Kluwer Patent Blog

Broad functional claims: A fair reward for patentee or an unfair attempt to “reach through” to future inventions by others?

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Different views from the EPO and Germany on the same case

1. Introduction

Functional features in patent claims may provide protection not only for specific embodiments disclosed in the patent specification, but also for undisclosed (future) embodiments. A classic example is a claim of the format “An inhibitor of protein P for the treatment of a disease X” or variants thereof in the second medical use claim format. Patentees naturally love such claims, competitors usually reject them as excessively broad and examiners commonly approach them at least with skepticism. Do such claims “reach through” to the use of compounds that have yet to be discovered or invented by others, or do they appropriately reward the Patentee for its contribution to the state of the art?

This question has now been answered by the German Federal Court of Justice in its decision “Dipeptidyl-Peptidase-Inhibitoren” (BGH X ZB 8/12, English translation available here) of 11 September 2013 with the opposite result than earlier by the EPO’s Board of Appeal (T 1151/04) in regard to the same invention.

2. “Reach-through claims”

In 2001, the trilateral cooperation group between the European Patent Office, the Japanese Patent Office and the USPTO published a joint Comparative Study on “reach-through-claims”. At that time, the Offices were confronted with a significant number of so-called “research tool” patent applications identifying new potential drug targets such as receptors or proteins. These applications, however, not only claimed the targets and the use of such targets for identifying new drugs in a screening assay, but also (not yet made) downstream developments. To the extent that these applications focused on new and inventive drug targets, inhibitors for such targets were not and could not have been known to the public by definition. The three Offices discussed four different case scenarios and unanimously agreed that “reach-through claims” at least in the narrow sense would not meet the requirements of inter alia clarity, support and sufficiency. Prototypical reach-through claims were compound claims to inhibitors of receptors, which could be identified by a screening assay, and claims to the therapeutic use of such (identifiable) inhibitors. Most applications in these cases did not disclose any inhibitors, nor were they known from the prior art. In some cases there was also no link between the receptor and the claimed therapeutic use. The

three Offices concluded that the general scope of such claims do not comply with enablement, support and/or written description requirements.

Even in a case where the application disclosed three working examples wherein agonists of a new and inventive receptor, i.e., compounds activating this receptor, namely X, Y, and Z were identified using a sufficiently disclosed screening procedure, and where the pharmacological mechanism involved in the treatment or inhibition of a certain disease by the activation of this receptor was described theoretically in the specification and confirmed by in vivo test data with regard to compound X, the three Offices concluded that except for compounds X, Y and Z, the general scope of functionally defined use claims do not comply with enablement, support and/or written description requirements (trilateral report, page 12).

However, it needs to be emphasized that all four case scenarios investigated by the trilateral group rested on the assumption that the application disclosed a new and inventive target molecule, which would then be used by applicants to support the patentability also of claims to downstream developments. The case that the target itself and inhibitors or activators of the same were already known or even formed part of a skilled person's common general knowledge, so that the actual invention solely rested in the use of the (known) inhibitors or activators was not considered.

The principal conclusions of the Comparative Study for "reach through" claims were later touched upon by one of very few EPO decisions that made their way into the Official Journal of the EPO (2009, 516). In T 1063/06, the Technical Board of Appeal 3.3.10 held as follows:

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).

Even though T 1063/06 was quite critical with the applicant and used the "reach through" terminology to condemn applicant's attempt to attain what he considered a fair reward to his invention, the Board did not deal with a situation where the functionally defined compounds were known per se, or formed part of the skilled person's common general knowledge. The Board even hinted that the result might be different if the compounds possessing the capability according to the claim could be identified by having recourse to common general knowledge, so that an unduly burdensome research programme can be avoided.

3. The Dipeptidyl Peptidase Inhibitor Case

Let us now take a closer look at a special case of the latter kind, involving broad claims with functional rather than structural features. First the facts:

The invention at stake went back to the mid 1990ies when a group of scientists around Hans-Ulrich Demuth, who later co-founded Probiodrug, realized that inhibiting the enzyme Dipeptidyl peptidase IV (DP IV), as a mode of action, would be suitable for treating hyperglycemic diseases including diabetes mellitus. Prof. Demuth claimed this concept in a German priority application and subsequent filings inter alia in the EPO. The specification of these filings explained the molecular mechanism of the pharmacological effects of DP IV inhibition, named several specific inhibitors and tested one in vitro as well as in an animal model, and included claims inter alia to the use of inhibitors of DPP IV for treating diabetes mellitus. DP IV had been known before the filing date and DP IV inhibitors had been disclosed in the prior art, albeit for different therapeutic purposes.

Both applications were granted in a pretty broad scope, leading to a national German patent DE 196 16 486 C2 and to European Patent 0 896 538 B1, respectively, claiming priority of the German patent application.

The granted EP claim read as follows:

„The use of activity lowering effectors of dipeptidyl peptidase IV (DP IV) or DP IV-like enzyme activity for the preparation of a medicament for the oral therapy of diseases which are based on glucose concentrations in the serum of mammals characteristic of hyperglycemia.“

To put it more simply, one can paraphrase this claim as “the use of DP IV inhibitors for the preparation of a medicament for treating diabetes”. The claimed inhibitors were not structurally limited, just by their function. The description of the patent contained a single working example with data. However, as the claims were so broad and Prof. Demuth’s concept proved to be unusually successful, it happened, unsurprisingly, that both patents were opposed by various major pharmaceutical companies. Indeed, the patents were arguably covering a whole new class of anti-diabetes drugs under development, which today are collectively referred to as gliptins. Marketed actives of this class include Sitagliptin, Vildagliptin and Saxagliptin.

4. The EP Decisions

In first instance opposition proceedings, EP 0 896 538 was revoked in toto lack of clarity, lack of support in the original application and a violation of Rule 57a EPC (now Rule 80 EPC2000). The Patent Proprietor filed an appeal and submitted requests A to J and – later on – K to M. During the Appeal Proceedings, these requests were further modified, partly deleted and additional requests A1 to M1 were submitted.

Auxiliary Request A had the following wording: „The use of activity lowering effectors of dipeptidyl peptidase IV (DP IV) or DP IV-like enzyme activity for the preparation of a medicament for the oral therapy of diseases which are based on glucose concentrations in the serum of mammals characteristic of hyperglycemia, by lowering the increased blood glucose concentration in the serum of the organism of the mammal.” Further auxiliary requests attempted to define the “activity lowering effectors” differently, e.g. by replacing this term with the expression “inhibitors”, which were then successively further defined as e.g. “wherein the

inhibitors are not inhibitors of the DP IV expression". In auxiliary request M the term "inhibitor" was then specified to be "aminoacyl-thiazolidids or alanine-pyrrolidids".

The Technical Board of Appeal 3.3.02 considered all of these claims to be insufficient, contrary to Article 83 EPC, and dismissed the appeal, even though all of the oppositions had been withdrawn at that time and none of the previous eight opponents appeared in the final oral proceedings. According to the Board's decision (T 1151/04), all requests had in common that the compounds were (exclusively or mainly) defined by functional rather than structural features. The functional feature was not limited to structures that were already known at the time of filing the underlying application, but encompassed as yet undefined novel compounds. According to the Board, the person skilled in the art would not be in possession of any structural indications to further characterize or select such compounds. The Board concluded that all possible organic and – as co-factors – even inorganic compounds, would be potentially encompassed. In the absence of any indication in the patent how to select a potentially active compound, an incalculable number of experiments would be necessary to actually find a suitable compound. This was considered to be true even for the auxiliary request M, defining the inhibitor as "aminoacyl-thiazolidids or alanine-pyrrolidids", since even these substance classes would still encompass a huge and unlimited number of possible candidates.

The additional indication that the compounds would have to be "inhibitors of the enzyme activity of DP IV" was not considered relevant in that context. The Board reasoned that the application did not comprise any assistance on the selection of possible compounds. The Applicants should have defined the class of compounds sufficiently at the time of filing. The present case was characterized as seriously disproportionate ("ein grobes Missverhältnis" in the original decision text in German) between a single exemplified compound and the immeasurable number of compounds claimed.

So the EP patent was finally revoked by the Board of Appeal and you may think: "What's new here? Broad functional claims reaching through to new inventions are dead. We knew that for years."

Not so fast, dear reader. A small village of indomitable Judges still resists Roman occupation, and maybe even for good reasons. The name of the "village" (dear Badeners, we beg your pardon) is Karlsruhe, and the Judges are the members of the renowned Patent Board of the German Federal Court of Justice (FCJ).

5. The German Decisions

The opposition division dealing with DE 196 16 486 C2 considered the claims to be novel and inventive, but likewise revoked the patent for lack of enablement. On appeal, the Federal Patent Court confirmed this result and held the broad claims as not being sufficiently disclosed across their breadth, since the characterization of the compounds by their function, rather than by their structure, would leave the skilled person with an undue burden when attempting to identify substances of the desired functionality. It would also not matter that other DP IV inhibitors than those disclosed in the specification were already known from the prior art. In its reasoning, the Federal Patent Court followed and explicitly approved the EPO's decision T 1151/04.

But applicant did not give up and filed a further appeal on a point of law to the Federal Court of Justice, for which the Federal Patent Court had granted leave under Sec. 100 (2) Patent Act. This

provision stipulates that the Federal Patent Court shall grant leave for an appeal on a point of law to the Federal Court of Justice (1) if a legal question of fundamental importance is to be decided or (2) if a decision by the FCJ is required to ensure uniform case law or further development of the law.

In its recent decision “Dipeptidyl-Peptidase-Inhibitoren”, the German Federal Court of Justice now endorsed functional features for second medical indication claims in the context of sufficiency of disclosure and arrived at the opposite result than the EPO’s Technical Board of Appeal. The decision of the Federal Patent Court patent was overturned and the case remitted to the Federal Patent Court for further consideration in view of the FCJ’s guidance!

In “Dipeptidyl-Peptidase-Inhibitoren”, the FCJ held that an applicant is entitled to use functional claim language in order to obtain full and appropriate coverage of his invention. Extensively citing German, United Kingdom and EPO case law, the Federal Court of Justice emphasized that the decisive question of an enabling disclosure is whether the scope of protection that is being sought does not extend beyond that which would appear to a person skilled in the art as the most generalized technical teaching to solve the problem underlying the invention. The scope of the claims must thus reflect the contribution made by the invention to the art. If this balance is met, the FCJ’s decision confirms that a claim with functional features may even encompass inventive embodiments of the future.

The Federal Court of Justice considered the decisions of both the Federal Patent Court and of the EPO in T 1151/04, but found their reasoning to be incorrect. The explicit deviation from the EPO’s decision on substantially the same patent, without providing a detailed discussion on the TBA’s arguments, is remarkable, given that the Federal Court of Justice had recently held in its decision “Walzenformgebungsmaschine” (Xa ZB 10/09) that a German Court has to provide reasons when deviating from decisions inter alia by the EPO that deal with similar issues. It seems that the FCJ thought that its conclusions were supported by other EPO decisions emphasizing the quid pro quo principle including T68/85, T 292/85 and T694/92 and British decisions. Remarkably, T1063/06 which the EPO Boards had considered so essential that they published it in the OJEPO was not mentioned by the FCJ at all, even though the file record shows that it must have been aware of this decision.

6. The Consequences

Where does this leave us? We think that it is fair to say that broad functionally defined substance or use claims are indeed back, at least for German national patents (EP patents with a designation of Germany will most likely not make it through the filter of EP opposition appeal proceedings) even though they also cover the use of compounds which still need to be invented. This may have far-reaching consequences, good ones and bad ones, for companies in the field of life sciences and biotechnology.

Groundbreaking mechanistic inventions now have a chance of obtaining much broader coverage in an important market such as Germany, and this is certainly good for innovators. On the other hand, companies working in this field may have to worry much more for competitors’ patents, and an FTO analysis will certainly not become easier in the future. Namely, it is not always so easy to find out whether a given compound is actually a protein P “inhibitor”, particularly if the patent to be considered offers little guidance on how inhibitory activity is to be assayed and how much (specific) inhibition is necessary for a compound to be designated as “inhibitor”.

The German Federal Court of Justice seemed to be quite convinced that its decision is both correct and important, perhaps even groundbreaking, since it decided to publish the judgment in its official collection of important decisions (BGHZ). It remains to be seen how this decision will be implemented by the Federal Patent Court and the Patent Office in the future. For the time being, however, it can be taken for granted that the FCJ will fiercely resist revoking broad functional claims just because they are what they are – very broad. In arriving at its decision, the FCJ strongly recurred on decisions from the EPO (T 292/85, T 694/92) and the UK (Regeneron/Bayer vs. Genentech) in the biotech field, where functionally defined claims are the rule rather than the exception. So it is tempting to speculate that the FCJ wanted to treat inventors in the field of small molecule compounds (most inhibitors of DP IV are small molecules) similarly as inventors in the biotech field. This raises the interesting question whether there is a fundamental difference between small molecule inventions which can adequately be defined structurally but also by way of their function, and biotech inventions such as antibodies, where an adequate structural definition is much more difficult or even impossible, and where the scope of such functionally defined claims is also clearer to ascertain (at least if the claim is directed to antibodies, fragments thereof or an isolated receptor as in the Regeneron case).

To what extent the FCJ wanted to send a signal that it will depart from the EPO's present tendency in the pharma and biotech area to refuse claims with broad functional claim language *per se*, is hard to gauge from the decision text. Be that as it may, it seems that the FCJ will not shy away from steering the German ship away from the EPO fleet if and when it thinks that inventors deserve a better treatment.

7. Disclosure

This post is a somewhat unusual one, since it has been pieceably drafted by three authors from two different firms acting on opposite sides of this case. Dr. Elisabeth Engelhard of Hoffmann Eitle represented one of the opponents in the EP opposition and appeal proceedings. Dr. Dirk Bühler of Maiwald acted on behalf of the applicant in the German proceedings and kindly provided the English translation of the FCJ's decision. Finally, Dr. Thorsten Bausch contributed by tying the various facets of this case together and is responsible for the overall content of this post (and the jokes).

This entry was posted on Thursday, December 5th, 2013 at 11:14 pm and is filed under antibodies, EPC, Germany, Scope of protection, Sufficiency of disclosure
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