases sharply from 60°C and is no longer detectable from 70°C (p. 110 right para. 1). Even if he had carried out further tests regardless of this, he would have come to the conclusion, as can be seen from the values documented in the patent in suit (para. 85 Tab. 9), that the activity drops to 0.1 of the initial value after 15 minutes of exposure to a temperature of 80°C, while other phytases still showed a residual activity of 50 to 69 percent of the initial value.

58 In view of this, the skilled person had to expect that, despite the high initial value documented in D8, no significant activity would remain at the temperatures required for the feed industry.

59 cc) Against this background, the prospect of improving thermostability by glycosylation did not justify a sufficient expectation of success.

60 (1) However, as the Patent Court correctly pointed out, there was evidence from various publications that the thermostability of enzymes can be increased by glycosylation, especially when expressed in yeast.

61 In particular, relevant publications include those by Romanos (Advances

in the use of Pichia pastoris for high-level gene expression, Current Opinion in Biotechnology 1995, 527-533, D13), Vegarud and Christensen (Glycosylation of Proteins: A New Method of Enzyme Stabilization, Biotechnology and Bioengineering XVII (1975), 1391-1397, D14), Curry et al. (Expression and Secretion of a Cellulomonas fimi Exoglucanase in Saccharomyces cerevisiae, Applied and Environmental Microbiology 1988, 476-484, D15), and Olsen and Thomsen (Improvement of bacterial ß-glucanase thermostability by glycosylation, Journal of General Microbiology 137 (1991), 579-585, D16).

62 (2) However, all these citations point out that the effects of glycosylation are not readily foreseeable and that glycosylation may lead to a reduction in enzymatic activity.

63 In D13, a decrease or even a complete collapse of activity is mentioned as a possible risk (p. 527, bottom right). In D14 it is reported that the specific activity has decreased due to glycosylation (p. 1396 bottom). In D15 it is stated that it remains to be clarified whether a sufficient yield can be achieved (p. 483 top right). In D16, a decrease from 1180 to 450 and from 3690 to 1940 units per milligram, respectively, is indicated for the two enzymes studied there (p. 583 middle left).

64 In addition, D16 indicates that the position and type of glycosylation is more important for thermostability than the amount of glycan added (p. 584 bottom left).

65 (3) Despite these risks, there may have been some incentive for the skilled person to conduct experiments to improve thermostability by glycosylation. However, a reasonable expectation of success existed only with respect to those phytases that already inherently achieved certain minimum values, thus justifying the prospect that glycosylation could achieve a level of thermostability sufficient for industrial use.

66 This prospect was not present in the case of phytase P2 due to the low level of residual activity remaining at a temperature of 80°C after 15 minutes. Even if glycosylation had led to a multiplication of the residual activity, there was little likelihood that a result suitable for industrial use would be obtained because

of the low initial value. In view of this, the skilled person had no reason to follow this route.

67 V. The contested decision does not prove to be correct in its result for another reason (Sec. 119(1) Patent Act).

68 1. The subject matter of the patent in suit is new.

69 a) Contrary to the opinion of the appellant's rejoinder, the subject matter of claim 13 is also not anticipated by the international patent application 99/08539 (D1), which has priority earlier but was published only after the priority date.

70 aa) D1 concerns the provision of an enzyme for the utilization of phosphate bound in phytate by monogastric animals such as pigs and poultry.

71 For the production of phytase, a nucleic acid sequence isolated from E. coli is used (p. 7 line 5 f.). Its structure is shown in Figure 1 under the designation SEQ ID NO:1, and the structure of the amino acid sequence encoded with it is shown in Figure 2 under the designation SEQ ID NO:2 (p. 7 lines 19-27).

72 As suitable methods for the production of the phytase, basically all common methods are designated in D1 (p. 12 lines 4-8). In one preferred embodiment described in more detail in the (only) embodiment example, the expression takes place in E. coli (p. 15 line 2). In addition, it is stated that recombinant techniques could also be used (p. 21 line 13 f.). Suitable host cells could be bacterial cells such as E.coli, Streptomyces, Bacillus subtilis, fungal cells such as yeast, insect cells such as Drosophila S2 and Spodoptera Sf9, animal cells such as CHO, COS or Bowes melanoma, adenoviruses, plant cells and others. The selection of a suitable host would be within the scope of action of the skilled person and the teachings known in the state of the art (p. 22 lines 16-20).

73 bb) Thus, the features of patent claim 1 are not directly and unambiguously disclosed.

74 It can be assumed in favor of the plaintiff that the gene disclosed in D1 is the appA gene from E.coli. Even on the basis of this premise, it was not clearly

and directly apparent to the skilled person that expression of this gene in yeast would lead to the result sought in D1.

75 Yeast is indeed named as a suitable host, along with many other substances. However, it follows from the reference that the host is selected on the basis of the teachings known in the state of the art that not every substance mentioned can be used without further ado with success, but that additional expertise is required. A finding that only arises with the use of expert knowledge is not sufficient for a clear and direct disclosure (Federal Court of Justice, judgment of 8 July 2010 - Xa ZR 124/07, GRUR 2010, 910 marginal no. 62 - Fälschungssicheres Dokument; judgment of 20 October 2020 - X ZR 158/18 marginal no. 29 - Zigarettenpackung).

76 cc) Contrary to the opinion of the plaintiff, there is also no anticipation of the subject matter of patent claim 13.

77 It can be assumed in favor of the plaintiff that the amino acid sequence disclosed in D1 is also obtainable by a process as protected by patent claim 1. Even under this premise, there is no clear and direct disclosure of feature group 13.2.

78 According to the statements in the patent in suit, the temperature and pH values provided therein are a consequence of expression in yeast. Such an expression is not clearly and directly disclosed in D1 for the reasons already stated. Irrespective of this, it cannot be assumed without further ado that the values specified in feature group 13.2 can be achieved by any process protected by patent claim 1.

79 b) Contrary to the assessment expressed by the Patent Court in its reference issued under Sec. 83(1) Patent Act, the subject matter of the patent in suit is not fully disclosed in D11.

80 It is true that D11 discloses, inter alia, the production of phytase by expression in yeast cells (Pichia pastoris) of a gene derived from the bacterium Selenomonas ruminantium. However, this gene, designated JY35 in D11, is of the phyA type and does not exhibit the characteristics of the appA gene shown above.

81 c) The same applies with respect to D7.

82 D7 discloses the production of phytase by expression of a gene derived from a microbial source, preferably from a bacterium of the genus Bacillus, in a prokaryotic or eukaryotic host, yeasts of the genera Pichia and Saccharomyces also being cited as examples of the latter (p. 9(4)).

83 However, the gene used is referred to as the phyC gene. That it has the minimum required structural similarities with the appA gene is neither claimed nor otherwise evident. Finally, the pH value of 7.5 given in D7 also speaks against the assumption that it is an acid phosphatase.

84 2. As the Patent Court correctly pointed out in its reference under Sec. 83(1) Patent Act, the subject matter of the patent in suit does not go beyond the content of the originally filed documents.

85 a) In the originally filed documents, the contents of which are published in document WO 99/67398 A3 (K8), claim 1 is directed to the production of phytase by expression of a heterologous gene in yeast. Claims 15 and 16 are directed to such a process using a gene from bacterial cells and the appA gene from E.coli, respectively.

86 In the description it is additionally stated that the invention provides a process for the production of phytase using an isolated appA gene. The appA gene from E.coli is cited as preferred (p. 14 lines 21-24).

87 b) It is sufficiently clear from the context of these statements that protection is also claimed for the use of an appA gene of any bacterial origin within the meaning of feature 1.2.

88 c) Contrary to the plaintiff's view, the combination with feature 1.4 is also open to origin.

89 It is true that the description names a large number of organisms as possible hosts. However, as already explained, claims 15 and 16 are directed to protection for the expression in yeast of the genes mentioned there. From the supplementary statements in the description, according to which the appA gene from E.coli represents only one preferred embodiment of an appA gene, it is

sufficiently clear that corresponding protection is also claimed for the expression of other bacterial appA genes in yeast. 3.

90 3. As the Patent Court also correctly pointed out in its reference, the invention is disclosed in such a way that a skilled person can carry it out.

91 a) Contrary to the plaintiff's view, sufficient disclosure is not lacking because an enzyme with phytase activity can be obtained by expression in yeast only by using suitable signal peptides.

92 As the Patent Court correctly pointed out, the patent specification expressly refers to this fact (paragraph 35). It also refers to publications in which suitable signal peptides are named (paragraph 36). It thus enables the skilled person to carry out the claimed method.

93 b) Contrary to the opinion of the plaintiff, an executable disclosure of the subject matter of patent claim 4 is not lacking because the connection of the appA gene with a transcription enhancement element provided therein is not possible in bacterial genes.

94 According to the defendant's uncontradicted argument, such a connection is also possible with bacterial genes if sequences of the eukaryotic host organism are also processed. Against this background, patent claim 4, notwithstanding its potentially misleading wording, is to be understood as referring (only) to this embodiment, but not to a connection with sequences of the bacterial gene, which is also not possible according to the defendant's argument.

95 c) The Patent Court also correctly affirmed an executable disclosure with regard to the subject matter of patent claim 13.

96 aa) According to the statements of the Patent Court, the skilled person was able on the priority date to determine by measurement whether the claimed temperature and pH values were observed. The fact that, according to the plaintiff's argument, there was no standard method for this is irrelevant in view of this.

97 bb) The objection that a pH optimum between 5.0 and 5.5 was

disclosed as executable only for phyA genes was taken into account by the defendant by deleting this variant.

98 d) Contrary to the plaintiff's view, an executable disclosure is not lacking with respect to the subject matter of claims 18 and 24 because individual examples are presented in the patent in suit that do not lead to success.

99 An executable disclosure does not require that every combination theoretically subsumable under the patent claim leads to the desired success. In principle, it is rather sufficient if a feasible way is shown for each claimed embodiment. The patent in suit meets this requirement.

100 e) Finally, the Patent Court was right to consider the subject matter of claim 30 as being disclosed as executable, because the term "inorganic phosphorus" provided therein is not to be understood in the sense of inorganic phosphorus as an element, but in the sense of readily usable phosphate.

101 VI. The legal dispute is ripe for decision (Sec. 119(5) sentence 2 Patent Act).

102 For the reasons stated above, the patent in suit proves to be legally valid in the version defended by the main request.

103 VII. The decision on costs is based on Sec. 121(2) Patent Act and Sec. 92(2) No. 1 Code of Civil Procedure.

Bacher Deichfuß Kober-Dehm

Rombach Rensen

Previous instance:
Federal Patent Court, judgment of 20 November 2018 – 3 Ni 45/16 (EP) –