Reference Work: yes
BGHZ: yes
BGHR: yes

Dipeptidyl peptidase inhibitors

PatG (German Patent Act) section 21 para. 2 no. 1, PatG section 34 para. 4

a) The patent applicant is in principle at liberty not to limit the claimed protection to embodiments that are explicitly described in the documents originally filed, but to make certain generalisations, provided that this takes account of the legitimate desire to cover the invention in its entirety.

b) Whether the wording of a patent claim that contains a generalisation satisfies the requirements of an enabling disclosure depends on whether a scope of protection is sought which does not extend beyond what would appear to a person skilled in the art, in view of the specification and the exemplary embodiments contained therein, to be the most generalised technical teaching by which the problem underlying the invention is solved.

c) Describing a group of compounds according to their function in a use claim is not precluded by the fact that claim wording of this kind encompasses not only compounds that are already known or are disclosed in the patent specification, but also the use of compounds that will only be provided at some time in the future; nor is it precluded by the fact that the provision of such compounds may require inventive activity.

BGH, decision of 11th September, 2013 - X ZB 8/12 - Federal Patent Court

FEDERAL COURT OF JUSTICE

DECISION

X ZB 8/12

dated

11th September, 2013

in the appeal on points of law

concerning the German Patent 196 16 486

Royalty Pharma Collection Trust, Wilmington (United States of America)

Patentee and Appellant -

- Counsel: Attorneys-at-law, Dipl.-Phys. Engel and Rinkler -

On 11th September, 2013, the 10th Civil Division of the Federal Court, sitting with the Presiding Judge Prof. Dr. Meier-Beck and Judges Dr. Bacher, Hoffmann, Dr. Schuster and Deichfuss

held:

Following the Patentee's appeal on points of law, the decision of the 14th Panel (Technical Appeal Panel) of the Federal Patent Court of 13th March, 2012, is set aside.

The case is remitted to the Patent Court for a new hearing and decision.

Reasons:

1 A. On 25th April, 1996, the Patentee's predecessor in title filed an application for a patent for the use of dipeptidyl peptidase effectors for lowering blood sugar levels. Claim 1 of patent 196 16 486 (the patent in suit), which was granted on the basis of that application, reads:

> "The use of dipeptidyl peptidase (DP IV) enzymatic activity effectors, or effectors for enzymatic activity analogous to DP IV, for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism."

2 Two oppositions were filed against the patent. Following the opponents' withdrawal of their oppositions, the Opposition Division of the Patent Office continued the opposition proceedings on its own motion, and, with its decision of 21st March, 2007, maintained the patent in amended form. The claim as amended according to the Patentee's Auxiliary Request 2 read as follows:

> "Oral use of aminoacyl thiazolidides or alanyl pyrrolidide as inhibitors of dipeptidyl peptidase (DP IV) enzymatic activity for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism, wherein administration of the aminoacyl thiazolidides or alanyl pyrrolidide to mammals serves to prevent or alleviate diabetes mellitus."

3 The Patentee filed an appeal against that decision and requested that the patent be maintained on the basis of a revised Main Request or, in the alternative, based on a number of Auxiliary Requests. The Main Request and Auxiliary Requests 1aa and 1ac read:

> Main Request:
>
> Use of inhibitors of dipeptidyl peptidase (DP IV) enzymatic activity for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism with diabetes mellitus.
>
> Auxiliary Request 1aa:
>
> Oral use of dipeptidyl peptidase (DP IV) enzymatic activity inhibitors for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism with diabetes mellitus using high-affinity, low-molecular-weight enzyme inhibitors.
>
> Auxiliary Request 1ac:
>
> Oral use of dipeptidyl peptidase (DP IV) enzymatic activity inhibitors for lowering blood sugar levels below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism with diabetes mellitus, said DP IV inhibitors being alanyl pyrrolidine, aminoacyl thiazolidide, N-valyl prolyl or O-benzoyl hydroxylamine.

4 The Patent Court maintained the patent on the basis of a claim in accordance with Auxiliary Request 1ac, an adapted description and the drawings; apart from that, it dismissed the appeal. The Patentee filed an appeal on points of law against the decision, as allowed by the Patent Court, requesting that the contested decision be set aside and that the case be remitted to the Patent Court.

5 B. The appeal on points of law, which is admissible by virtue of having been allowed and also in other respects, is successful and leads to the contested decision's being set aside (PatG [German Patent Act] section 108 para. 1).

6 I. The patent relates to the use of certain compounds for lowering blood sugar levels in mammals.

7 1. In the state of the art, it was known to administer insulin in order to influence pathologically elevated blood sugar levels (hyperglycaemia). In the description of the patent in suit, it is explained that previously known conventional methods are often associated with the use of a considerable amount of material, high costs and often also a drastic impairment of the patient's quality of life. Newer methods such as installing subcutaneous depot implants or the implantation of intact islet of Langerhans cells are technically complex and risk prone.

8 Against this backdrop, the patent in suit relates to the technical problem of providing a simple, cost-effective and, for the patient, minimally invasive procedure for lowering blood sugar levels.

9 2. To solve this problem, the only remaining claim as defended with the Main Request proposes:

1. The use of dipeptidyl peptidase IV (DP IV) enzymatic activity inhibitors

2. for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism

3. in cases of diabetes mellitus

10 II. In the written reasons for the contested decision, the Patent Court essentially explained that the use pursuant to the Main Request and Auxiliary Requests 1a, 1aa and 1ab was not disclosed in a manner sufficiently clear and complete for it to be carried by a person skilled in the art. The only claim of the Main Request claimed the use of inhibitors, which were characterised only by their reaction with DP IV, i.e. by functional features. That meant they would include a non-limitable number of compounds with the same functionality, regardless of their actual compositional features. The skilled person, viz. a team comprising a biochemist, a chemist specialising in organic chemistry and a physician specialising in internal medicine focused on diabetology, received no guidance as to what compounds he might also consider, in addition to the four dipeptide derivatives mentioned, in order to solve the problem. It was not apparent what, apart from the four compounds mentioned, was to be subsumed under the term "inhibitor" with the effect specified in the claim. In order to identify such compounds, a large number of complex experiments would be necessary, for which the skilled person found no instructions in the patent specification. Thus, the subject matter of the claim was not sufficiently disclosed. Because of the general wording of the solution made available to the skilled person in the entirety of the application documents, the subject matter claimed was generalised to such an extent that the patent protection sought went beyond the contribution of the invention to the prior art teaching. The claim according to the Main Request also violated the public's interest in legal certainty, since it was not discernible to a third party what was protected. Whether it was a pioneering invention, as the Patentee maintained, was irrelevant,

since enablement depended on the active agents to be used for the purpose stated in the claim. These already needed to be disclosed in individualised form in the application documents as initially filed, without recourse to the common general knowledge of the skilled person. The solution was not the explanation of the mode of action, i.e. that blood sugar levels could be reduced by the inhibition of the DP IV enzyme. Rather, the solution was to be seen in providing the specific means by which the desired success could be achieved. This was also true of Auxiliary Requests 1a, 1aa and 1ab.

11 III. This assessment does not stand up to legal review in one crucial point.

12 1. The requirement of an enabling disclosure of the invention does not generally preclude wording a patent claim with a certain degree of generalisation.

13 a) As the point of departure, the Patent Court rightly assumes that a patent is to be revoked in opposition proceedings if it does not sufficiently disclose the invention. PatG section 34 para. 4 stipulates that the invention is to be disclosed in a manner sufficiently clear and complete for it to be carried by a person skilled in the art. According to PatG section 21 para. 1 no. 2, the patent shall be revoked in opposition proceedings if this requirement is not met. The requirement of a clear and complete disclosure of the invention is intended to ensure that the monopoly right that is granted to the applicant corresponds to the scope of the invention which it provides to the general public.

14 While the Patent Court also objected to the wording of the claim on the grounds of lack of clarity, this is not a ground for revocation. The elimination of avoidable ambiguities has to be done in the examination procedure. Quite apart from that, the Patent Court's reasoning in this respect is not correct. The fact that a multitude of compounds are potentially covered by dipeptidyl peptidase inhibitors does not render the claim unclear.

15 b) In general, the applicant is at liberty not to limit the protection claimed to embodiments which are described explicitly in the documents originally filed but to make certain generalisations. If a patent claim contains generalised wording, this can result in its also encompassing embodiments that are not specifically addressed in the description. However, it does not necessarily follow that the invention is wholly or partially no longer sufficiently disclosed for it to be put into practice by the skilled person. Rather, the circumstances of the individual case are decisive.

16 If protection is being sought for a product, the applicant is in principle required to describe the subject matter in terms of its physical characteristics. If it concerns the protection of a chemical substance, this can, for instance, be described by its scientific name or its structural formula. However, the characterisation may be provided in some other way if it is otherwise impossible or impractical to capture the teaching disclosed.

17 The same applies, *mutatis mutandis*, to other categories of claims. In the case of a patent on a method of chemical synthesis, a particular process step may still be claimed in the form of a common reaction described in general terms, even if established methods of carrying out the reaction fail but the patent specification discloses at least one feasible way of performing that reaction. This generalisation is permissible if, from the point of view of the skilled person, the reaction described in general terms – and not just the specific reaction set forth in the specification – can be understood as part of the solution (Federal Court of Justice, judgment of 3rd May, 2001 - X ZR 168/97, BGHZ - German Supreme Court Official Journal for Civil Matters - issue 147, 306, 317 et seq. - Taxol; see also

Meier-Beck, Festschrift für Ullmann, 2006, 495, 501). If, in such a case, one were always to limit the protection to the reaction specifically described, this could result in the property right's not encompassing the full scope of the invention.

18 On the other hand, generalised wording in a claim contravenes the requirement of a clear and complete disclosure if that wording generalises the scope of protection conferred by the patent beyond the inventive solution provided to the skilled person by the description (Federal Court of Justice, judgment of 25th February, 2010 - Xa ZR 100/05, BGHZ issue 184, 300, 306 et seq. -Thermoplastische Zusammensetzung [Thermoplastic composition]; Federal Court of Justice, judgment of 27th November, 2012 - X ZR 58/07, BGHZ issue 195, 364 no. 38 - Neurale Vorläuferzellen [Neural precursor cells] II; cf. also EPO Technical Board of Appeal, decision of 9th March, 1994 - T 435/91, GRUR Int. 1995, 591, no. 22.1 - Reinigungsmittel [Detergent]/UNILEVER). It is also inadmissible to characterise a thing or a process to which an invention relates by means of parameters which only describe the problem underlying the invention (Federal Court of Justice, decision of 19th July, 1984 - X ZB 18/83, BGHZ 129, 135 et seq. - Acrylfasern [Acrylic fibres]).

19 In view of these criteria, it may be admissible to list a group of compounds in a claim in generalised form, even if not all the compounds belonging to that group are suitable for the purpose of the invention, provided that a skilled person can easily determine the suitability of the individual compounds by means of experiments (Federal Court of Justice, judgment of 22nd December, 1964 - Ia ZR 27/63, GRUR 1965, 473, 475 - Dauerwellen [Permanent waves]; Federal Court of Justice, decision of 9th October, 1990 - X ZB 13/89, BGHZ issue 112, 297, 305 - Polyesterfäden [Polyester filaments]). The fact that such a claim also covers compounds which do not yet exist, or which have not yet been identified, does not give grounds for concern. If employing them makes use of the invention, it does not matter if compounds are also covered which cannot be identified without inventive activity.

20 c) It is in line with these principles that, according to the case law of the Technical Boards of Appeal of the European Patent Office, it is permissible to choose a functional feature, if the underlying generalisation takes account of the legitimate interest in covering the entire scope of the invention (EPO Technical Board of Appeal, decision of 27th November, 1986 - T 68/85 no. 8.4 - Synergistische Herbizide [Synergistic herbicides] /CIBA-GEIGY; decision of 27th January, 1988 - T 292/85 nos. 3.1.2 to 3.1.5 - Polypeptide Expression/GENENTECH I; decision of 8th May, 1996 - T 694/92, GRUR Int. 1997, 918 - Modifying plant cells/MYCOGEN; see also Lord Hoffmann in House of Lords, judgment of 31st October, 1996, RPC 1997, 1, 47 et seq., German translation in GRUR Int. 1998, 412, 417 - Biogen v. Medeva; also recently Lord Justice Kitchin in Court of Appeal, judgment of 21st February, 2013 - [2013] EWCA Civ 93 nos. 94 et seq.). There is no conflict between this and the fact that a functional definition of the feature encompasses the use of currently unknown possibilities which might only be provided or invented in the future, if this is the only way to ensure appropriate protection (EPO Technical Board of Appeal, decision of 27th January, 1988 - T 292/85 no. 3.1.2 - Polypeptide Expression/GENENTECH I). In such a case, the invention is in principle sufficiently disclosed if it provides the skilled person with at least one way of carrying it out. The need for a sufficiently clear and complete disclosure does not, on the other hand, require the description to contain indications as to how all conceivable variants of the components which are covered by the functional definition can be realised (EPO Technical Board of Appeal, decision of 27th January, 1988 - T 292/85 no. 3.1.5 - Polypeptide Expression/GENENTECH I). If one were to stipulate such a

requirement, a generalised definition of the claim would always fail to comply with the requirement of a clear and complete disclosure.

21 Whether a claim containing generalised wording is permissible thus depends in the individual case on whether protection is sought which extends beyond what appears to a skilled person, taking into account the description and the example embodiments, to be the most general form of the technical teaching which solves the problem underlying the invention (EPO Technical Board of Appeal, decision of 9th March, 1994 - T 435/91, GRUR Int. 1995, 591 no. 2.2.1 - Reinigungsmittel/UNILEVER; decision of 8th May, 1996 - T 694/92, GRUR Int. 1997, 918 no. 5 - Modifying plant cells/MYCOGEN; Meier-Beck, Festschrift für Ullmann, 2006, 495, 502).

22 2. In accordance with these principles, the contested decision by the patent court cannot prevail.

23 The claim of the Main Request contains a functional feature. Claimed is not only the use of a specific compound or a plurality of specifically defined compounds to lower blood sugar levels in the case of diabetes mellitus, but rather the use of any and all compounds which act as dipeptidyl peptidase IV (DP IV) inhibitors. Contrary to the view of the Patent Court and Technical Board of Appeal 3.3.02 of the European Patent Office, which revoked the European patent no. 896 538 on similar grounds, wording the claim in this way cannot, in and of itself, serve as the basis for objecting on the grounds of insufficiency of disclosure.

24 Although the wording of the claim covers not only the dipeptide derivatives specifically referred to in the description, but any and all dipeptidyl peptidase inhibitors, this alone is not enough to establish insufficiency of disclosure, as explained. The facts and circumstances underlying the decision on the appeal on points of law do not justify the presumption that the wording of the claim according to the Main Request goes beyond what a skilled person would gather from the patent specification as the most general form of the technical teaching described.

25 a) According to the patent specification, the invention concerns a simple procedure to lower blood sugar levels. The technical problem is described as providing a low-cost and simple procedure for lowering blood sugar levels. The problem is supposed to be solved by administering dipeptidyl peptidase inhibitors. According to the details in the description, the underlying reasons are as follows: the consumption of food and the associated rise in the blood sugar level lead to the release of specific incretins, which are known as GIP_{1-42} and GLP-1_{7-36}. These incretins cause an increased secretion of insulin and, at the same time, reduce the secretion of glucagon, a peptide hormone causing a rise in blood sugar levels. In healthy human beings, they ensure that blood sugar levels are not excessive. This mechanism may be impaired by a disease such as diabetes mellitus. Nonetheless, even in type 2 diabetes patients, GLP-1_{7-36} retains its ability to increase insulin secretion and to reduce glucagon secretion.

26 The stability of these endogenous incretins is affected by the activity of the enzyme dipeptidyl peptidase. The administration of an inhibitor suppresses or reduces the activity of that enzyme, thus leading to an increased endogenous stability of the incretins referred to. This in turn leads to increased insulin levels and, ultimately, to a decrease in the elevated blood sugar level.

27 b) In the absence of findings to the contrary in the decision under appeal, the factual statements offered by the Patentee concerning the scope of the invention as described in the patent specification must be taken as the basis when assessing the appeal on points of law; the patent court in principle did the same when assessing the patentability of the subject matter of Auxiliary Request 1 ac.

28 According to those statements, the significance of the above-mentioned endogenous incretins for the blood sugar level and the impairment of their stability by dipeptidyl peptidase were known at the priority date. The efforts to influence that mechanism for therapeutic purposes went in different directions, however. For instance, it was attempted to deliver additional incretins to patients (exogenously), or to search for analogous incretins which were not influenced by DP IV. The targeted use of dipeptidyl peptidase inhibitors was known *per se*, though only for other therapeutic purposes. For the medicinal treatment of type 2 diabetes, only other classes of substances (insulin, sulfonylureas, biguanides, and combinations of those substances) were common. Applying the arguments of the Patentee, the technical teaching of the patent is not just that very specific substances defined in the description of the patent should be used for lowering pathologically elevated blood sugar levels by influencing dipeptidyl peptidase. Rather it teaches – in a generalised manner – to use dipeptidyl peptidase inhibitors.

29 It must also be assumed that, at the filing date, a number of dipeptidyl peptidase inhibitors were known, even though they had exclusively been used for other purposes up until then. How a skilled person could determine whether such an inhibitor might be suitable for the proposed use is described in the patent specification (column 4, ll. 40 et seq.). It is not concluded that the tests to be carried out involve an undue burden.

30 3. Consequently, the contested decision must be set aside.

31 The Court did not consider an oral hearing necessary (PatG section 107 para. 1).

Meier-Beck Bacher Hoffmann

Schuster Deichfuss

Lower Court:
Federal Patent Court, decision of 13th March, 2012 - 14 W(pat) 7/07