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BGH: *Custodiol I*

The principles of determining the scope of protection also apply without restriction to claims containing numerical and dimensional indications.

Technical background/teaching of the patent

575 The patent in suit, EP 0 054 635, granted with effect in the Federal Republic of Germany, relates to a protective solution for the heart and kidney and a method for its production.[4] The invention intends to improve the protection of the heart and kidney (and others) against damage caused by a stoppage of the blood flow during operations and transplants, by prolonging the ischemia tolerance time (i.e. the period time during which the immobilised organ will survive during the operation). Patent claim 1 has the following wording:

1 'Protective solution for preventing ischemic damage to the heart and kidneys, as well as other organs during operations and transplantations of the organs, characterised in that it contains the following additives per litre:

Potassium or sodium hydrogen α-ketoglutarate	4 ± 3 millimoles
Sodium chloride	15 ± 8 millimoles
Potassium chloride	10 ± 8 millimoles
Magnesium chloride	10 ± 2 millimoles
Tryptophan	2 ± 1 millimole
Histidine	150 ± 100 millimoles
Histidine hydrochloride	16 ± 11 millimoles
Mannitol	50 ± 50 millimoles
Fructose	50 ± 50 millimoles
Ribose	50 ± 50 millimoles
Inosine	50 ± 50 millimoles

the osmolarity of the solution being about 300 to 350 mOsm and the pH of the solution being between 6.8 and 7.4'.

2 The applicant has applied for a supplementary protection certificate […] in respect of that basic patent. In support of that application, the applicant claims that the basic patent protects the pharmaceutical product 'Custodiol', for which it has obtained a marketing authorisation in Germany.

3 The following medicinally active substances are contained in this product at the concentration per litre indicated:

Sodium chloride	15.0 millimoles
Potassium chloride	9.0 millimoles
Magnesium chloride × 6 H_2O	4.0 millimoles
Tryptophan	2.0 millimoles
Histidine	180.0 millimoles

[4] *Custodiol I.* The following summarises mn. 1 et seq. of the decision.

Histidine hydrochloride monohydrate	18.0 millimoles
Mannitol	30.0 millimoles
Calcium chloride × 2 H_2O	0.015 millimole
Potassium hydrogen-2-oxopentanedioate	1.0 millimole

Reasoning

576 The question arises as to whether the basic patent protects a product that, with regard to an ingredient, clearly leaves the quantity range indicated in the basic patent (here: 10 ± 2 mmol/l) (here: in the product 4 mmol/l). With regard to numerical and dimensional indications, the BGH states that such indications are generally open to interpretation, whereby it depends on how the person skilled in the art understands the indications in the overall context of the claim.[5] Fundamentally, the BGH also clarifies the importance of figures and dimensions in the context of the patent claim:

> *10* b) The principles of determining the scope of protection shall also be applied if the patent claim contains numerical or dimensional indications. Such indications participate in the binding character of the patent claim as the decisive basis for determining the scope of protection. The inclusion of numerical or dimensional indications in the claim makes it clear that they are intended to co-determine, and thus also limit the subject matter of the patent […]. It is therefore not possible to regard such indications as less binding, merely exemplary definitions of the protected technical teaching, as has been considered possible in the case law on the legal situation in Germany before the entry into force of Art. 69 EPC and the corresponding revision of national law […].
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> […]
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> *13* […] An unambiguous numerical indication determines and limits the protected subject matter conclusively in this respect; therefore, where these are exceeded or fallen below is as a rule, no longer to be counted as part of the subject matter of the patent claim […].

577 However, a person skilled in the art may consider a certain degree of vagueness, for example including usual tolerances, to be compatible with the technical meaning of a numerical indication. Whether this is the case or whether the precise observance of the indications is important must, however, be determined based on the interpretation of the claim itself.[6]

> *14* […] An understanding that a value must be precisely complied with will, above all, correspond to the person skilled in the art's conception if they recognise that it is a 'critical' value. How a particular numerical or dimensional indication in the patent claim is to be understood is a question of how the person skilled in the art understands it in the individual case, which is subject to the court's assessment of the facts.

578 To determine whether a scope of protection extends beyond the patent claim in the sense of a solution having the same effect, the Court attaches the following importance to these principles:

> *15* e) […] When examining the question as to whether the person skilled in the art can find an embodiment with a numerical value deviating from the claim as a solution having the same effect, on the basis of considerations oriented to the meaning of the invention described in the claim, the limitation of the objective success to be achieved, according to the invention resulting from the numerical specification must be taken into account. An embodiment can only be regarded as having the same effect in the sense of the patent claim if the person skilled in the art can find one that not only achieves the effect of a feature of the invention – limited numerically in the claim – but also precisely the effect which, according to their

[5] *Custodiol I* mn. 11.
[6] *Custodiol I* mn. 12.

understanding, is to be attributed to the numerical limitation of this feature in accordance with the claim. […]

[…]

17 […] It is therefore insufficient for the inclusion of deviating embodiments in the scope of protection that, according to the person skilled in the art's knowledge, the effect according to the invention occurs irrespective of compliance with the numerical value. If no deviating numerical value is apparent to the person skilled in the art as having the same effect in the sense of the value according to the claim, then the scope of protection does not extend beyond the meaning of the patent claim in this respect. In this case, according to the understanding of the person skilled in the art, the claimed effect of the numerically determined feature is defined by the (exact) observance of a numerical value, and can therefore inevitably not be achieved by a deviating numerical value. […]

579 In the case in question, there is no reason for the BGH to extend the meaning of the patent beyond the values set out in the claim. The BGH does not consider an equivalent patent infringement to exist.[7]

B. Scope of protection of substance claims

I. Development and concept

580 In Germany, absolute substance protection for chemical inventions has been the subject of intense debate for more than a century.[8] The Patent Act 1877 initially excluded product protection for chemical patents by law. The amendment of the Patent Act by the Patent Amendment Act of 1967 (Preliminary Act)[9] finally ended the prohibition of substance protection. The BGH decision *Imidazoline*[10] in 1972 can be regarded as the birth of absolute substance protection.

581 For over 50 years, the substance patent has granted unlimited – hence 'absolute' – substance protection, which grants the patent holder a fully exclusive right with regard to any commercial use for the duration of the patent protection. Following *Imidazoline*, the effect of the substance or its possible uses is not the subject matter of the claim and thus cannot be used to limit protection for the substance. Substance protection covers any and all commercial uses, whether or not a use had been identified by the inventor.[11] The protection is neither limited to a particular use nor to a particular manufacturing process.[12] This also applies if the patent description describes (only) one production method or (only) one use. In this case, the technical progress may result from the superior effect of the new substance. Furthermore, the indication of the surprising technical effect does not have to be included in the original application documents, but may be filed subsequently.[13]

[7] For equivalence → mn. 598.

[8] See on the history Bruchhausen, GRUR-FS 1991, 323 (325); Uhrich, Stoffschutz, p. 5 et seq.; Haedicke, GRUR 2010, 94.

[9] BGBl. 1967 I, 953.

[10] BGH, 14.3.1972 – X ZB 2/71, GRUR 1972, 541 – *Imidazoline*; → mn. 583.

[11] *Imidazoline* mn. 54.

[12] BGH, 5.12.1995 – X ZR 26/92, GRUR 1996, 190 – *Polyferon*; → mn. 917 et seq.

[13] *Imidazoline* mn. 16.

II. Substance protection for chemical inventions

582 The *Imidazoline* decision is fundamental to the recognition of absolute substance protection.

BGH: *Imidazoline*

1. Patent protection for substances produced by chemical means shall not be limited to a specific purpose.
2. The technical or therapeutic effect need not be disclosed in the original application documents in the case of a substance invention.

583 The applicant applied for unrestricted substance protection for 2-(2'-chloro-4'-methylanilino)-1,3-diazacyclopentene- (2) and 2-(2'-chloro-4'-ethylanilino)-1,3-diazacyclopentene- (2) comprising substance claims.[14] In its reasoning, the BGH links the comprehensive description of the subject matter of the application to the effect of absolute substance protection:

20 b) […] The invention disclosed therein concerns substances produced by chemical means. In the case of chemical inventions, the technical problem (the task) underlying the invention is to provide a new chemical substance of a more precisely defined type of constitution […]. In the present case, it follows that the technical problem (task) underlying the substance invention disclosed in the original application documents, is to produce imidazolines of a different constitution. In a chemical invention, this problem is solved by creating a new substance or a new chemical compound. Accordingly, in the present application, the solution to this problem consists of the two chemical compounds shown as a formula in claim C, and in their physiologically compatible acid addition salts with inorganic or organic acids. Accordingly, with the problem thus defined and the solution presented, the subject matter of the invention claimed by the present divisional application is comprehensively described. The details of the technical or therapeutic effect of the claimed substances are not part of the subject matter of the substance invention. Therefore, they need not yet be disclosed in the original application documents. […]

21 c) The above description of the subject matter of a chemical invention results in an unrestricted exclusive right of the patent proprietor, with respect to the commercial use of the chemical substances according to the invention. The patent proprietor can prohibit any commercial use of the chemical substances according to the invention, whether they recognised such use or not. Even if a third party finds a non-obvious and therefore inventive use for the chemical substance according to the invention, they are not allowed to use it commercially without the patentee's consent. Thus, the substance protection is in principle, absolute. […]

III. Special features of substance protection for biological material

584 For sequences or partial sequences of plant, animal or other genes, absolute substance protection is also considered possible in principle, since it is unnecessary to include the function of the claimed sequences in the claim here. However, Art. 9 Biotechnology Directive provides that

[14] *Imidazoline* mn. 9.

> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1) [Biotechnology Directive], in which the product is incorporated and in which the genetic information is contained and performs its function.

In *Monsanto Technology*[15], however, the ECJ imposes a general restriction on the absolute protection of material for DNA sequences, irrespective of their origin. The genetic information must be capable of actually fulfilling its function in the material, because the wording makes it clear that fulfilment of the function in the past is insufficient. Furthermore, it is insufficient that the function can only be fulfilled again after a separate introduction into the organism. **585**

1. ECJ: *Monsanto Technology*

1. Art. 9 Biotechnology Directive is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.
2. Art. 9 Biotechnology Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.
3. Art. 9 Biotechnology Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.

Legal background

The ECJ's referral decision is issued in connection with patent infringement proceedings. The decision deals with the scope of substance protection granted by patent claims directed to gene sequences.[16] The case concernes patent protection for a gene sequence the insertion of which into the respective DNA made soybean plants resistant to the herbicide glyphosate. **586**

The question arose as to whether the mere presence of the sequence was sufficient for a finding of infringement of Monsanto's European patent, on the occasion of marketing the meal in the European Community, even though the DNA present in the soy meal was dead material that can no longer perform its function. The question was therefore whether it was sufficient that the DNA had fulfilled its function at some time in the plant or could fulfil it again after it had been isolated from the soy meal and introduced into living material. **587**

Technical background/teaching of the patent

Monsanto is the holder of EP 0 546 090 concerning glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthases. Glyphosate is a non-selective herbicide. In a plant, it blocks the active site of 5-enolpyruvylshikimate-3-phosphate synthases (hereafter EPSPs) class I enzymes, which plays an important role in plant growth. This mode of action results in the death of the plant. The patent describes a subclass of class II EPSPs enzymes that do not respond to glyphosate. Plants with class II EPSPs enzymes **588**

[15] ECJ, 6.7.2010 – Case C-428/08, ECLI:EU:C:2010:402.
[16] ECJ, 6.7.2010 – Case C-428/08, ECLI:EU:C:2010:402.

survive the use of glyphosate, while other plant species die. Monsanto opposed, on the basis of this patent, the importation of soybean meal from Argentina that contained the gene sequence protected in the patent in suit, whereas the imported soybean meal was not protected.

Reasoning

589 The ECJ rules that Monsanto can not oppose the sale of the soy meal solely on the grounds that the DNA was present in the soy meal. The ECJ limits the scope of protection of the patent on gene sequences to the function of the gene sequence indicated in the patent application.[17] There was no absolute protection of the substance, but rather the protection of the substance was limited to its purpose.[18]

590 First, the ECJ turns to the question of whether patent protection is granted if the patented product is contained in soybean meal, where it does not perform the function for which it is patented, but had previously performed that function in the soybean plant from which that meal was obtained as a processed product.[19] The Court also considers the possibility that the product could potentially perform that function again after the material has been isolated from the soy meal and then introduced into the cell of a living organism. In conclusion, the ECJ rejects this extension of patent protection.

591 Next, the ECJ answers the question as to whether Art. 9 Biotechnology Directive provides a final harmonisation of the protection it confers, so that it precludes a national rule that provides for absolute protection of the patented product as such, irrespective of whether or not it fulfils the function it possesses in the material in which it is incorporated:

> *55* It follows from those statements that the Community legislature intended to effect a harmonisation which was limited in its substantive scope, but suitable for remedying the existing differences and preventing future differences between Member States in the field of protection of biotechnological inventions.
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> […]
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> *59* Uniform protection appears to be the means to eliminate or prevent differences between the Member States and to obtain the desired balance between the interests of patent holders and those of other operators whereas, conversely, a minimalist harmonisation approach which would favour patent holders would, on the one hand, compromise the balance sought between the interests at stake and, on the other hand, only entrench or give rise to differences between the Member States, thereby fostering barriers to trade.
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> *60* It follows that the harmonisation effected by Article 9 of the Directive must be regarded as exhaustive.

592 The ECJ goes on to answer the question of whether Art. 9 Biotechnology Directive prevents the proprietor of a patent, granted before the adoption of the Directive, from claiming absolute protection of the patented product conferred by the national provision in force at the time. The ECJ rejects this argument:

> *66* In order to answer that question, it must be borne in mind that, according to settled case-law, new rules apply, as a matter of principle, immediately to the future effects of a situation which arose under the old rule […].
>
> […]
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> *69* The answer to the third question is therefore that Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.

[17] *Monsanto Technology* para. 45.
[18] *Monsanto Technology* para. 47 et seq.
[19] The following summarises para. 36 et seq. of the decision.

2. OLG Düsseldorf: *Lysine*

The ECJ case law in *Monsanto Technology* does not limit the protection of process products, and is not applicable to patents that do not relate to biological material, i.e. any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (§ 2a(3) No. 1 Patent Act = Art. 2(1)(a) Biotechnology Directive).

Technical background/teaching of the patent

The patent in suit relates to a new lysine decarboxylase gene and a process for the preparation of lysine: an essential amino acid required by animal organisms for their growth and tissue repair.[20] However, animals cannot produce lysine themselves, therefore – with the help of fermentation and conversion processes – lysine is produced and added to animal feed. **593**

The task (the technical problem) of the invention protected by the patent in suit is to obtain a new lysine decarboxylase gene from *E.coli*, and to produce a lysine-producing microorganism of the genus *Escherichia*, having restricted expression of the gene and/or the cadA gene and to provide a method for producing lysine by encoding the microorganism of the genus *Escherichia.* **594**

This task is to be solved according to the proposal of the patent in suit in the asserted upheld combination of claims by a method with the following features: **595**

45 1. Lysine is produced by culturing a microorganism in a liquid medium.
2. The microorganism belongs to the genus *Escherichia* and has lysine productivity.
3. The microorganism has a gene,
   a) encoding lysine decarboxylase having the amino acid sequence defined in (A) or (B): (A) the amino acid sequence of SEQ ID NO: 4 of Sequence Listing.
   b) An amino acid sequence with substitution, deletion or insertion of three amino acid residues or less, in amino acid sequence of SEQ ID NO: 4 of the Sequence Listing without substantially affecting lysine decarboxylase activity,
   c) the gene, a promoter sequence of the gene or a region between an SD sequence and an initiation codon of the gene, is modified by substitution, deletion, insertion, addition or inversion of one or more nucleotides in the nucleotide sequence of the gene, promoter sequence or region between an SD sequence and an initiation codon.
   d) The activity of a lysine decarboxylase encoded by the gene has been reduced or eliminated in cells.

   This modification inactivates the Idc gene […].

Reasoning

In its reasoning, the OLG Düsseldorf distinguishes between *Monsanto Technology* and the present case: **596**

80 […] The decision [of the ECJ] deals with the scope of substance protection of patent claims directed to gene sequences. The case there concerned patent protection for a gene sequence which, when inserted into the DNA of soybean plants, made them resistant to the herbicide glyphosate. However, the relevant process claims contained in the patent there were directed to the production of glyphosate-resistant plants, and the soybean meal produced from the beans of correspondingly modified soybean plants was not a process product within the meaning of § 9 sentence 2 No. 3 Patent Act. In this case, however, it is not a question of protecting a substance for a gene sequence contained in the contested product, but rather of protecting a process product (lysine) which was produced using a patent-protected process involving the use of a modified microorganism. The DNA traces of the production organism found in the examined lysine samples, only serve as evidence in the dispute that the

[20] OLG Düsseldorf, 18.7.2013 – I-2 U 100/11, BeckRS 2013, 18738.

microorganism used for the production of the process product was modified in accordance with the requirements, but they do not constitute grounds for patent infringement […]. It is irrelevant for the patent infringing property of the challenged lysine whether DNA traces of the microorganism used for the production can still be found in the lysine marketed by the defendants.

597 Furthermore, the OLG Düsseldorf distinguishes the question of patent infringement by the lysine at issue, from the substance protected in *Monsanto Technology* and explains the term 'biological material':

81 […] On the one hand, the ECJ has not dealt with this issue [note: protection of process products] at all. On the other hand, the defendants overlook the fact that the lysine produced according to the patent in suit is not 'biological material'. According to the legal definition in § 2a(3) No. 1 Patent Act, which is consistent with Art. 2(1)(a) of the Directive on the legal protection of biotechnological inventions, biological material is material that contains genetic information and can reproduce itself or be reproduced in a biological system. The process protected here is used for the production of lysine. This does not contain any genetic information. The process according to the patent in suit is therefore not a process for the production of biological material within the meaning of § 2a(3) No. 1 Patent Act. Thus, the question as to whether lysine is a direct process product does not have to take into account the significance of the function inherent in biological material as claimed by the defendants. […] The process according to the patent in suit uses a modified bacterium and thus microbiological material to produce lysine, which is why it is a microbiological process within the meaning of § 2a(2) of the Patent Act. The lysine produced by this process is indeed a product obtained by a microbiological process. However, it is not biological material within the meaning of § 2a(3) No. 1 Patent Act, for which § 9a Patent Act contains a special provision.

IV. Substance protection for product-by-process claims

1. Concept and admissibility

598 If a product cannot be unambiguously identified either by the indication of a chemical structural formula or by other parameters, a product can also be made by way of a process for its manufacture. In this case, one refers to product-by-process claims: the substance is characterised by the combination of physical features and the process used to produce it. Such claims are characterised by the fact that, although the patent protection is directed to an object, the patent-protected object is – in whole or in part – defined by the process for its manufacture. Case law considers product-by-process claims to be admissible for both chemical and biotechnological inventions.

2. Scope of protection

599 The scope of the property protection afforded by product-by-process claims is directed to the fact that the product is, in principle, protected irrespective of its manufacturing process.

a) BGH: *Trioxane*

600 Although now considered outdated case-law, the decision in *Trioxane* is nonetheless noteworthy because of the distinction drawn on the scope of protection on the basis of the formulations 'obtainable by' and 'obtained by'.[21] The wording 'obtained by', stated that it depended on the specific method of manufacture, whereas in the case of the

[21] BGH, 6.7.1971 – X ZB 9/70, GRUR 1972, 80.