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Federal Supreme Court endorses functional claim language

For biotechnology and pharmaceutical inventions, it is common practice to generalise experimental findings into a conceptual teaching by using functional features in patent claims. Applicants can thereby obtain protection not only for specific embodiments disclosed in the patent specification, but also for undisclosed embodiments – including future embodiments – which fairly make use of the invention. However, functional features frequently encounter scepticism from examiners. Such claims are often rejected as excessively broad and not sufficiently disclosed, allegedly because the claimed subject matter may not be realised by the skilled person across the full breadth of claim without an undue burden.

In its September 11 2013 decision entitled "Dipeptidyl-Peptidase-Inhibitors" ("Dipeptidyl-Peptidase-Inhibitoren", BGH X ZB 8/12), the German Federal Supreme Court decided, on an appeal which had been admitted by the Federal Patent Court, the question of whether a second medical use claim would not meet the requirement for sufficiency of disclosure simply because it includes, due to a functional characterisation of the compounds to be used, not only substances of the prior art but also future substances. The claims in question relate *inter alia* to the use of inhibitors of the enzyme dipeptidyl peptidase IV (DPP IV) for treating diabetes mellitus. The underlying patent (DE 196 16 486 C2) disclosed that inhibition of DPP IV as a mode of action would be suitable for treating hyperglycemic diseases including diabetes mellitus, named several specific inhibitors, and tested one of these *in vitro* and in an animal model. The Federal Patent Court had rejected the claims as not being enabled across their breadth because the characterization of the compounds by their function, rather than by their structure, would leave the skilled person with a large number of unduly burdensome experiments to identify substances of the desired functionality. In such cases, it would allegedly not matter that certain DPP IV inhibitors were already known as such from the prior art. In its reasoning, the Federal Patent Court had essentially followed (and explicitly cited) the 2008 European Patent Office (EPO) Board of Appeal decision, T 1151/04 – 3.3.02, dealing with EP 0 896 538 B1, which claims the priority benefit of DE 196 16 486 C2.

In "Dipeptidyl-Peptidase-Inhibitors", the German Federal Supreme Court unequivocally revoked the decision of the Federal Patent Court and clarified that a patent applicant may indeed use generalisations of specific embodiments, and thus functional claim language, in order to obtain full and appropriate coverage of an invention. Extensively citing German, United Kingdom and EPO case law, the Federal Supreme Court emphasised that the decisive question of an enabling disclosure is: whether a scope of protection is being sought which does not extend beyond what would appear to a person skilled in the art, in view of the specification and the embodiment examples contained therein, as the most generalised technical teaching by which the problem underlying the invention is solved. Thus, the scope of the claimed subject matter needs to be balanced versus its contribution to the art. If this balance is met, the Court confirmed that a claim having functional features may even encompass inventive embodiments of the future. Notably, the Federal Supreme Court considered the conclusions of both the Federal Patent Court and of the EPO in T 1151/04 – 3.3.02 to be incorrect. The new decision thus arrived – for the same invention – at the opposite result from the EPO.

This landmark national decision is good news for innovators and their investors. According to the decision, functional features can be used to claim an invention if this is the best way of ensuring full protection of what has been contributed by an inventor. The Federal Supreme Court's explicit rejection of the EPO approach on such a fundamental question of patentability also highlights the benefits of using the national patent system in addition to the EPO for important inventions.