

Decision of Technical Board of Appeal 3.3.10 dated 3 February 2009

T 1063/06 - 3.3.10

(Translation)

COMPOSITION OF THE BOARD:

Chairman:

R. Freimuth

Members:

C. Komenda, J.-P. Seitz

Applicant/Appellant:

Bayer Schering Pharma Aktiengesellschaft

Headword:

Reach-through claim/BAYER SCHERING PHARMA AKTIENGESELLSCHAFT

Relevant legal provisions:

Article 83, 123(2) EPC

Keyword:

"All requests: reach-through claim – chemical compounds defined in functional terms – future inventions also claimed – limiting claim to actual contribution to the art both reasonable and imperative – invention cannot be carried out within the entire scope claimed without undue effort – research programme"

Headnote

I. A formulation of a claim whereby functionally defined chemical compounds are to be found by means of a new kind of research tool using a screening method set out in the description constitutes a reach-through claim which is also directed to future inventions based on the one now being disclosed. As the applicant is entitled to claim patent protection only for his actual contribution to the art, it is therefore both reasonable and imperative to limit the claim's subject-matter accordingly. Patent protection under the EPC is not designed for the purpose of reserving an unexplored field of research for a particular applicant, as reach-through claims do, but to protect factual results of successful research as a reward for making concrete technical results available to the public.

II. A functional definition of a chemical compound (in this case in a reach-through claim) covers all compounds possessing the capability according to the claim. In the absence of any selection rule in the application in suit, the skilled person, without the possibility of having recourse to his common general knowledge, must resort to trial-and-error experimentation on arbitrarily selected chemical compounds to establish whether they possess the capability according to the claim; this represents for the skilled person an invitation to perform a research programme and thus an undue burden (following T 435/91).

Summary of facts and submissions

I. The appeal, received on 26 May 2006, challenges the examining division's decision, posted on 3 April 2006, refusing European patent application No. 00 962 413.1 (publication No. WO 01/19776).

II. The examining division took the view that the invention was insufficiently disclosed. The original wording of claim 1 of the main request underlying that decision was as follows:

"1. Use of compounds, which are also capable of stimulating the soluble guanylate cyclase independently of the heme

group in the enzyme, to manufacture medicaments for the treatment of cardiovascular disorders such as angina pectoris, ischemia and cardiac insufficiency."

III. In its decision, the examining division stated that claim 1 encompassed the use of any conceivable compound possessing the claimed capability to stimulate the soluble guanylate cyclase independently of the heme group in the enzyme. Since the application in suit identified as suitable only compounds with the structure defined in claim 3, and contained no pointer towards other alternatives which were also suitable, the skilled person had to select individual representatives at random from amongst all conceivable compounds and test them for the capability desired. That placed an undue burden on the skilled person wanting to carry out claim 1 over its entire scope. The invention was therefore not sufficiently disclosed within the meaning of Article 83 EPC.

IV. In oral proceedings before the board on 3 February 2009 the appellant filed two auxiliary requests, each comprising two claims.

In claim 1 of auxiliary request 1, a passage was added at the end of claim 1 as per the main request, setting out a further functional feature of the compounds to be used. It thus read as follows:

"1. Use of compounds, which are also capable of stimulating the soluble guanylate cyclase independently of the heme group in the enzyme, for the manufacture of medicaments for the treatment of cardiovascular disorders such as angina pectoris, ischemia and cardiac insufficiency, the compounds selected stimulating both the heme-containing and the heme-free soluble guanylate cyclase in *in vitro* tests."

Claim 1 of auxiliary request 3 differed from claim 1 as per the main request by expanding on the word "also" to indicate that the compounds stimulated the soluble guanylate cyclase "both dependently on and independently of" the heme group in the enzyme. It thus read as follows:

"1. Use of compounds, which are capable of stimulating the soluble guanylate cyclase both dependently on and independently of the heme group in the enzyme, for the manufacture of medicaments for the treatment of cardiovascular disorders such as angina pectoris, ischemia and cardiac insufficiency."

V. The appellant argued that the very broad formulation of claim 1 was appropriate given the invention's special contribution to the art. According to T 68/85 (OJ EPO 1987, 228), features could be defined in purely functional terms; the EPO's Guidelines for Examination supported its right to broad functional definitions. Adding to claim 1 the compounds' structural definition as per formula I would unduly limit the invention. As regards sufficiency of disclosure, page 65 of the application gave detailed instructions for testing compounds to establish their capability to stimulate the soluble guanylate independently of the heme group in the enzyme. As these tests were very easy to perform, their realisation did not place an undue burden on the skilled person. With regard to sufficiency where the compounds to be used were defined in purely functional terms, the appellant also cited T 216/96 (not published in OJ EPO) in which a kit for the detection of specific nucleic acid sequences was claimed, containing two primers. These primers were defined in terms not of their chemical structure but merely of the nucleic acid sequence (also not structurally defined) to be detected, without being considered as insufficiently disclosed. In the application in suit too, therefore, a purely functional definition of chemical compounds was allowable and not to be objected to on the grounds of insufficient disclosure. Regarding the two auxiliary requests, the compounds to be used as per auxiliary request 1 also stimulated the heme-free soluble guanylate cyclase and the test procedure was conducted *in vitro*, whilst auxiliary request 3 made clear that the compounds to be used stimulated the soluble guanylate cyclase both dependently on and independently of the heme group in the enzyme.

VI. Under Article 15(1) RPBA, in an annex to the summons, the board expressed its provisional opinion that the sufficiency-related deficiencies noted in the contested decision still existed.

VII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of its main request filed in its letter of 23 May 2006 or, subsidiarily, on the basis of its auxiliary request 1 or 3, both filed during oral proceedings before the board.

VIII. At the end of the oral proceedings, the board announced its decision.

Reasons for the decision

1. The appeal is admissible.

Main request

Formulation of the claim

2. Claim 1 concerns the use of compounds for the manufacture of medicaments to treat an illness (in this case cardiovascular diseases). However, the compounds used therein are defined in terms not of their chemical structure, their composition or other verifiable parameters, as chemical products usually are (T 248/85, OJ EPO 1986, 261, Reasons 3), but solely of their specific capability to stimulate the soluble guanylate cyclase independently of the heme group in the enzyme, which the skilled person can establish only by means of the screening method set out in the description as a new kind of research tool.

This type of functional definition of the chemical compounds to be used is directed not only to the compounds actually found according to general formula I of the application in suit, but also to any compound not yet structurally defined on the priority or filing date of the application in suit and found only by means of the screening method set out in the description as a new kind of research tool. Such a formulation of a claim thus constitutes a "reach-through" claim, i.e. a claim which is also directed to future inventions based on the one now being disclosed.

3. Citing T 68/85 (*loc. cit.*), the appellant argued that a formulation of a claim in which the compounds to be used are defined in purely functional terms was allowable.

3.1 However, applicants cannot simply define a technical feature in a claim as they wish; they must define their invention for which protection is sought in the objectively most precise form possible (see T 68/85, *loc. cit.*, Reasons 8.4.2). The characterisation of chemical compounds in a claim in non-structural, purely functional terms (in this case in terms of a specific capability) is therefore allowable only in those exceptional cases in which the invention cannot be defined more precisely in any other way without simultaneously unduly limiting its technical contribution to the art (T 68/85 *loc. cit.*, Reasons 8.4.1 and 8.4.2).

3.2 Since however patent protection is limited to applicant's actual contribution to the art, i.e. their actual invention, it is both reasonable and indeed imperative to limit the claims' subject-matter to the invention actually disclosed in the application, which at least does not include the use of chemical compounds not yet structurally defined on its priority date and to be found only in the future using the new kind of research tool set out in the description. This follows from the principle that inventions for which patents are granted under the European Patent Convention must make a contribution to the state of the art, i.e. provide a technical solution to a problem arising from the state of the art. Patent protection under the EPC is not designed for the purpose of reserving an unexplored field of research for a particular applicant, but to protect factual results of successful research as a reward for making concrete technical results available to the public.

3.3 The appellant objected that, at the time it made the invention, only such compounds were known which stimulated the soluble guanylate cyclase either by releasing NO or by interacting directly with the enzyme's heme group. The invention, for the first time, had found compounds capable of activating the soluble guanylate cyclase independently of the heme group in the enzyme by means of a new mechanism of action. The screening method set out in the description as a new kind of research tool could detect compounds which showed this heme-independent mechanism of action. Medically, this was a very important contribution to the art, so a very broad claim formulation extending to chemical compounds not yet found and disclosed was justified to reward that contribution adequately and prevent circumvention by third parties.

But the claims as filed are directed neither to the screening method for detecting the chemical compounds nor to any other research tool *per se* for detecting that they possess the desired capability, but merely to the use of chemical substances. The appellant's objection therefore fails to address the actual subject-matter of the claims on file.

And the "circumvention by third parties" referred to relates rather to future inventions which are by definition not yet disclosed in the application in suit and therefore not part of its actual contribution to the state of the art. The inventor is entitled only to the protection of its actual contribution. Therefore, the appellant's argument must fail.

Nor can the appellant successfully rely on the EPO's Guidelines for Examination to support its right to a functional definition of chemical compounds before the board. It may be left open whether or not the appellant's contentions with respect to the contents of the Guidelines are correct, because the Guidelines are issued by the President of the European Patent Office and have no normative binding effect on the boards of appeal (T 162/82, OJ EPO 1987, 533, Reasons 9). Under Article 23(3) EPC, in exercising their judicial powers, the members of the boards are not bound by any instructions, including the Guidelines, but only by the European Patent Convention.

4. The board therefore concludes that in the present case it is indeed reasonable to require the appellant-applicant to replace the chemical compounds' functional definition with the invention actually disclosed in its application, i.e. to limit itself to its actual contribution to the state of the art.

Sufficiency of disclosure (Article 83 EPC)

5. It is the established jurisprudence of the boards of appeal that the requirement of sufficiency of disclosure is only met if the invention as defined in the independent claims can be performed by a skilled person within the entire scope claimed without undue burden, using common general knowledge and having regard to further information given in the application (see T 409/91, OJ EPO 1994, 653, Reasons 3.5; T 435/91, OJ EPO 1995, 188, Reasons 2.2.1). That principle applies to any invention irrespective of the way the claims are defined, be it by way of a structural or a functional feature. The peculiarity of the functional definition of a technical feature resides in the fact that it is defined by means of its effect. That mode of definition comprises an indefinite and innumerable host of possible alternatives of diverse structure, which is acceptable as long as all these alternatives achieve the desired result and are available to the skilled person. This reflects the general principle in law whereby the protection sought must match the technical contribution made by the disclosed invention to the state of the art. Therefore, it has to be established whether or not the application in suit discloses a technical concept fit for generalisation which makes available to the skilled person the host of variants encompassed by the functional definition of a technical feature as claimed.

5.1 In the present case, the invention seeks to "develop medicaments to treat cardiovascular disorders or other disorders treatable in organisms by influencing the cGMP signal path" (application in suit, page 4, lines 1 to 3).

The means provided to achieve this as indicated in claim 1 is to use compounds which are also capable of stimulating the soluble guanylate cyclase independently of the heme group in the enzyme. A technical feature of the subject-matter of the invention is therefore defined in the claim in purely functional terms because the chemical compounds to be used are characterised solely by indicating their capability, i.e. to stimulate the soluble guanylate cyclase independently of the heme group in the enzyme. This functional formulation in claim 1 therefore encompasses all chemical compounds possessing the aforementioned capability; it thus covers a priori every conceivable chemical compound of whatever structure, including every conceivable organochemical family in organic chemistry, where applicable with the most diverse functional or reactive groups, organometallic compounds, their salts, etc. Since the claim contains no structural limitation, not even with regard to the claimed compounds, it encompasses an indefinite and innumerable host of alternatives, which is acceptable as long as all these alternatives possess the desired capability to stimulate the soluble guanylate cyclase independently of the heme group in the enzyme.

5.2 However, at the time of filing of the application in suit, the only compounds known as guanylate cyclase stimulants were those which stimulate the enzyme either by direct interaction with the heme group or by heme-dependent interaction (see also the application in suit, page 3, lines 27 to 30). Thus not all conceivable compounds possess the capability of stimulating the soluble guanylate cyclase independently of the heme group in the enzyme as required by the claim, and it is up to the skilled person to pick from this indefinite and innumerable host of alternatives the suitable ones.

In order to pick from that host the skilled person cannot draw on his common knowledge to identify from the host of possible alternatives those suitable chemical compounds which, along with the compounds of general formula (I) exemplified in the application in suit, are also covered by the functional definition in the claim, because the application in suit (page 1, lines 5 and 6) discloses that the invention is based on a "new mechanism of action". In selecting the

chemical compounds possessing the necessary capability, all he has to rely on is the information provided in the application in suit. In the absence of any selection rule in the application in suit, not even in the form of a structure-activity relationship on the basis of which he could identify from the outset suitable compound classes, the skilled person must resort to trial-and-error experimentation on arbitrarily selected chemical compounds using the screening method cited in the application in suit to identify within the host of possible alternative compounds those which stimulate the soluble guanylate cyclase independently of the heme group in the enzyme. Nor does he have any information at his disposal in the application in suit leading necessarily and directly towards success through the evaluation of initial failures. Nor would the simple structural identification of one suitable compound class of general formula (I) in the application in suit be of any help to the skilled person. To find all the suitable alternatives, he would therefore have to test every conceivable chemical compound for the claimed capability; this represents for the skilled person an invitation to perform a research programme and thus an undue burden (see T 435/91, *loc. cit.*, Reasons 2.2.1, last paragraph, and T 1151/04, not published in OJ EPO, Reasons 3.1.2).

5.3 Moreover, the fact that claim 1 is formulated as a "reach-through claim" would cast doubt on the sufficiency of the invention's disclosure throughout the entire area claimed, since this open-ended formulation, as stated above in point 2, is also directed to future inventions based on the present one, i.e. inventions not yet made by the priority date of the application in suit.

5.4 The appellant submitted that the skilled person merely had to apply the screening method which was disclosed in the application in suit and which provided sufficient information as to its implementation to the various chemical compounds in order to identify them. Since the screening method was very easy and quick to implement, the effort involved was reasonable, so the invention could be carried out in its entirety.

However, the fact that the application in suit contains enough information to implement the screening method described is only a necessary requirement for its performability, but the indication of the method alone is not sufficient to carry out the subject-matter of the claim within the entire area claimed because it only shows the skilled person the presence or absence of the claimed capability, but in the absence of any selection rule provides no guidance as to how to purposively select suitable chemical compounds.

5.5 The appellant submitted with reference to T 216/96 (*loc. cit.*) that a purely functional definition of the chemical compounds to be used was allowable. Claim 13 in the cited decision referred to a kit, for the detection of specific nucleic acid sequences, containing each of two primers defined in terms not of their chemical structure, but merely of the nucleic acid sequence (also not structurally defined) to be detected, and regarded as sufficiently disclosed because the manufacture of a primer was described in an example. As some examples of compounds were also given in the application in suit, here too a purely functional definition of chemical compounds was allowable and not exceptionable for insufficient disclosure.

However, the primers claimed in the cited decision do not constitute an innumerable host of alternatives from which the skilled person has to pick the suitable ones but rather a finite number, which have already been narrowed down to a single chemical family by reference to their function of primer, and are also defined by the nucleic acid sequence, which is to be determined, as being its complementary sequence in accordance with the lock-and-key principle. That is why the basis for the decision in T 216/96 (*loc. cit.*) is different, and consequently the conclusions reached in that case do not apply here either. The board therefore does not concur with this argument on the part of the appellant.

6. For these reasons, the board concludes that, since the chemical compounds to be used are characterised in functional terms only, the skilled person cannot carry out the claimed invention within the entire scope claimed without undue burden, so the requirements of Article 83 EPC are not met.

Auxiliary requests 1 and 3

Amendments (Article 123(2) EPC)

7. Claim 1 of auxiliary request 1 differs from claim 1 of the main request only by the additional wording "the compounds selected stimulate both the heme-containing and the heme-free soluble guanylate cyclase in *in vitro* tests" at the end of the claim (see point IV, *supra*). A basis for this amendment is to be found on page 4, lines 15 to 17, of the application as filed. Reference is made to "*in vitro* tests" on pages 64 to 65 of the application as filed.

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in stipulating, vis-à-vis the original version, that the compounds to be used are capable of stimulating, both dependently on and independently of the heme group (see point IV, *supra*). The basis for this resides in the application as filed on page 4, lines 15 to 17.

The amendments to claim 1 of the auxiliary requests are therefore allowable within the meaning of Article 123(2) EPC.

Sufficiency of disclosure (Article 83 EPC)

8. In claim 1 of both auxiliary requests, the chemical compounds to be used are still characterised exclusively in functional terms and not by structural definitions. The functional definition of the compounds to be used, which was already objected to in respect of the main request, i.e. that they should be capable of stimulating the soluble guanylate cyclase independently of the heme group in the enzyme, is still present in claim 1 of both auxiliary requests. The indication of an additional capability in auxiliary request 3, i.e. that the compounds stimulate the soluble guanylate cyclase "both dependently on and independently of" the heme group in the enzyme, does not contribute to meeting the objection in respect of the functional definition comprised in the main request. Introducing in auxiliary request 1 a further functional definition of the compounds to be used, i.e. the further capability to stimulate in *in vitro* tests both the heme-containing and the heme-free soluble guanylate cyclase, also does not contribute to meeting the objection raised against the main request with respect to sufficiency of disclosure. Introducing further required capabilities in the form of an additional functional feature renders it even more difficult for the skilled person to find suitable chemical compounds, i.e. compounds possessing all these capabilities.

9. Consequently, the considerations and conclusions in respect of the main request also apply to the two auxiliary requests, i.e. that, because the chemical compounds to be used are characterised in terms of the same functional feature as in the main request, the skilled person cannot carry out the claimed invention within the entire scope claimed without undue burden, so the requirements of Article 83 EPC are not fulfilled.

Order

For these reasons it is decided that:

The appeal is dismissed.