Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2014-02-25
Docket Number / Aktenzeichen:	X ZB 5/13
Name of Decision / Name der Entscheidung:	Collagenase I

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– X ZB 5/13 –
German Patent Appln. 198 13 748.6-41

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English translation of the judgment issued by the Federal Court of Justice
on February 25, 2014

FEDERAL COURT OF JUSTICE

JUDGMENT

X ZB 5/13

of February 25, 2014

in the appeal proceedings

regarding the German Patent Application 198 13 748.6-41

Applicant and Appellant

– Counsel:

Reference book: yes
BGHZ: yes
BGHR: yes

Collagenase I

PatG [German Patent Act] Section 3 Subsection 4, Section 2a Subsection 1 No. 2

a) The subject matter of a patent claim directed to a new use of a drug is the suitability of a known substance for a specific medical purpose and thus ultimately a property inherent to the substance (confirmation of BGH, decision of October 5, 2005 – X ZB 7/03, BGHZ 164, 220, 222 = GRUR 2006, 135, Ann. 11 – *Arzneimittelgebrauchsmuster*). This corresponds, in fact, to a purpose-limited substance protection as is now also explicitly provided for in Section 3 Subsection 4 PatG and Art. 54(5) EPC for further indications, independently of whether the wording of the patent claim is directed to the use of the drug, its preparation for use for a certain purpose, or explicitly to purpose-limited substance protection.

b) The specific use of a substance for a therapeutic treatment is not only determined by the disease to be treated and the dosage of the substance but also by other parameters which influence the effect of the substance and can therefore be of essential significance for achieving the desired success of the use.

c) Due to Section 2a Subsection 1 No. 2 PatG, instructions regarding therapeutic treatment can only contribute to patentability if they objectively aim at allowing, reinforcing, accelerating or otherwise improving the effect of the substance, but not if they relate to therapeutic measures which are additionally suitable, independently of the effects of the substance, for treating the disease at issue.

PatG Section 4

In the assessment of whether a specific use of a drug is based on inventive step, methods which were obvious to the person skilled in the art because they were part of the standard medical repertoire at the priority date have to be taken into account as well.

BGH [Federal Court of Justice], judgment of February 25, 2014 – X ZB 5/13 – Federal Patent Court

On February 25, 2014, the X. Civil Senate of the Federal Court of Justice presided over by Judge Prof. Dr. Meier-Beck, with Judges Dr. Grabinski, Dr. Bacher, and Hoffman and Judge Schuster

has found:

> Following the appeal on a point of law, the decision issued by the 14th Senate (Technical Board of Appeal) on December 11, 2012 is set aside. The matter is remanded to the Federal Patent Court for a new hearing and decision.

Grounds:

A. The appeal on a point of law is directed to the refusal of a patent application.

The application was filed on March 27, 1998, claiming a priority of March 27, 1997, and is directed to the use of collagenase for treating Dupuytren's disease. The latest valid wording of claim 1 reads as follows:

> Collagenase for use in treating Dupuytren's disease wherein the collagenase has been adapted for injection into a fibrous Dupuytren's cord of a hand of a total amount of at least 8,000 ABC units of collagenase in a concentration of about 15,000 to about 75,000 ABC units per ml carrier, and for immobilizing the hand immediately after injection for several hours.

The Patent Office refused the application on the grounds that the subject matter of the claim is not based on an inventive step. Applicant's appeal was unsuccessful. It is against that decision that the Applicant filed an appeal on a point of law allowed for by the Patent Court.

B. The appeal on a point of law, which is allowable as a legal remedy and also otherwise admissible, results in the decision under appeal being set aside and the matter being remanded to the Federal Patent Court.

I. The application is directed to a purpose-limited substance protection for collagenase for the treatment of Dupuytren's disease.

1. According to the statements in the application, Dupuytren's disease is characterized by thickening and contracture of the connective tissue (fascia) of the palm, usually progressing to flexion deformities and involvement of one or more fingers. According to the application, the most commonly performed therapy is the surgical removal of the affected connective tissue. Other methods mentioned in the application include the injection of collagenase into the fibrous cord.

The application does not specifically state which technical problem is addressed by the invention. It can be inferred from the description that the invention is directed to providing an improved use of collagenase for treating Dupuytren's disease.

2. For solving this problem, the application suggests the following use of collagenase according to the primarily sought wording of claim 1, whose features can be structured as follows:

0. The use is for treating Dupuytren's disease.

1. The collagenase is injected into a fibrous Dupuytren's cord of a hand.

2. The injected total amount is at least 8,000 ABC units of collagenase.

3. The concentration is about 15,000 to about 75,000 ABC units per ml carrier.

4. Immediately after injection, the hand is immobilized for several hours.

II. The Federal Patent Court essentially substantiated their decision as follows:

The subject matter of claim 1 is suggested by the prior art.

Feature 4, according to which the hand is to be immobilized immediately after

injection must not be taken into account in the assessment of patentability. This feature is not an element of the preparation of a substance for use in the treatment of a disease. It does not serve to characterize the claimed collagenase or the formulation intended for administration. Rather, it is a mere instruction for the attending physician and thus relates to a therapeutic process which is excluded from patent protection. The previous decisions of the Enlarged Board of Appeal of the European Patent Office and the case law of the British courts do not suggest otherwise. The relevant decisions relate to novel dosage instructions. They are not comparable to the constellation to be evaluated here.

Independently, the subject matter of claim 1 is not even based on an inventive step if feature 4 is taken into account. The high dosages provided in features 2 and 3 inevitably lead to an immobilization of the hand in order to prevent a diffusal of the collagenase and possible complications resulting therefrom. This precaution is known to the attending physician from daily practice to prevent side effects.

III. This substantiation cannot withstand legal review.

1. Contrary to the opinion of the Federal Patent Court, feature 4 has to be taken into account in the examination of whether the subject matter of the application is patentable.

a) As the Patent Court correctly stated, patent protection can be sought for a substance for treating a disease – be it in the form of a use claim, be it in the form of a claim directed to purpose-limited substance protection according to Section 3 Subsection 4 PatG in the version in force since December 13, 2007 – even if the use for which the protection is sought only differs from the uses known in the prior art in a different dosage regimen.

aa) The Senate has repeatedly decided that patent protection for these constellations is possible if the patent claim provides that the drug is adapted for use in the dosage in question (BGH, decision of December 19, 2006 – X ZR 236/01, BGHZ 170, 215 = GRUR 2007, 404 Ann. 51 – *Carvedilol II*; decision of September 24, 2013 – X ZR 40/12,

GRUR 2014, 54 Ann. 34 – *Fettsäuren*).

The subject matter of such a patent claim is the suitability of a known substance for a specific medical use and thus ultimately a property inherent to the substance (BGH, decision of October 5, 2005 – X ZB 7/03, BGHZ 164, 220, 222 = GRUR 2006, 135, Ann. 11 – *Arzneimittelgebrauchsmuster*). In fact, this corresponds to purpose-limited substance protection as it is now explicitly provided in Section 3 Subsection 4 PatG and Art. 54(5) EPC for further indications. This applies independently of whether the wording of the patent claim is directed to the use of the drug, its preparation for a certain purpose, or – which in view of the new legal provision will probably be most expedient in the future – explicitly to purpose-limited substance protection.

bb) This is consistent with the previous decisions of the European Patent Office and the case law in other contracting states of the European Patent Convention.

According to the previous decisions of the European Patent Office, the medical use of a substance or substance mixture was even patentable according to the version of the European Patent Convention in force prior to December 12, 2007 if the new use is not the treatment of a different disease. The stipulation of Art. 54(5) EPC in force since December 13, 2007 – which, concerning its contents, corresponds to Section 3 Subsection 4 PatG – only changed this fact in that such uses now exclusively have to be purpose-limited substance claims instead of the previously mandatory claims worded in the Swiss format (decision of the Enlarged Board of Appeal of February 19, 2010 – G 2/08, OJ 2010, 456 Ann. 5.10.7 et seq. – *Dosierungsanleitung*/Abbott Respiratory with further references). According to both versions of the Patent Convention, patent protection is not excluded, either, if the only feature not included in the prior art is a dosage regimen (*loc. cit.* Ann. 6.1 et seqq.). The Court of Appeal for England and Wales (Actavis UK Limited v. Merck & Co. Inc., [2008] EWCA Civ 444 Ann. 44 et seqq.) and the Swiss *Bundesgericht* (Federal Supreme Court of Switzerland) (decision of March 4, 2011 – 4A_435/2010, GRUR Int. 2012, 183, 186 et seq.) take the same view.

Both the Enlarged Board of Appeal and the Court of Appeal have reached the correct conclusion that the decision "*Carvedilol II*" does not contain anything to the contrary. The concerns expressed therein only refer to claims wordings which are directed to a pure dosage regimen completely removed from the adaptation for use of the substance. Whether these concerns should be taken into account in view of the legal provisions in force since December 13, 2007 is irrelevant in the present context. In any case, they are irrelevant if the claim is directed to a purpose-limited substance protection in the sense of Art. 54(5) EPC or Section 3 Subsection 4 PatG. This also applies independently of whether the wording of the claim is directed to the use of the drug, its preparation, or the protection of a substance for a limited use.

b) The same applies to instructions which do not relate to the dosage regimen but to other modalities of the claimed use.

aa) The Enlarged Board of Appeal has decided that a specific use (*eine spezifische Anwendung, toute utilization spécifique*) in the sense of Art. 54(5) EPC in the version in force since December 13, 2007 does not have to constitute the treatment of a different disease.

The revised version of the regulation was essentially designed to anchor the previous decision-making practice of the European Patent Office in the Patent Convention (EPO, OJ 2010, 456 Ann. 5.10.3 et seq. – *Dosierungsanleitung*/Abbott Respiratory). According to previous decisions of the European Patent Office, patent protection cannot only be sought for uses for treatment of a different disease or with a different dosage regimen. Rather, it is sufficient if the use differs from the uses known in the prior art – i.e. if it is novel – and if it is based on an inventive step. For this reason, patent protection was for example granted if the use related to a new group of patients to be treated, a new method of administration or another technical effect (*loc. cit.* Ann. 5.10.7 with further references).

bb) The same applies to the German patent law.

In this respect, the wording of Section 3 PatG corresponds to the wording of Art. 54 EPC. In 2007, it was adapted to the revised version of the Patent Convention in order to maintain the parallelism of European and national law (BT public. 16/4382, page 11). In view of this alone, it is out of the question that patentability should be evaluated differently according to German law than according to the Patent Convention.

In the Senate's view, the interpretation of Art. 54(5) EPC underlying the established case law of the European Patent Office is correct. The new version of the regulation does not make the grant of purpose-limited substance claims conditional on whether the protection sought is directed to a disease whose treatment with the substance at issue was not known in the prior art. Rather, a patent can be granted on any specific use of a substance in a process for the surgical or therapeutic treatment of the human or animal body if it is novel and inventive. The legal situation prior to December 13, 2007 was no different in this respect. As was already stated, the insertion of Art. 54(5) EPC and Section 3 Subsection 4 PatG was not intended to modify but rather to codify this situation.

Limitations to certain aspects of the use – for example to the dosage – are excluded by the very wording of the mentioned regulations. It would not be possible to reconcile them with the intents and purposes of these regulations anyway. The specific use of a substance for the therapeutic treatment is not only defined by the disease to be treated and the dosage. Rather, depending on the circumstances of the individual case, the method of administration (for example, orally, transdermally, or by way of different kinds of injections), the consistency of the substance (solid, liquid, gaseous), the patient group, or other parameters are relevant as well. All these parameters have in common that they influence the effect of the substance, i.e. that they can be of essential significance for achieving the desired success of the use. In any event, if a use not known in the prior art nor suggested to the person skilled in the art offers the prospect of improving the effects of the substance or of bringing about these effects under conditions previously considered impossible, it is the goal of the law to grant patent protection, as long as the other requirements for patentability are met as well.

cc) No different assessment can be inferred from Section 2a Subsection 1 No. 2 PatG and Art. 53(c) EPC.

According to these regulations, patents shall not be granted for processes for the treatment of humans or animals by surgery or therapy. Even in accordance with the established case law of the Senate regarding the previous version of the law, this did not exclude the grant of patents for the use of a chemical substance for therapeutic purposes and thus their obvious adaptation for use in such a process (basic ruling, BGH, decision of September 20, 1983 – X ZB 4/83, BGHZ 88, 209, 216 et seqq. = GRUR 1983, 729, 730 et seqq. – *Hydropyridin*). The same has to apply according to the current version of the law which explicitly provides for a limited substance protection for such inventions.

Under this aspect as well, patentability cannot depend on whether the use for which protection is sought is directed to a disease which has previously not been treated with the substance or to the dosage regimen. Just like all other aspects of the effect of the substance, the treatment of a patient with a certain drug and its dosage are an integral part of the physician's activity. If the exclusion from patentability referring to this activity does not contradict the patentability of this substance limited to certain uses, this has to, in principle, apply to all the aspects of said use.

However, according to Section 2a Subsection 1 No. 2 PatG and Art. 53(c) EPC, the assessment of patentability must not take into account those aspects of the use which are not related to the properties of the substance for which protection is sought, and to its effect on the human or animal body. Therefore, instructions regarding therapeutic treatment can only contribute to patentability if they objectively aim at allowing, reinforcing, accelerating or otherwise improving the effect of the substance, but not if they relate to therapeutic measures which are additionally suitable, independently of the effects of the substance, for treating the disease at issue.

c) In the present constellation to be evaluated, the use to which the desired purpose-limited substance protection refers shows the required connection with the effect of

the substance.

According to the explanations in the application, the immobilization of the hand for several hours immediately after injection according to feature 4 serves the purpose of minimizing expression of the collagenase solution out of the cord and allowing sufficient but not excessive time for action of the collagenase on the cord (column 2, lines 49 to 53). This corresponds to the actual findings of the Federal Patent Court, according to which the immobilization of the hand is intended to prevent diffusal of the highly dosed active ingredient into the patient's body.

Thus, the immobilization of the hand is not only an additional measure for treating Dupuytren's disease independent of the effects of the collagenase. Rather, the measure is intended to improve the effect of the administered substance. Thus, it relates to the way the substance is used and therefore to an aspect which – regardless of the exclusion from patentability according to Section 2a Subsection 1 No. 2 PatG and Art. 53(c) EPC – has to be taken into account in the assessment of patentability.

Contrary to the view of the Federal Patent Court, instructions which chemically or physically characterize the formulation intended for administration are not the only ones which should be considered. A dosage instruction does not necessarily influence the chemical or physical composition of the substance, either. It can, as was initially realized by the Federal Patent Court as well, be limited to the information that the drug should be administered at a certain dosage. The same applies analogously with respect to the method of administration. For instance, the instruction to administer the substance orally or transdermally may require certain types of dosage forms. However, as far as the protected use is concerned, the limited substance protection also refers to those dosage forms which can be administered in different ways. This also applies to the usage instructions at issue – injection immediately followed by immobilizing the hand for several hours.

2. Even in view of the Federal Patent Court's additional reasoning, the decision under appeal cannot be upheld.

a) However, contrary to the view expressed in the appeal on a point of law, the decision under appeal is not based on an error of law simply because the Federal Patent Court did not provide any references in the literature to substantiate their opinion that the immobilization of the hand after injection is a common measure.

aa) As the appeal on a point of law recognizes, it is not sufficient for the affirmation of patentability that the instruction to administer a certain substance in a certain way is novel, i.e. that it is not clearly and unambiguously disclosed in the prior art for this substance. Rather, the assessment of inventive step also has to take into account methods which were obvious to the person skilled in the art because they were part of the standard medical repertoire at the priority date. In particular in the case of measures which are not intended to produce an effect specific to the substance at issue but rather to prevent undesired effects of a general nature or to limit the effects of the substance in terms of location or time, it will often be a matter of chance whether the application of this measure can be documented just so for a certain substance as well. At any rate, such documentation is not necessary if it is certain that at the priority date the person skilled in the art considered the measure at issue as a general means for a number of applications, and that there were no special circumstances which would make the application appear impossible or unfeasible in the specific constellation to be evaluated.

bb) In view of this background, the legal conclusion of the Federal Patent Court cannot be objected to per se.

According to the statements of the Federal Patent Court, it is a common measure to immobilize a body into which a high dose of a drug has been injected for several hours if the drug is supposed to develop its effect only close to the injection site. If so, no additional suggestion was necessary in the prior art to also consider this measure for the application at issue.

According to the application, the effect of the collagenase is the cleaving of the

collagen contained in the thickened connective tissue (column 2, lines 14 et seq.). The administration by injection into the affected connective tissue, which is known from the prior art and described in the application, releases the active ingredient directly at the location where its effect should take place. In view of the foregoing, the person skilled in the art has every reason, especially given the relatively high dose claimed in the application, to ensure that the effect is limited to a certain area by common additional measures even without specific suggestions in the prior art. According to the Federal Patent Court, these common measures include immobilizing the body part in question.

b) Nonetheless, the decision under appeal cannot be upheld because the Federal Patent Court failed to point out this aspect to the Applicant prior to the decision.

aa) It is true that a court does not have to inform the parties to the proceedings how they will likely acknowledge the facts on which their decision will be based. Rather, it is usually sufficient if the legal and factual situation is discussed and the parties are thus shown which aspects will likely be of importance for the decision (BGH, decision of April 15, 2010 – Xa ZB 10/09, GRUR Int. 2010, 761 Ann. 22 – *Walzenformgebungsmaschine*; decision of November 28, 2012 – X ZB 6/11, GRUR 2013, 318 Ann. 10 – *Sorbitol*, each with further references). However, the requirements resulting from Section 93 Subsection 2 PatG and Art. 103(1) GG [*Grundgesetz*, German Basic Law] are not satisfied if the parties to the proceedings are unable to recognize, while practicing the due diligence that can be expected, which submissions may and will be relevant for the court's decision (BGH, GRUR 2013, 318 Ann. 10 – *Sorbitol*, with further references). For example, a procedural error has been committed if the patent court denies patentability on the basis of a prior art publication which the Opponent only mentioned in passing in connection with another claimed ground for opposition without first pointing out to the Patentee that this publication could be detrimental to patentability (BGH, decision of September 8, 2009 – X ZB 35/08, GRUR 2009, 1192 Ann. 16 – *Polyolefinfolie*; decision of April 12, 2011 – X ZB 1/10, GRUR 2011, 656 Ann. 7 – *Modularer Fernseher I*).

In the present dispute it cannot be inferred from the files that prior to issuing their

decision, the Federal Patent Court pointed out to the Applicant that patentability could be denied for the reasons set forth above when also taking into account feature 4. Such an indication was not required from the legal point of view of the Federal Patent Court because they already considered patentability to be lacking for different reasons. However, they were not to base their decision on a further, independently weighing deliberation without giving the Applicant the option of commenting thereon first.

bb) Even though the appeal on a point of law only provides a cursory glance at what the Applicant would have submitted in the appeal proceedings had they been given a corresponding suggestion, it cannot be completely excluded that the Federal Patent Court would have reached a different conclusion when taking into account these submissions.

It is claimed in the appeal on a point of law that in reply to a corresponding suggestion, the Applicant would have explained that, and why, the immobilization of the body part at issue was not a known measure the attending physician would routinely perform, at least not in connection with the injection of collagenase, and that it therefore constituted a significant contribution to the state of the art.

These arguments do not necessarily lead to the affirmation of patentability. However, based on the protective purpose of Section 93 Subsection 2 PatG, Applicant has to have the option, in the present procedural situation, to submit their arguments to the Patent Court so that the court can examine whether and to what extent further clarification of the fact situation is necessary. Against this background, it cannot be excluded that the decision under appeal was based on the claimed procedural error.

IV. In view of Section 109 Subsection 1 Sentence 1 PatG, no order for payment of costs is deemed appropriate. Applicant is the only party to the proceedings.

V. The Senate did not consider it necessary to schedule oral proceedings (Section 107 Subsection 1 Half-sentence 2 PatG).

Meier-Beck Grabinski Bacher

Hoffmann Schuster

Previous instance:
Federal Patent Court, decision of December 11, 2012 – 14 W(pat) 12/09 –