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Editors: Roy P. Issac and Debora Plehn-Dujowich

Submissions to the Newsletter: Articles for publication in the Newsletter can be submitted to the editors, Roy P. Issac (rissac@elmorepatents.com) and Debora Plehn-Dujowich (Debora.Plehn-Dujowich@dbr.com)

Reach-Through Claims in Europe – A New Hope

Dr. rer. nat. Holger Tostmann[1]

In general, the term "Reach-Through Claims" relates to claims that are directed at the possible results/ effects obtainable by applying the mechanism of the invention. In the particular context of the present article, the term refers to claims directed to a chemical compound (or its use) defined only in functional terms, i.e. without providing a structural limitation for the compound.

An example of such a reach-through claim, which is of relevance to the cases discussed below, is claim 1 of European Patent EP 896 538 as granted by the European Patent Office (EPO):

> *Use of activity-lowering effectors of dipeptidyl peptidase IV(DPP IV) [...] [for the] oral therapy of diseases that are based on a glucose concentration in the serum of a mammalian organism characteristic of hyperglycemia [diabetes mellitus].*

Such a definition of a chemical compound exclusively in functional terms / terms of mechanism covers all conceivable compounds possessing the activity or effect specified in the claim, including compounds found to have this activity after filing or grant of the application/patent.

According to established practice before the EPO, as summarized in the Guidelines for Examination, F-III,9, it would be an "*undue burden*" to require from the public subjected to the monopoly of the patent to isolate and characterize all potential compounds, "*without any effective pointer to their identity*", or to test every known compound and every conceivable future compound for this activity to see if it falls within the scope of the claim. In effect, in established EPO practice, such a "reach through"-claim is seen as an attempt to patent what has not yet been invented. Even if the applicant discloses a test for the effect used to define the compounds, this does not necessarily confer sufficiency on the claim. Rather, according to established case law of the EPO Boards of Appeal, this constitutes an "*invitation for the skilled person to perform a research programme*" [see landmark cases T 435/91 (Reasons 2.2.1), followed by T 1063/06 (Headnote II)].In such cases, the EPO considers it "*both reasonable and imperative*" to limit the subject-matter of the claims to the "*actual contribution to the art*" (see T 1063/06 (Headnote I)), i.e. to concrete classes of compounds, or even individual compounds, which are limited by their structure.

As an illustration of these principles, Board of Appeal 3.3.02, which is one of the most prominent

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Dr. Holger Tostmann is a partner at the Law Firm of Wallinger, Ricker, Schlotter, Tostmann. Dr. Tostmann's IP expertise includes Opposition Proceedings (European Patent Office, German Federal Patent Court) Appeal Proceedings, and IP opinion work. Dr. Tostmann is also active in drafting and prosecuting protective rights (patents, utility models, design patents) in national (German Patent and Trademark Office) and supranational proceedings (European Patent Office, WIPO) as well as strategic patent portfolio management.

second instance boards of the EPO for pharma/biotechnology cases, has revoked EP 896 538, in its entirety, in decision T 1151/04 of July 29, 2008. Before I discuss how the highest German court for material patent matters, the Federal Supreme Court (Bundesgerichtshof, "BGH") came to a different conclusion in regard to the same reach-through claim, I briefly summarize the reasoning behind this EPO decision, which applies to reach-through claims in proceedings before the EPO in general.

In case T 1151/04, several pharmaceutical companies engaged in developing treatment for diabetes (*BMS, Takeda, Pfizer, Glaxo, ...*) have attacked the validity of EP 896 538 (as issued to *Prosidion Ltd.*) in opposition proceedings before the EPO. EP 896 538 is one of the first patents to describe and protect the use of (effectors of) dipetidyl peptidase IV ("DPP-IV") in treating *diabetes mellitus*. DPP-IV

was described previously for other medical indications, hence the drafting of the claim of relevance here as "*second medical use*"-claim. The mechanism of how reducing the activity of DPP-IV favorably affects the glucose level in the human bloodstream is of no relevance for understanding the repercussions of the cases of interest and is therefore not discussed in detail. It suffices to highlight that the broad and functional second medical use claim as reproduced above was seen as particularly relevant to the commercialization activities of pharmaceutical companies working in the field.

In line with the principles outlined above in regard to reach-through claim, EPO Board of Appeal 3.3.02 came to the conclusion that the second medical use claim as reproduced above includes no structural limitations and therefore encompasses all conceivable organic (and, as co-factors, inorganic) compounds, which need to be tested, in a "*trial and error*" scheme, for their potential suitability as effectors of DPP-IV. This poses an "*undue burden*" on the public, and therefore constitutes a violation of the requirement that the Patentee must provide an enabled technical teaching commensurate with the scope of the claimed subject-matter.

In response to the Board of Appeal's rejection of the above-reproduced reach-through claim, Patentee amended the main independent claim to read:

> *Use of* ***aminoacyl-thiazolidides*** *or of* ***alanine-pyrolidide*** *as inhibitor of the enzyme activity of dipeptidyl peptidase IV(DPP IV) [in the] oral therapy of diseases that are based on a glucose concentration in the serum of a mammalian organism characteristic of hyperglycemia.*

i.e. Patentee now specifies *classes* of chemical compounds that are seen as having the required enzyme inhibiting binding properties. However, the Board of Appeal has maintained the objection that an "*unmanageable pool*" of compounds exists that fall under this broad (now) structurally defined class. Again, it would constitute an "*undue burden*" to test all conceivable claimed thiazolidides and pyrolidides for their effectiveness in inhibiting DPP-IV. In fact, EP 896 538 discloses only one compound that falls within the claimed classes (isoleucine thiazolidide). EP 896 538 also provides no rule of selection how to choose effective compounds from the pool of compounds claimed. Therefore, the subject-matter is, again, not enabled over the entire range claimed and the patent was revoked for that reason.

The German Federal Patent Court, which had to decide on the validity of DE 196 16 486, which is the granted German patent based on the priority application to EP 896 538, essentially came to the same conclusions as the EPO Board of Appeal and revoked DE 196 16 486. However, on appeal, the second (and last) instance in patent validity matters in Germany, the Federal Supreme Court ("BGH") reversed the Patent Court's decision and has allowed a claim essentially identical to the functionally defined reach-through claim as reproduced above (BGH decision X ZB 8/12 of September 11, 2013).

The BGH explicitly cites EPO Board of Appeal decision T 1151/04 as discussed above but comes to a very different conclusion. The BGH relies on the accepted notion that it is allowable, in principle, to characterize claimed subject-matter in functional terms, in particular in case no suitable structural definition is available or if defining the feature structurally would constitute an undue restriction of the inventor's contribution to the art. The BGH extensively cites EPO, German and UK case law in respect to functional features and holds that the principle of allowing functional features also applies, on a case-by-case basis, for second medical use claims. Specifically, the BGH states in paragraph 19 of the above-reference decision (partly also included in the headnote):

> *"In view of these criteria, it may be admissible to list a group of compounds in a claim, in a generalized 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 [...]*
>
> *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 use of a claimed compound means that the claimed invention is used, it does not matter if compounds are also covered which cannot be identified without inventive activity"*

Basically, the BGH acknowledges that the scope of the claimed subject matter must be commensurate with the application's contribution to the art. If the contribution is commensurate, for example in the present case, where the inventors have realized, for the first time, that DPP-IV inhibitors are (surprisingly, based on the complicated signaling cascade involved) suitable to treat diabetes, the BGH has confirmed that a "reach-through" claim delimited from the art solely by functional features may be allowable and may even encompass "inventive" future embodiments.

Important "**take-home messages**", based on the different criteria for allowing reach-through claims, in different jurisdictions, are:

- For proceedings before the EPO, an application directed at the use of a known (class of) compound(s) for a novel purpose/indication should be drafted so that sequentially more narrow classes of *structurally* defined compounds are available for claim limitation, since the Boards of Appeal very likely will not accept broad functional definitions and also will likely not accept broad classes of compounds, in which the majority of compounds is likely to not fulfill the effect/ mechanism underlying the invention.

- In case a new mechanism for treating a disease is discovered, it seems prudent to not only file for patent protection before the EPO (which will likely decline broad protection for a functionally defined class of compounds), but also to file for patent protections before national patent offices, in particular the German Patent Office and possibly the UK IPO. The German PTO is bound by the BGH decision discussed above. UK courts also may take a more favorable approach towards reach -through -claims and have been known in the past to explicitly deviate from EPO case law precedent.