Machine Translation

FEDERAL SUPREME COURT

IN THE NAME OF THE PEOPLE

JUDGEMENT

X ZR 83/21

Delivered on:
28 November 2023
Wieseler
Clerk of the Court
as Clerk of the
Court Registry

in the patent nullity case

Reference book: yes
BGHZ: no
BGHR: yes

Sorafenib tosylate

EPC Art. 54 para. 1; German Patent Act (PatG) Section 3 para. 1
The disclosure of more than 100 active ingredients which are described as suitable for the treatment of cancer, either alone or in the form of a pharmaceutically acceptable salt with numerous salt formers under consideration, is not sufficient for the direct and unambiguous disclosure of a specific salt of a single active ingredient in a form suitable for oral administration.

German Patent Act (PatG) Section 87 para. 1
a) There is a rebuttable presumption in favor of the entitlement to claim a priority right when applying for a European patent.

b) The joint filing of a PCT application designating the applicant of the priority application for one or more destination states and another person for one or more other destination states implies an agreement between the parties entitling the other person to claim priority (likewise EPO, decision of 10 October 2023 - G 1/22 - Priority entitlement).

German Code of Civil Procedure (ZPO) Section 286 G
In patent nullity proceedings, the burden of presentation and proof regarding the requirements for an effective claim of priority lies with the nullity action.

ECLI:DE:BGH:2023:281123UXZR83.21.0

The X. Civil Senate of the Federal Supreme Court, at the hearing on 10 October 2023, by the Presiding Judge Dr. Bacher, the Judges Hoffmann, Dr. Marx and Dr. Rombach and the Judge Dr. Rensen

ruled:

On appeal by the defendant, the judgment of the 3rd Senate (Nullity Senate) of the Federal Patent Court of 29 September 2021 is amended.

European patent 2 305 255 is declared partially invalid with effect for the Federal Republic of Germany in that the following words are added to the end of claim 12:
"in an oral dosage form".

The remainder of the complaint is dismissed.

The further appeal is rejected.

The plaintiffs shall each bear two fifths and the defendant one fifth of the costs of the proceedings.

By law

Facts of the Case:

1 The defendant is the proprietor of European patent 2 305 255 (patent in suit) granted with effect for the Federal Republic of Germany, which arose from a second-generation divisional application, the parent application for which was filed on 3 December 2002, claiming a US priority of 3 December 2001. The patent in suit relates to aryl urea compounds and comprises twelve claims.

2 Contested claim 12 reads in the procedural language:

> Aryl urea compound, which is a tosylate salt of N-(4-chloro-3-(trifluoromethyl)phenyl-N'-(4-(2-(N-methylcarbamoyl)-4-pyridyloxy)phenyl)urea.

3 The plaintiffs have argued that the contested subject matter is not patentable. The defendant has defended the patent in suit as granted and, in the alternative, in four amended versions.

4 The Patent Court declared the patent in suit invalid in the contested scope. This is the subject of defendant's appeal, which pursues its requests at first instance. The plaintiffs oppose the appeal.

Reasons of the decision:

5 The admissible appeal is justified insofar as the defendant defends the patent in suit with auxiliary request 2.

6 I. The patent in suit concerns aryl urea compounds.

7 1. The description of the patent in suit states that the p21 oncogene (ras) would make a significant contribution to the development of human solid cancers and is mutated in 30 % of all human cancers.

8 In its non-mutated form, the ras protein would be a key element of the signal transduction cascade, which was controlled by growth factor receptors in almost all tissues. Biochemically, ras would be a guanine nucleotide-binding GTPase protein that would cycle between a GTP-bound activated form and a GDP-bound inactive form. In the case of mutations, the endogenous GTPase activity would be reduced. Therefore, the protein would deliver constitutive growth signals to downstream effectors, such as the raf kinase enzyme. It was shown that the inhibition of the raf kinase signaling pathway led to the reversal of transformed cells (para. 2).

9 Therefore, compounds that acted as raf kinase inhibitors represented an important group of agents for the treatment of many types of cancer (para. 3).

10 On this basis, the problem underlying the patent in suit can be summarised as providing an effective and well-tolerated raf kinase inhibitor.

11 2. The patent in suit discloses a substance designated as compound A in the description (para. 73). This is a tosylate salt of the compound N-(4-chloro-3-(trifluoromethyl)phenyl-N'(4-2-(N-methylcarbamoyl)-4-pyridyloxy)phenyl)urea (para. 60). The latter has the international non-proprietary name sorafenib.

12 a) The unchallenged claims 1 to 11 protect the use of sorafenib tosylate and 5-fluorouracil for the treatment of cancer.

13 b) The challenged claim 12 protects sorafenib tosylate as a substance.

14 As the plaintiff 1 correctly argues in essence and the High Court for England and Wales has explained in more detail (Mellor J, [2021] EWHC] 2690 (Pat) para. 21), this protection is independent of any particular use or suitability of the said compound.

15 II. The Patent Court essentially gave the following reasons for its decision:

16 The subject matter of claim 12 was suggested to the skilled person, a team comprising a medicinal chemist, a pharmacologist and a physician, each with many years of experience in the development and use of chemotherapeutic agents for antitumor treatment, based on the publication of Lyons et al. (Endocrine-Related Cancer 2001, 8, 219-225, NiK2) in conjunction with the expertise documented in the publications of Aulton (Pharmaceutics The Science of Dosage Form Design, 1988, reprint 1994, chapter 13 "Preformulation", NiK5; 2nd ed. 2002, p. 113). (Organic Process Research & Development 2000, 4, pp. 427-435, NiK11) and Sucker et al. (Pharmazeutische Technologie, Georg Thieme Verlag Stuttgart New York, 2nd ed. 1991, pp. 144-173, NIB15).

17 NiK2 would deal with the biology of ras signalling and the epidemiology of ras mutations in relation to cancer as a background for the development of the raf kinase inhibitor and would represent a suitable starting point for solving the task of providing an oral administration form of sorafenib. The skilled person would understand from NK2 that raf kinase is an attractive target for antitumor treatment

and that sorafenib would prove to be an effective oral inhibitor of raf kinase with significant activity in various human tumors while being well tolerated. Even if NiK2 lacked more detailed information on the galenics of the orally administered sorafenib tablets, the fact that the sorafenib formulation used had been successfully clinically tested provided a strong incentive for the skilled person to search for a sorafenib composition with which the reported efficacy and tolerability could be verified. Faced with the task of providing a suitable oral form of administration of sorafenib, the skilled person, starting from NiK2, first of all looked at the results of the preformulation studies on the free base of sorafenib, which showed that sorafenib is poorly soluble in water. As a measure to achieve better solubility and thus better bioavailability, the expert envisaged salt screening. The choice of tosylate was obvious. Only strong acids with pKs values in the negative range could be considered as possible salt formers, since it is a matter of specialised knowledge that for the formation of stable salts there must be a difference of at least three units between the pKs values of the basic group and the counterion. As pharmacologically suitable and customary counterions of strong acids with pKs values in the negative range, four anions in particular are known to the skilled person, namely hydrochloride, sulphate, mesylate and tosylate. He includes all of these in his salt screening programme due to their manageable number.

18 There was no obstacle for the skilled person to determine the pKs value of sorafenib. He was aware that spectroscopy, a more sensitive measurement method than potentiometry, should be used to determine the pKs value of poorly soluble active substances. Furthermore, at the time of prioritisation, software was already available that could have been used to calculate pKs values based on the chemical structure of an active substance, at least approximately. According to the specialist literature, such a calculation was also standard practice. Accordingly, the

pKs value of the most basic nitrogen atom in sorafenib was calculated in the KNK19 citation.

19 When routinely performing the salt screening, the skilled person also noted that sorafenib according to NK2 showed good efficacy when administered orally despite its poor solubility. He therefore classified sorafenib as a class 2 active substance according to the Biopharmaceutics Classification System (BCS), i.e. as an active substance with poor solubility and good gastrointestinal permeability. From this he inevitably draws the conclusion that the decisive factor for the bioavailability of sorafenib when administered orally is not its solubility but its dissolution rate. The skilled person would therefore not stop at determining the solubility of sorafenib tosylate, which is no better than that of sorafenib free base. On the basis of the aforementioned classification, he was rather motivated to determine the dissolution rate of sorafenib tosylate in comparison to the free base. He was neither deterred by the difficulties due to the poor solubility nor by the assessment of the measurement method described as an example in NIB5 as unsuitable. The determination of the dissolution rate is a standard test measure in pharmacology. Among the various measurement methods available to him, the skilled person would turn to other methods, for example spectroscopy or conductivity measurement, taking into account the explanations in NIB5.

20 The fact that there were various options for improving the solubility and thus the bioavailability did not lead to a different assessment. As the defendant also acknowledged in its expert opinion NIB2, salt formation was a common and, according to NiK11, even the preferred way to improve the solubility of a poorly soluble active ingredient. The time and cost involved in salt screening was only of secondary importance in the assessment of inventive step. The physico-chemical

analysis of an active ingredient in the pre-formulation phase is part of the daily routine work of the pharmacologist who is part of the expert team.

21 There was also no prejudice against the use of tosylate salts. Tosylate had been proposed as a possible counterion in the specialised literature at the time of priority. The fact that tosylate was no longer listed in the table of potential pharmaceutical salts in the second edition of Aulton also did not indicate any reservations. The second edition also would continue to refer to the use of tosylate.

22 In addition, international patent application 00/42012 (NiK4) would provide a suggestion for the skilled person to consider tosylate. NiK4 would show the use of tosylate salts as a preferred pharmaceutically acceptable salt for aryl urea compounds and discloses sorafenib as a preferred example of a raf-kinase inhibiting aryl urea compound.

23 The defendant, who had the burden of proof, would not provide any evidence that pure p-toluenesulfonic acid could not be procured in sufficient quantities. Furthermore, it would be part of the routine work of the chemist who is a member of the expert team to purify substances and excipients, if necessary, using standard methods customary in the trade, in such a way that they are suitable for pharmaceutical applications.

24 The skilled person would also not disregard the tosylate salt because no active substance formulated as a tosylate salt and to be administered orally had been authorised up to the priority date. In addition to the most commonly used hydrochloride salt, other salts would also be listed in general textbooks. In the case of poor solubility of the hydrochloride salt, the tosylate salt was even in the foreground for the skilled person. Contrary to the defendant's view, the skilled person would not merely attach secondary importance to the common ion effect

underlying the suboptimal solubility of hydrochloride salts. According to NIB5, hydrochloride salts often showed suboptimal solubility in the gastrointestinal environment due to this effect.

25 With its objection that the dissolution rate would only be determined for promising candidates, the defendant would disregard the fact that the skilled person, knowing the results from NiK2 and the poor solubility of the free base, would attach much greater importance to this parameter.

26 It was not yet possible to calculate the dissolution rate from the (saturation) solubility at the time sorafenib was developed. Furthermore, a low solubility would not necessarily mean a low dissolution rate. For this reason, the dissolution rate was mentioned in the specialist literature as a standard measurement to be carried out in the preformulation phase.

27 The deviating judgement of the District Court Munich I cannot be followed. The District Court misjudged the function of an indication pursuant to Section 83 (1) PatG. A deviation from the assessment of the Patent Court should only be possible and appropriate if the infringement court has a sufficient basis on the basis of expert statements.

28 The subject-matter of claim 12 was also disclosed in the versions defended in the alternative. The additional features provided therein were known from NiK2. The reformulation of a substance claim into a use claim could not constitute an inventive step because sorafenib had already been used in NiK2 for the treatment of human cancer.

29 III. This assessment does not stand up to review in the appeal proceedings on one decisive point.

30 1 The Patent Court rightly concluded that the subject-matter of the granted version of claim 12 was obvious on the basis of NiK2.

31 a) NiK2 describes the significance of ras mutations and raf kinase inhibitors in relation to cancer.

32 A study of many thousands of compounds from the class of bis-aryl ureas showed that a compound designated BAY 43-9006 significantly inhibited tumor growth (p. 223 et seq.).

33 A clinical trial of oral tablets with BAY 43-9006 began in July 2000. So far, the compound was well tolerated and the dose increase will be continued. The preliminary clinical data would be encouraging. BAY 43-9006 would be an orally available potent inhibitor of raf kinase with significant activity in four different human tumor types, including colon, pancreatic, lung and ovarian tumors (p. 224).

34 b) This gave rise to the need to conduct a preformulation study to find a form of sorafenib suitable for oral administration.

35 aa) The results reported in NiK2 gave reasons to expect that oral administration of BAY 43-9006 - i.e. sorafenib - in the form of tablets would be a successful way to treat cancer patients.

36 bb) In order to follow this path, not only a suitable formulation was required, but also more detailed information on the form in which sorafenib should be included in this formulation.

37 NiK2 contains no information on this.

38 A preformulation study was therefore necessary in order to rework and further develop the teaching revealed in NiK2.

39 cc) Contrary to the opinion of the appeal, the fact that a suitable form of sorafenib was apparently already available for the trials described in NiK2 did not speak against this approach.

40 More detailed knowledge about the form used there was neither available from NiK2 nor from other publications. Persons not involved in the development of the drug used in NiK2 were therefore dependent on gaining more detailed knowledge through their own studies.

41 In view of the great importance of raf kinase inhibitors already known in the prior art, also according to the statements in the patent in suit, and the promising results from NiK2, the effort required for such studies in the relevant overall view did not constitute a sufficient reason to refrain from pursuing this promising path.

42 dd) Contrary to the opinion of the appeal, based on NiK2 there were no sufficient indications that sorafenib can be used as a free base and that the search for suitable salts is therefore not necessary.

43 The fact that NiK2 does not mention a sorafenib salt did not provide any reliable information that the free base was used in the experiments described there.

44 The fact that the free base showed a measurable bioavailability in the animal tests presented by the defendant (NIB3 p. 4 et seq. with Table 2) does not lead to a different assessment, if only because the results of these tests - which also included the tosylate salt - were not known in the prior art.

45 In view of this uncertainty, refraining from a preformulation study would have been associated with high risks. From this point of view, it also made sense to conduct such a study first.

46 c) The Patent Court also rightly concluded that there was reason to search for suitable salts in a preformulation study and to include tosylate in the investigation.

47 aa) As the appeal also does not call into question, the search for suitable salts was one of the measures that were obvious in the context of a preformulation study because it was recognised that sorafenib is only slightly soluble in water.

48 bb) The Patent Court rightly decided that there was reason to include tosylate in this investigation because priority was given to acids whose dissociation constant (pKa or pKs) had a very low value and the choice was limited in this respect.

49 (1) As the appeal also states, a salt can form if the pKs value of an acid is lower than the pKs value of the ionisable group of the basic active substance.

50 Against this background, there was reason to first determine the pKs value of sorafenib.

51 (2) A pKs value between 2.03 and 4.5 was assumed for sorafenib.

52 According to the plaintiff's submissions, which remain uncontradicted in this respect, appropriate calculations lead to values in the aforementioned range. The value of 2.66, which is shown in the extract from the SciFinder database (as of 2021, KNK19) submitted by plaintiff 2 and which the Patent Court used as a basis, is within this range.

53 In contrast, the additional value of 12.89 cited by the appeal, which is also stated in CNK19, is not relevant. According to the information in CNK19, it relates to the most acidic group. However, according to the unchallenged findings of the Patent Court, the value of the most basic group is decisive.

54 (3) Even if it is assumed in favor of the appeal that prior to the priority date the value shown in CNK19 could not be readily determined and therefore only the range between 2.03 and 4.5 resulting from calculations could be taken as certain, the inclusion of tosylate was obvious for the reasons given by the Patent Court.

55 (a) Based on the state of the art, it was obvious to consider only those substances whose pKs value is at least three units below the pKs value of sorafenib.

56 This follows from the Patent Court's findings, according to which it is customary to choose such a minimum distance for the formation of strong salts, as reproduced in NiK11 (p. 427 bottom right).

57 The fact pointed out by the appeal that NiK1 1 itself reveals stable salts, although the difference in the pKs values is only in the range of 1, does not lead to a different assessment.

58 Even if the rule referred to by the Patent Court is only a rule of thumb that does not exclude exceptions, in the absence of concrete findings on Sorafenib, it was obvious to first investigate substances that fall under the rule mentioned and therefore offer a higher chance of success based on experience. NiK11 also does not draw the conclusion from the results found there, which deviate from the rule, that it could generally be appropriate to investigate substances with a smaller interval from the outset.

59 (b) Against this background, substances that are suitable for the manufacture of pharmaceuticals and whose pKs value is negative or at most slightly above 0 were suitable for a preformulation study with sorafenib.

60 These substances included tosylate.

61 Of the salts listed in Table 8.4 (p. 117) of the second edition of the informative textbook by Aulton (NIB5), only hydrochloride (pKs -6.10), sulphate (pKs -3.00) and mesylate (pKs -1.20) have such a low pKs value that the minimum distance of 3 can be maintained in any case.

62 In contrast, maleate (pKs 1.92) and phosphate (pKs 2.15) are in a range where the above-mentioned distance is not maintained even if the pKs value of sorafenib is at the upper end of the calculated range, i.e. 4.5.

63 Given this initial situation, there was reason to consider Tosylate as another candidate.

64 Tosylate is still listed as a potential pharmaceutical salt in the first edition of Aulton's textbook (NiK5) in Table 13.4 (p. 227). The stated pKs value of -1.34 lies between the values of sulphate and mesylate.

65 The corresponding table in the second edition of the textbook (NIB5 Table 8.4, p. 117) no longer lists tosylate. However, tosylate is also presented in this edition as an alternative in the event that solubility is impaired by the so-called common ion effect (NIB5 p. 124 left).

66 Even if it may be inferred from this that tosylates were not generally counted among the salts that were primarily considered, in view of the limited selection of substances that could even be considered as salt formers for sorafenib due to their pKs value, it nevertheless made sense to consider tosylate as a possible alternative from the outset. This applies regardless of whether there were any indications that the common ion effect could play a role in sorafenib. The low pKs value of sorafenib alone suggested that particular attention should be paid to salt formers, which also have a low pKs value. For the same reason, the fact that tosylates have only been used in medicinal products in a few individual cases did not provide sufficient grounds to disregard this substance.

67 d) As the High Court for England and Wales has also ruled, the subject matter of claim 12 is already obvious.

68 As already explained above, claim 12 protects sorafenib tosylate as a substance. The manufacture of this substance and the investigation of its solubility form part of the protected subject-matter.

69 With the inclusion of sorafenib tosylate in a preformulation study, the substance was therefore also suggested.

70 2. With regard to the subject matter defended with auxiliary request 1, there is no deviating assessment.

71 a) After auxiliary request 1, the words "for oral delivery" are to be added to the granted version of claim 12.

72 This indication of purpose is not directed to a specific use. It merely limits the subject matter of the patent to the effect that the protected substance must be suitable for oral administration. A specific formulation is not required for this.

73 b) This subject-matter is obvious for the same reasons as sorafenib tosylate itself, because this substance readily exhibits the property claimed in auxiliary request 1.

74 3. However, a different assessment arises with regard to auxiliary request 2.

75 a) After auxiliary request 2, the words "in an oral dosage form" are to be added to the granted version of claim 12.

76 This additional feature requires sorafenib tosylate to be formulated so that it can be administered orally without further processing or conversion.

77 b) The subject-matter thus defended does not go beyond the content of the application (KNK2) and the parent application (NiK6).

78 Like the patent in suit, the application deals primarily with a combination of sorafenib tosylate with other substances. However, the separate administration of the individual substances is also disclosed as belonging to the invention, also in oral form (NiK6 p. 8, KNK2 para. 29 et seq.).

79 c) Contrary to the opinion of the Patent Court, this subject-matter was not obvious on the basis of NiK2.

80 aa) However, the Patent Court rightly assumed that, despite the low solubility of sorafenib tosylate, there was reason to additionally examine the dissolution rate.

81 As the appeal does not call into question, the dissolution rate is a parameter that is important for bioavailability. It is indeed proportional to solubility. However, according to the Patent Court's findings, this does not mean that a poorly soluble substance necessarily has a low dissolution rate.

82 Whether, in view of this, there is always reason to investigate the dissolution rate even for substances whose solubility has proven to be low does not require a final decision.

83 As the Patent Court rightly assumed, a special situation existed in the case in dispute because, according to the description in NiK2, sorafenib had proved to be suitable for oral administration in the form of tablets. It was therefore not certain that there must be a suitable salt. However, there was in any case reason not to reject a salt included in the study as unsuitable simply because it showed low solubility, but also to consider the dissolution rate as a second decisive parameter.

84 bb) Contrary to the opinion of the Patent Court, however, there was no reason to use measurement methods for investigating the dissolution rate which were not customary in the prior art for preformulation studies.

85 (1) According to the appeal, which is not disputed in this respect, NIB5 (p. 122) and NiK11 (p. 429 Table 2) state that the usual procedure in the context of preformulation studies is to determine the intrinsic dissolution rate, i.e. the rate that occurs in the salt under investigation without the influence of other factors.

86 According to the findings of the Patent Court, no relevant findings were to be expected from the procedure proposed in NiB5 in this regard because the solubility of sorafenib tosylate is too low. Concrete indications which cast doubt on the completeness or correctness of this finding are neither shown nor otherwise apparent.

87 (2) Contrary to the opinion of the Patent Court and the plaintiffs, there was no reason to use other measurement methods, even against the background of the positive results from NiK2.

88 (a) It does not follow from the Patent Court's findings that other standard measurement methods, such as spectroscopy or conductivity measurement, were available that these methods were also customary for preformulation studies.

89 According to the arguments of the appeal, which remain unchallenged in this respect, spectroscopy is also used in the process proposed in NIB5. According to the plaintiffs' submissions, improvements can be achieved by adding solubilisers, for example in the form of surfactants. In this way, however, the intrinsic dissolution rate cannot be determined, but only a relative comparison between individual analysed substances can be made.

90 (b) The same applies to the use of flow-through cells, which the plaintiffs have identified as a further alternative.

91 As the plaintiffs have shown, in particular on the basis of the publication by Langenbucher et al. (Standardised Flow-cell Method as an Alternative to Existing Pharmacopoeial Dissolution Testing, Pharm. Ind. 51 (1989), 1276, KNK25), suitable devices such as those used by the defendant after the priority date to prepare a submission to the European Patent Office (NiK14) were already known before the priority date.

92 However, there was no suggestion from KNK25 to use such devices - which also only allow a relative comparison - in the context of preformulation studies.

93 KNK25 emphasises as an advantage of flow cells that active ingredients, granules and finished formulations can be tested with the same type of device. However, these statements are related to the introductory statement that the use of flow cells has developed into an established tool for testing oral dosage forms. Only the testing of rectal forms is mentioned as a possible further application, which is the subject of investigations (bottom right of p. 1280). There is no indication from these statements that flow-through cells could also be considered in the context of preformulation studies.

94 cc) Against this background, the increased likelihood of success justified by NiK2 did not give rise to any suggestion to use methods for measuring the dissolution rate of sorafenib tosylate that are not commonly used in preformulation studies.

95 However, the statements in NiK2 gave reason in principle to consider measures that went beyond the usual scope, provided that these were not associated with disproportionate effort. According to the plaintiffs' arguments, which remained unchallenged in this respect, the cost of an investigation using a small measuring cell would also have been manageable.

96 From this initial situation, however, there were no indications as to which measures beyond those customary in the context of preformulation studies promised success and that a comparison of the dissolution rate of the salts investigated - all of which have a low solubility - could lead to the goal. Against this background, neither the use of solubilisers nor investigations with flow-through cells were an obvious option.

97 dd) Contrary to the plaintiffs' view, against this background there was also no reason to determine the bioavailability of various forms of sorafenib without further laboratory tests in animal experiments.

98 NiK2 did give reasons to believe that there must be a form of sorafenib suitable for oral administration. However, this did not provide a sufficient guarantee that the substance in question belonged to the group of investigated substances.

99 IV. The contested decision with regard to auxiliary request 2 is not correct as a result for other reasons (Sec. 119 (1) Patent Act).

100 1. Contrary to the opinion of plaintiff 1, the subject-matter of claim 12 is not anticipated by NiK4.

101 a) NiK4 deals with compounds which are suitable as inhibitors of raf kinase against the same background as the patent in suit.

102 NiK4 proposes compounds with the general structural formula A -D -B, where D has the structure -NH-C(O)-NH-, i.e. it is a urea compound. Components A and B can consist of a variety of different structures.

103 NiK4 describes a method for synthesising such compounds and lists a total of 103 compounds that were produced in such experiments, together with their chemical names (p. 53, line 17 to p. 75, line 9) and structural formulae (Tables 1 to 7, p. 76, line 1 to p. 88, line 4).

104 Sorafenib is recited as entry 42 and is claimed in claims 61 and 67, respectively, together with other compounds as a per se substance and for the treatment of cancerous raf kinase-mediated cell growth.

105 NiK4 states pharmaceutically acceptable salts as also belonging to the invention. As examples, the citation mentions, among many others, salts of p-toluenesulfonic acid (p. 6 line 15), i.e. tosylates. Such salts, including tosylates, are claimed in claim 50 for all compounds according to claim 1 and in subsequent claims for compounds according to subclaims 2, 33, 38 and 39.

106 b) Thus, as the Patent Court rightly stated in the reference issued pursuant to Sec. 83 (1) Patent Act, sorafenib tosylate is not directly and unambiguously disclosed.

107 Contrary to the opinion of plaintiff 1, the reference contained in NiK4 to the fact that the listed salts are in principle suitable for all disclosed urea compounds is not sufficient for a direct and unambiguous disclosure of this compound. This reference does not provide the teaching protected in claim 12 in the version of auxiliary request 2 that the tosylate of sorafenib is particularly suitable for oral administration.

108 2. The prior art published in the priority interval is not relevant for the decision of the dispute.

109 The plaintiffs have not shown any concrete circumstances that cast doubt on the effective claiming of the priority right from US application 60/3344609.

110 a) The Enlarged Board of Appeal of the European Patent Office decided in a decision announced on the day of the oral proceedings in the present case, but which only became known to the Senate afterwards, that the validity of a priority claim for a European patent application pursuant to Art. 87 para. 1 EPC is to be assessed autonomously on the basis of the European Patent Convention, that there is a rebuttable but strong presumption of entitlement to claim priority and that the joint filing of a PCT application in which the applicant of the priority application

is designated for one or more destination states and another person is designated for one or more other destination states implies an agreement between the parties which entitles the other person to claim priority (EPO, decision of 10 October 2023 - G 1/22, para. 86, para. 101 et seq. and para. 122 - Priority entitlement).

111 The Senate agrees with this interpretation of the provision in Article 87(1) EPC, which is also decisive for the decision of the dispute. It is carefully and convincingly reasoned and leads to realistic results that are in line with the interests of the parties.

112 b) Applying this standard, priority is effectively claimed in the case in dispute.

113 aa) The presumption of legitimate claiming arising from the European Patent Convention cannot be rebutted by asserting speculative doubts. Rather, concrete circumstances must be shown which give rise to serious doubts as to the reasons for the subsequent applicant's entitlement (EPO, decision of 10 October 2023 - G 1/22, para. 110 - Priority entitlement).

114 The plaintiffs have not shown such circumstances.

115 The mere denial of the opposing party's submission with ignorance is not suitable for rebutting the presumption.

116 The fact that the defendant submitted contracts providing for the assignment of rights to inventions arising in the course of employment for only some of the eighteen applicants in the earlier application may make it appear possible that some of the employees did not conclude a written contract or concluded a contract

without the clause submitted. However, this does not rule out the possibility that an individual agreement was reached in connection with the patent in dispute. Such an agreement does not require any special form and is also possible by implication (EPO, decision of 10 October 2023 - G 1/22, para. 100 - Priority entitlement).

117 Nothing else applies with regard to the fact that the employment relationship of one of the eighteen applicants was possibly subject to German law and the assignment agreement concluded with this applicant could therefore be qualified as invalid. Even under these premises, it cannot be ruled out that there was an individual assignment agreement in the case in dispute.

118 bb) Furthermore, in the case in dispute, an agreement between the parties entitling them to claim priority is also implied because the eighteen applicants of the earlier application were also parties to the PCT application from which the patent in suit arose (by way of multiple division) and are named therein as applicants for the United States.

119 c) The fact that the decision of the Enlarged Board of Appeal only became known after the oral proceedings in the present case does not require the reopening of the oral proceedings.

120 On the basis of the German law discussed with the parties, there is no deviating assessment.

121 aa) Under German law, the burden of presentation and proof with regard to the conditions for a valid priority claim also lies with the plaintiffs.

122 (1) In patent nullity proceedings, the burden of proof with regard to all facts from which the nullity of the granted patent is to be inferred shall in principle lie with the nullity action plaintiff.

123 Notwithstanding the principle of investigation applicable in patent nullity proceedings, it is to the detriment of the nullity action plaintiff if the result of the hearing and the taking of evidence has not led to a clear finding in the sense of the claim. After the patent has been duly granted, the patent owner can only be deprived of the legal status obtained thereby if it is established beyond doubt that he obtained it wrongly (Federal Supreme Court (BGH), judgment of 23 January 1990 - X ZR 75/87, GRUR 1991, 522, juris para. 36 - Feuerschutzabschluss; judgment of 12 May 1992 - X ZR 109/. May 1992 - X ZR 109/90, BGHZ 118, 221 = GRUR 1992, 839, juris para. 49 - Linsenschleifmaschine; judgment of 4 May 1995 - X ZR 29/93, GRUR 1996, 757, juris para. 77 - Zahnkranzfräser; judgment of 11 May 2010 - X ZR 51/06, GRUR 2010, 901 para. 32 - Polymerisierbare Zementmischung; judgment of 22 March 2018 - X ZR 128/15 para. 42).

124 (2) The basis for the judgement is generally the parties' submissions.

125 The principle of official investigation standardised in Section 87 (1) PatG merely states that the court is not bound by the submissions and requests for evidence of the parties involved. In nullity proceedings organised as party proceedings, however, it is not the court's task to compile the facts relevant for the decision from vague information provided by the plaintiff or to find out the facts itself from other sources. Rather, it is a matter of impartially weighing up whether the statement of claim justifies the relief sought (Federal Supreme Court (BGH), judgment of 27 August 2013 - X ZR 19/12, BGHZ 198, 187 = GRUR 2013, 1272 para. 36 - Tretkurbeleinheit).

126 (3) With regard to the question of whether a patent rightly claims a priority, it follows from this that it is not the task of the court to determine in detail the actual events which led to the transfer to the patent applicant of a priority right to which other persons were originally entitled and to examine their legal validity. Rather, it

is generally up to the nullity action plaintiff to show circumstances from which the invalidity of the relevant transactions results.

127 Contrary to the plaintiffs' view, this does not impose an unreasonable burden on the nullity action plaintiff. As a rule, the nullity action plaintiff was not involved in the agreements from which the entitlement to claim priority arises. However, if he suspects that the patent applicant may have wrongly claimed the priority right to which a third party is entitled, he is free to question the third party about this. If the third party does not provide any information, this typically indicates that he agreed to the claiming of the priority right.

128 bb) The plaintiffs have not shown any circumstances that could lead to the conviction that at least one of the transfer transactions was ineffective or did not take place.

129 The mere denial of the opposing party's submission with ignorance is not sufficient. The burden of proof with regard to the relevant facts lies with the party bearing the burden of proof, i.e. the plaintiffs in the case in dispute.

130 The fact that the defendant only submitted transfer agreements for some of the eighteen notifying parties does not give rise to any reasonable doubt that an individual agreement was reached in the case in dispute. The same applies to the fact that the agreement with one of the applicants may be invalid if German labor law is applicable.

131 The fact that the eighteen original applicants were also involved in the PCT application and were named therein as applicants for the United States also speaks in favor of the conclusion of individual agreements on the basis of German law.

132 V. The case is ready for a final decision (Section 119 (5) sentence 2 PatG).

133 It follows from the circumstances set out above that claim 12 as defended by auxiliary request 2 is valid.

134 VI. The decision on costs is based on Section 121 (2) PatG and Section 92 (1) Code of Civil Procedure (ZPO).

Bacher Hoffmann Marx

Rombach Rensen

Lower Court:
Federal Patent Court, decision of 29 September 2021 - 3 Ni 12/20 (EP) -