FEDERAL SUPREME COURT

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZR 22/20

Pronounced on:
February 8, 2022
Schönthal
Judicial Employee
as Clerk of the
Court Registry

in the patent invalidity case

ECLI:DE:BGH:2022:080222UXZR22.20.0

In response to the oral proceedings of February 8, 2022 the X. Civil Senate of the Federal Supreme Court by the judges Dr. Grabinski, Hoffmann and Dr. Deichfuß, the judge Dr. Marx and the judge Dr. Crummenerl

has ruled:

The appeal against the judgment of the 4th Senate (Nullity Senate) of the Federal Patent Court of December 3, 2019, is dismissed at the defendant's expense.

By law

Facts of the Case:

1 The defendant is the owner of European Patent 2 293 078 (patent in suit), which was granted with effect for the Federal Republic of Germany and was filed as a divisional application on August 1, 2008, claiming the priorities of August 3, 2007, and March 12, 2008. The patent in suit relates to a method for diagnosis of bacterial infections.

2 Claim 1, to which a further claim is referred back, reads in the language of the proceeding as follows:

> "An *in vitro* method for diagnosis of the presence of a bacterial infection in a patient, the method comprising: determining the level of procalcitonin or fragments thereof of at least 12 amino acids in length, in a sample obtained from said patient wherein said sample is selected from the group comprising a blood sample, a serum sample, a plasma sample or an extract of any of the aforementioned samples (i) at least once before the start of an antibiotic treatment or within six hours after the start of the treatment, and (ii) at least once from 12 hours to 1 week after the start of an antibiotic treatment of the patient; and correlating said level of procalcitonin or fragments thereof to the presence of a bacterial infection, wherein a decrease of said level of at least 20% per 24 h is indicative for the presence of a bacterial infection in the patient and wherein the threshold level of procalcitonin or fragments thereof of at least 12 amino acids in length, in blood, serum or plasma samples of said patient is below 0.25 ng/mL."

3 The plaintiffs claim that the teaching of the patent in suit is not disclosed so clearly and completely that a skilled person could carry it out, that the subject matter of the patent in suit goes beyond the content of the original application and that it is not patentable. The defendant defended the property right as granted and, in the alternative, in an amended version.

4 The patent court declared the patent in suit to be invalid. The defendant's appeal is directed against this, in which it continues to pursue its first-instance claims and additionally defends the patent in suit with a second auxiliary claim. The plaintiffs oppose the appeal.

Reasons for Decision:

5 The admissible appeal is unsuccessful.

6 I. The patent in suit concerns a method for diagnosis of a bacterial infection with the administration of antibiotics.

7 1. According to the patent in suit, procalcitonin (PCT) is known in the prior art as a proven biomarker for the diagnosis of sepsis.

8 In addition, the role of PCT is increasingly being discussed in patients suffering from infection-based diseases other than sepsis, such as pneumonia, bacterial meningitis, or malaria.

9 In this respect, PCT had also been used to guide antibiotic therapy. Patients with symptoms of lower respiratory tract infection in an emergency department had been treated with antibiotics only if the PCT concentration had been measured above 0.25 ng/mL or above 0.5 ng/mL. Apparently, this regimen resulted in a clinical outcome that was indistinguishable from the control group, which included patients with PCT concentrations less than 0.25 ng/mL. Patients with relevant comorbidities such as heart failure had been excluded from the study. It was unclear whether such an underlying disease burdened the interpretation of PCT concentrations, because this could allow a biomarker such as PCT to indicate

infection, even if the concentration was lower than a value that would be expected in the absence of such an underlying disease.

10 2. Contrary to the statements of the patent court, the problem underlying the teaching of the patent in suit does not lie in providing the physician with a useful diagnostic regime with which the indicator of a bacterial infection expressed by a drop in the PCT value forms the essential instrument by means of a progress monitoring accompanied by PCT measurements. This is because it does not sufficiently take into account that elements belonging to the technical solution are not already to be taken into account in the determination of the problem underlying the invention. Rather, the technical problem is to be formulated in such a general and neutral manner that the question of which suggestions the skilled person received from the prior art arises exclusively in the examination of the inventive step (settled case law, for example BGH, judgment of November 11, 2014 - X ZR 128/09, GRUR 2015, 356, para. 9 - Repaglinid; judgment of January 13, 2015 - X ZR 41/13, GRUR 2015, 352, para. 17 - Quetiapin; judgment of January 21, 2020 - X ZR 65/18, GRUR 2020, 603 para. 12 - Tadalafil).

11 Applying these principles, the problem underlying the teaching of the patent in suit is to demonstrate an improved diagnostic method for the presence of a bacterial infection, particularly in patients suffering from a non-bacterial pre-existing condition.

12 3. To solve this, the patent in suit proposes in claims 1 and 2 a method with the following features:

13

1.	An in vitro method for diagnosis of the presence of a bacterial infection in a patient, comprising:	Ein In-vitro-Verfahren zur Diagnose auf das Vorliegen einer bakteriellen Infektion bei einem Patienten, umfassend:
2.	Determining the level of procalcitonin or fragments thereof of at least 12 amino acids in length, in a sample obtained from said patient.	Ermitteln des Spiegels von Procalcitonin oder Fragmenten davon mit einer Länge von mindestens 12 Aminosäuren in einer Probe, die dem Patienten entnommen wurde.
2.1	Said sample is selected from the group comprising a blood sample, a serum sample, a plasma sample or an extract of any of the aforementioned samples.	Die Probe ist aus der Gruppe ausgewählt, die eine Blutprobe, eine Serumprobe, eine Plasmaprobe oder ein Extrakt aus einer dieser Proben enthält.
2.2	(i) The sample is obtained at least once before the start of an antibiotic treatment or within six hours after the start of the treatment, and	(i) Eine Probe wird mindestens einmal vor Beginn einer Antibiotikabehandlung oder innerhalb von sechs Stunden nach Beginn der Behandlung, und
2.3	(ii) at least once after 12 hours to 1 week after the start of an antibiotic treatment of the patient.	(ii) mindestens einmal zwischen 12 Stunden und 1 Woche nach Beginn einer Antibiotikabehandlung beim Patienten entnommen.
2.4	The threshold level of procalcitonin or fragments thereof is at	Der Schwellenwert von Procalcitonin oder Fragmenten davon mit einer

	least 12 amino acids in length, in blood, serum or plasma samples of said patient below 0.25 ng/mL.	Länge von mindestens 12 Aminosäuren in Blut-, Serum- oder Plasmaproben des besagten Patienten liegt unter 0,25 ng/mL.
3.	Said level of procalcitonin or fragments thereof is correlated to the presence of a bacterial infection.	Es wird ein Bezug zwischen dem Spiegel von Procalcitonin oder Fragmenten davon und einer vorhandenen bakteriellen Infektion hergestellt.
3.1	A decrease of said level of at least 20 % per 24 h is indicative for the presence of a bacterial infection in the patient.	Eine Abnahme besagten Spiegels um mindestens 20 % pro 24 Std. deutet auf eine vorhandene bakterielle Infektion beim Patienten hin.

14 Claim 1, as amended by auxiliary claim 1, further provides as follows:

15

2.5	wherein the patient has a primary disease not being an infection.	Der Patient leidet an einer Grunderkrankung, die keine Infektion ist.

16 4. The patent court correctly defined the relevant skilled person as a graduate chemist specializing in biochemistry, a graduate biochemist or a molecular biologist, in each case with several years of experience in the field of immunology as well as the development of diagnostic methods based on blood proteins, whereby the latter may also work in a team with a medical doctor active in applied infectiology.

17 5. Some features of the demanding doctrine require further consideration:

18 a) As the patent court correctly pointed out, feature 2.4 defines the target group eligible for the in vitro diagnostic method according to the invention to mean that the threshold value of PCT or a fragment thereof with a length of at least 12 amino acids in blood, serum or plasma samples must be below 0.25 ng/mL. Only in the case of a patient whose PCT level is below this threshold before the start of antibiotic treatment or within six hours after the start thereof, the diagnostic method according to the invention is to be applied.

19 b) For such a patient, according to features 2.2 and 2.3 the level of PCT or fragments thereof with a length of at least 12 amino acids must be determined at least once before the start or within six hours after the start of antibiotic treatment and at least once between 12 hours and one week after the start of antibiotic treatment, whereby the sample in each case must meet the requirements of feature group 2.1.

20 c) The relationship between the level of PCT or fragments thereof and an existing bacterial infection, as referred to in feature 3.1, is established by comparing the concentration of PCT or fragments thereof with the initially measured level (cf. also para. 24), whereby a decrease in the level by at least 20% per 24 hours indicates an existing bacterial infection in the patient.

21 Claim 1 does not contain any statement as to whether and to what extent, when the process according to the patent is carried out, a falling below the acceptance rate contained in feature 3.1 indicates the absence of a bacterial infection.

22 d) There must be a period of 24 hours between the decrease of the PCT values to be used for the comparison (feature 3.1). In this respect, there is no contradiction with feature 2.3, which permits a measurement already after 12 hours, since the skilled person, according to the findings of the patent court, is able on the basis of his technical knowledge to transfer the PCT value, which may have already been determined beforehand within the framework of the specifications of feature 2.3, to the relevant period of time according to feature 3.1.

23 e) According to claim 1 in the version of the first auxiliary request, the patient group eligible for the in vitro diagnostic method according to the invention is determined not only by the threshold value according to feature 2.4, but additionally also by feature 2.5, according to which the patient must suffer from an underlying disease that is not an infection.

24 II. The patent court gave the following main reasons for its decision:

25 The subject-matter of claim 1 as granted impermissibly goes beyond the content of the parent application as the original application. It discloses a diagnostic method with an initial PCT value of less than 0.25 ng/mL only for patients suffering from a further non-infectious underlying disease according to feature 2.5.

26 The subject-matter of claim 1 according to auxiliary request 1, to which feature 2.5 had been added, was not based on inventive step.

27 NK12 (Stolz et al., "Antibiotic Treatment of Exacerbations of COPD" in Chest, Vol. 131, 2007, Iss. 1, pp. 9-19), according to its title, concerned the antibiotic treatment of exacerbating COPD and thus patients with a non-infectious underlying disease undergoing PCT-supervised antibiotic treatment. Antibiotic administration

would also be performed in the range of 0.10 to 0.25 ng/mL. The patients were monitored daily with the aid of their PCT value. Insofar as NK12 did not teach an acceptance rate of at least 20% according to feature 3.1, it was obvious for the skilled person to also think about the acceptance rate with regard to the PCT values measured by the skilled person

28 Also on the basis of the international patent application WO 2008/040328 (NK11), the subject-matter of claim 1 in the version of auxiliary request 1 was not based on inventive step. NK11 concerns the diagnosis of infections in a group of patients who have heart failure as a pre-existing condition. The threshold value for antibiotic administration is between 0.03 and 0.06 ng/mL. NK11 is aimed at a therapy-accompanying course assessment and thus encourages a repeated PCT value measurement. NK11 thus discloses features 1 to 3. The temporal sequence and the rate of decrease of the PCT value could not constitute an inventive step, because the determination of suitable parameters for this purpose is part of the usual professional practice. Since a therapy is supposed to show a quick success, a decrease rate of more than 20% per 24 hours is inevitably associated in case of success.

29 III. This stands up to review in the appeal proceedings.

30 1. The patent court correctly held that the subject matter of claim 1 as granted is not disclosed in the parent application without feature 2.5 (non-infectious underlying disease).

31 a) The content of the application is to be determined on the basis of the entirety of the documents originally filed. Decisive is what the skilled person can directly and unambiguously take from these documents as belonging to the invention (BGH, judgment of September 15, 2015 - X ZR 112/13, GRUR 2016, 50 para. 24 - Teilreflektierende Folie; judgment of February 17, 2015 - X ZR 161/12, BGHZ 204, 199 = GRUR 2015, 573 para. 21 - Wundbehandlungsvorrichtung).

When exhausting the content of the disclosure, generalizations of originally disclosed embodiments are permissible if only one or only individual features of an embodiment, which taken together but also considered individually are conducive to the success of the invention, have been included in the claim (BGH, judgment of February 11, 2014 - X ZR 107/12, BGHZ 200, 63 para. 22 - Kommunikationskanal; decision of November 8, 2016 - X ZB 1/16, BGHZ 212, 351 para. 45 - Ventileinrichtung; decision of April 23, 2020 - X ZR 38/18, GRUR 2020, 974 para. 39 - Niederflurschienenfahrzeug). In contrast, a generalization is inadmissible if it can be inferred from the originally filed documents that individual features are inseparably connected with each other, but the claim does not provide for these features in their entirety (BGH, judgment of 21. June 2016 - X ZR 41/14, GRUR 2016, 1038 para. 48 - Fahrzeugscheibe II; decision of September 11, 2001 - X ZB 18/00, GRUR 2002, 49 - Drehmomentübertragungseinrichtung; decision of February 17, 2015 - X ZR 161/12, BGHZ 204, 199 para. 31 - Wundbehandlungsvorrichtung). The claiming of protection without a specific feature may in particular be precluded by the fact that in the application all embodiments have a specific feature or a specific combination of several features and that it can be inferred from the content of the application that the means provided for in the claim serve to solve a problem which presupposes the existence of the feature or combination of features in question (see BGH, judgment of November 7, 2017 - X ZR 63/15, GRUR 2018, 175 para. 35 - Digitales Buch).

32 b) The parent application (NK4) discloses, in the context of antibiotic administration below a threshold of 0.25 ng/mL, only possible solutions that lead to an improved diagnostic procedure for patients with an (additional) non-infectious underlying disease. Regarding the prior art, it is stated that antibiotics above a PCT

threshold of 0.25 ng/mL or above 0.50 ng/mL are given irrespective of whether these patients (additionally) suffer from a non-infectious underlying disease (NK4, p. 2 lines 18-23). Healthy patients had PCT concentrations well below 0.25 ng/mL (NK4, p. 2, line 31 to p. 3, line 2).

33 Based on this prior art, the invention is summarized in the parent application to the effect that, surprisingly, samples from patients with a non-infectious underlying disease very frequently showed a slight increase in the PCT level. This could be an indication that there is a risk of contracting another disease that is not yet clinically manifested or is still asymptomatic, or an extended medical condition related to a local infection (NK4, p. 3, lines 10-21). Patients with a non-infectious underlying disease had not been routinely evaluated for their PCT levels. The invention teaches to determine the PCT value in such patients in order to enable a prognosis of the risk of further disease and thus to adapt the therapy (NK4, p. 3, lines 26-30). Accordingly, the description and claim 27 of the parent application also provide the in vitro diagnostic method of claim 26 for patients suffering from a primary non-infectious underlying disease and in whom the PCT level is below 0.25 ng/mL (NK4, p. 14, lines 5-7 and p. 20, lines 17-31).

34 Thus, the diagnostic method according to the invention is disclosed in the parent application as a whole and in particular with regard to the embodiments only for patients in whom the cumulative PCT level is below 0.25 ng/mL and a non-infectious underlying disease exists. With regard to the diagnosis of an infectious disease in patients without such an underlying disease, however, the parent application leaves it at the prior art referred to, does not propose any

improvements in this respect and thus does not indicate any solution for a problem relating to this group of patients. If the skilled person had nevertheless thought of applying the diagnostic procedure to patients without an underlying disease, this would have resulted from independent considerations and would therefore no longer be covered by the disclosure content of the parent application.

35 2. In the version according to auxiliary request 1, claim 1 is not patentable.

36 a) The subject matter of claim 1 is new.

37 aa) As the patent court correctly pointed out and as the parties do not object to, the claimed priorities are not to be considered for the examination of patentability.

38 bb) It did not result from NK11.

39 (1) NK11 relates to a method for diagnosing respiratory and pulmonary infections or inflammatory diseases with associated heart failure. In the citation, it is pointed out that cardiac insufficiencies can be a decisive risk factor for the development of pneumonia, which is why both diseases are associated with each other. Appropriate therapy requires early diagnosis and differentiation of the underlying disease. The biomarker PCT, which is used in the state of the art with a threshold value of >0.50 ng/mL to differentiate bacterial sepsis, is suitable for this purpose. According to studies, patients with PCT values of >0.10 ng/mL or >0.25 ng/mL could also be detected for clinically relevant lower respiratory tract infections.

40 NK11 sets out to provide a method for the diagnosis of respiratory and pulmonary infections associated with heart failure and proposes as a solution to

determine the marker PCT for such diagnosis, preferably using threshold values of 0.01 to 1.00 ng/mL and in particular 0.03 to 0.06 ng/mL for the determination of PCT (NK11, p. 7; claims 1 and 2).

41 In addition, it is proposed that the diagnostic procedure with the above-mentioned threshold values can also be used for risk stratification (i.e., for estimating the risk of disease progression), for therapy control of antibiotic treatment, and for therapy-accompanying course assessment of an infection of the respiratory tract and lungs with associated heart failure (NK11, p. 8 et seq.; subclaims 16 to 18).

42 (2) The procedure taught in NK11 thus has features 1 to 2.2 as well as 2.4 and 2.5.

43 (3) With the reference to using PCT also as a marker for the therapy-accompanying course assessment of an infection or inflammatory disease of the respiratory tract and lung with associated heart failure, it is also disclosed in NK11 that the PCT value should not only be determined in the patient at the beginning of the antibiotic treatment, but that this should also be repeated during the further course of the treatment. The skilled person reads on the basis of its expertise to the extent that such a further determination of the PCT value as a marker must be carried out in the case of antibiotic treatment between 12 hours and one week after the start of treatment, so that feature 2.3 is also disclosed.

44 (4) A follow-up assessment accompanying the antibiotic treatment serves to relate the PCT value measured at the beginning of the treatment to the PCT values determined in the subsequent measurements in such a way that the values are compared with each other in order to be able to draw conclusions about the course of the antibiotic treatment. If the comparison of the PCT values allows

the conclusion that the antibiotic treatment is successful, this also implies or indicates the presence of a bacterial infection. Feature 3 is thus also disclosed.

45 (5) However, there is a lack of disclosure of feature 3.1, since NK11 does not describe basing the indicator for a successful course of antibiotic treatment or the presence of a bacterial infection on a decrease in the patient's PCT level by at least 20% per 24 hours.

46 cc) NK12 also does not fully disclose the subject matter of claim 1.

47 (1) NK12 is a study report concerning antibiotic treatment of exacerbations of COPD, which is an exacerbation of chronic obstructive pulmonary disease. In view of the fact that antibiotics influenced recovery from COPD exacerbations only in selected cases, the control of antibiotic prescriptions had been evaluated on the basis of PCT values compared with standard therapy that did not take such values into account. The study would have involved 208 consecutive patients who required hospitalization for an exacerbation of COPD and were randomly assigned to PCT-guided therapy or standard antibiotic therapy according to index exacerbation. In the PCT-guided group, antibiotic administration had been based on measurement of PCT levels on admission to the hospital. A PCT level of <0.1 µg/L had been assumed not to be a bacterial infection. A level of 0.1 to 0.25 µg/L had indicated a possible bacterial infection, and antibiotic administration had been recommended or discouraged based on the patient's clinical condition. If the PCT level was above this level, the presence of a bacterial infection was assumed and antibiotics were advised (NK12, p. 10, right col., last para. transition 11, left col.,

para. 1). It had been recommended to re-evaluate circulating PCT levels and clinical status when antibiotic administration had been withheld (NK12, p. 11, left col., para. 2). Patients had been followed daily until hospital discharge (NK12, p. 11, para. 3). At the short-term follow-up (after 14 to 21 days), patients had been evaluated on the basis of clinical laboratory and pulmonary function criteria and classified according to clinical success or failure. In addition, long-term follow-up had taken place (NK12, p. 11, paras. 4 and 5).

48 NK12 concludes that considering PCT values, the administration of antibiotics could be reduced without a clinically measurable difference, especially a difference in lung volume (first-second capacity, FEV_1).

49 (2) Features 1 to 2.2 and 2.5 are thus disclosed.

50 (3) It does not follow with the necessary clarity from the statements in NK12 that the patients were monitored daily until discharge from the hospital that the PCT value was measured again in the PCT-treated patients within the period provided for in feature 2.3. For the study, this was not important, since for the evaluation of the success of PCT-guided antibiotic administration compared to standard therapy, the follow-up examinations of the patients, which were performed later than one week after the start of antibiotic therapy, were decisive. Accordingly, no comparison with the PCT level collected at the start of antibiotic treatment is disclosed, and NK12 also lacks a disclosure of the teaching that a decrease in PCT level of at least 20% per 24 hours is indicative of an existing bacterial infection.

51 dd) The subject matter of claim 1 is also not apparent from NK17 (Christ-Crain et. al, "Procalitonin Guidance of Antibiotic Therapy in Community-acquired Pneumonia," American Journal of Respiratory and Critical Care Medicine, Vol. 174

(2006), pp. 85-93). American Journal of Respiratory and Critical Care Medicine, Vol. 174 (2006), p. 8593).

52 (1) NK17 concerns a randomized trial of PCT management of antibiotic therapy for community-acquired pneumonia. The study enrolled 302 consecutive patients who were randomly assigned to a group in which antibiotic treatment was guided by PCT levels or to a control group treated with antibiotics according to normal practice. In both groups, many of the participating patients also suffered from a non-infectious additional disease, such as coronary artery disease, diabetes mellitus, etc. (NK17, p. 86, table 1). In the PCT-guided group, antibiotic treatment was strongly discouraged at a level of 0.1 µg/L and discouraged at less than 0.25 µg/L. In contrast, it was recommended at greater than 0.25 µg/L and strongly recommended at greater than 0.5 µg/L. PCT levels were reassessed after four, six, and eight days (NK17, p. 84, left col., abstract; p. 86, right col., para. 1).

53 (2) Features 1 to 2.3. and 2.5. are thus disclosed.

54 (3) It can be left open whether NK17 discloses feature 2.4. On the one hand, the citation just advises against antibiotic treatment of patients with a PCT value below 0.25 ng/mL. On the other hand, contrary to this advice, it also reports the treatment of 20 patients with particularly severe pneumonic disease in whom PCT levels below 0.25 ng/mL had been detected (NK17, p. 88, right col., para. 1).

55 With regard to these patients, however, it is not clear from NK17 whether the PCT level decreased by at least 20% per 24 hours after the start of antibiotic treatment. NK17 does describe a general decrease in PCT levels within the measured time periods. However, it does not follow that this also applies to the

aforementioned 20 patients who were treated with antibiotics contrary to the general recommendation, so that there is a lack of disclosure of feature 3.1 in NK17, both overall and with regard to these 20 patients.

56 b) The teaching protected in claim 1 according to auxiliary request 1 resulted in an obvious way for the skilled person due to the prior art.

57 aa) The skilled person, who had set itself the task of developing an improved diagnostic procedure for the presence of a bacterial infection in patients suffering from a non-bacterial previous disease, had reason to deal with NK11, since a procedure for the diagnosis and therapy-accompanying course assessment of an infection or inflammatory disease of the respiratory tract and lungs in patients with associated heart failure is described therein.

58 bb) With the indication to use PCT also as a marker for the therapy-accompanying course evaluation of an infection or inflammatory disease of the respiratory tract and lung with associated heart failure, it is taught in NK11 to compare the PCT value, which was determined at the beginning of the antibiotic treatment in the blood or serum of the patient, with values obtained during the further course of treatment, in order to be able to assess the success of treatment on the basis of such a comparison, which from a professional point of view also results in an indication for the presence of a bacterial infection.

59 cc) In NK11, however, no differential values for the PCT measurements are mentioned, the presence of which indicates the success or failure of antibiotic treatment. Therefore, there was reason for the expert to take a closer look at the dynamics of PCT as a diagnostic marker in the antibiotic treatment of bacterial infections.

60 NK17 mentions PCT as a diagnostic marker and control element for the study disclosed there. In this regard, it is stated that the PCT level decreases with a successful treatment with a half-life of 20 to 24 hours, i.e., with an exponential rate of decrease of at least 50% (p. 84, right col., last par.). Furthermore, NK17 teaches to re-survey the PCT level after four, six and eight days (p. 86, left col., para. 1).

61 NK17 also reports that a PCT value below 0.10 ng/mL means the absence of a bacterial infection and that the further administration of antibiotics should be urgently discouraged, and that a PCT value between 0.10 and 0.25 ng/mL means a bacterial infection is unlikely and the (further) administration of antibiotics should be discouraged (NK17, p. 86, left col., para. 1). Nevertheless, based on NK11, which suggests antibiotic administration to patients suffering from heart failure even at PCT levels below 0.25 ng/mL, the expert had reason to believe that antibiotic administration even at such low initial PCT levels would lead to a substantial reduction in PCT levels within a period of 20 to 24 hours.

62 According to the correct findings of the patent court, which were not specifically challenged by the defendants, the skilled person knew that the PCT value drops sharply when an antibiotic is administered at the beginning of treatment if the patient responds to the drug and it is successful against a bacterial infection. Since NK17 reports an exponential rate of decrease, a reduction in relation to the initial value, i.e. also in the sense of an exponential rate of decrease, was therefore to be expected even below a PCT value of 0.25 ng/mL. The actual level of such a rate of decrease was then to be determined on the basis of further simple tests. According to the findings of the patent court, values were to be expected which ultimately showed a rate of decrease of more than 20% per 24 hours.

63 3. The defense of the patent in suit according to auxiliary request 2 is inadmissible.

64 Claim 1 according to auxiliary claim 2 differs from that according to auxiliary claim 1 in that the patient to be examined must not suffer from heart failure as a non-infectious underlying disease according to feature 2.5.

65 The auxiliary request is not relevant because the defendant had reason to file it already in the first instance after it had been pointed out in the reference of the patent court according to Sec. 83 (1) Patent Act. 1 that the teaching of the patent in suit was obvious, inter alia, in view of the prior art known from NK11 and NK17, and the patent court had also expressly taken into account in this respect that NK11 deals with the diagnosis of, inter alia, bacterial infections or inflammatory diseases of the respiratory tract and lungs associated with heart failure and thus associated with a primary disease in the sense of the invention.

66 IV. The decision on costs is based on Sec. 121 (2) Patent Law, Sec. 97 (1) ZPO.

Grabinski Hoffmann Deichfuß

Marx Crummenerl

Lower court:
Federal Patent Court, decision of December 3, 2019 - 4 Ni 24/17 (EP) -