Federal court stakes new ground for reach-through claims

Reach-through claims – which allow broad protection for an invention – have been a contentious issue for years. The German Federal Court's recent decision on dipeptidyl-peptidase inhibitors suggests that the matter is far from settled

By **Ralph Minderop**, **Arwed Burrichter** and **Corinna Lueg,** COHAUSZ & FLORACK

Germany is one of the largest pharmaceutical markets in the world — in 2011 its state healthcare system spent over €30 billion on pharmaceuticals, according to the German Federal Statistic Office. Owing to the large size of the market and its high research output, Germany often plays a key role when it comes to a pharmaceutical company's IP portfolio in Europe.

The dipeptidyl-peptidase inhibitors case

The Federal Court of Justice's patentee-friendly decision concerning dipeptidyl-peptidase inhibitors focused on an invention by Professor Hans-Ulrich Demuth (co-founder of Probiodrug AG in Halle, Germany) and his fellow researchers at the University of Halle in the mid-1990s.

The basic principle discovered by Demuth and his fellow researchers was the complex issue of the enzyme dipeptidyl peptidase IV (DP IV) in the treatment of hyperglycemic diseases such as diabetes mellitus type 2.

Diabetes mellitus type 2 is a disorder characterised by variable severity of insulin action and insulin secretion, from hyperinsulinism to the malfunction of insulin secretion. The sensitivity of the body's cells to insulin is reduced and the cells become insulin resistant, leading to a poor or no response to insulin.

DP IV breaks down distinctive hormones (incretins), which trigger the formation of insulin in the pancreas after food intake. The importance of these incretins for glucose levels in the plasma and metabolism by the enzyme dipeptidyl peptidase was already known. The efforts to modulate this mechanism therapeutically led to attempts to obtain analogous incretins or administer additional incretins to diabetes patients. The standard therapy of diabetes mellitus type 2 encompassed other classes of substances — such as the administration of insulin, sulfonylureas, biguanides and combinations of those substances.

The European view

In 1996 Demuth proved the therapeutic value of DP IV inhibitors in diabetic rats and subsequently filed a German patent application (DE 196 16 486) and a European patent application (EP 0 896 538) for his invention. The explicit use of DP IV inhibitors to treat diabetes mellitus type 2 had not been considered previously, although today such DP IV inhibitors (so-called 'gliptins') are now an established therapeutic treatment for type 2 diabetes. The German and European patents were granted in August 1999 and April 2001, respectively.

Claim 1 of European Patent 896 538, as granted, reads: "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."

The patents provided one working sample, with data using a known inhibitor

> "On the one hand, a reach-through claim might be considered an appropriate reward for a patentee for its innovative findings and research expenses. However, competitors often criticise reach-through claims as functional and overly broad"

Ralph Minderop
Senior Partner
COHAUSZ & FLORACK
Germany
Tel: +49 211 90 490 0
Fax: +49 211 90 490 49
rminderop@cohausz-florack.de

Ralph Minderop is a senior partner with the law firm COHAUSZ & FLORACK and a European and German patent attorney. He has extensive experience in the prosecution and litigation of cases in the life sciences, pharmaceutical chemistry and general chemistry sectors on behalf of German and international clients, to which he offers strategic IP advice. Dr Minderop obtained his PhD in biochemistry.

of DP IV (isoleucin-thiazolidine). The therapy using DP IV inhibitors was extremely successful and led to the development of similar compounds by various pharmaceutical companies in the years that followed.

In 2002 both of Demuth's patents were opposed by eight pharmaceutical companies, including Pfizer, Novartis and Glaxo.

The European opposition proceedings for European Patent 896 538 focused on the main request, which claimed the use of any and all compounds acting as DP IV inhibitors. The patent was revoked at first instance, prompting the patentee to appeal the decision. The Board of Appeal dismissed the appeal and confirmed the first-instance decision. The claims were deemed too broad and functional and not limited to already-known structures leading to undiscovered future compounds. Taking account of the claims and description, a person skilled in the art would be unable to conduct a structural characterisation; nor would he or she be aware of other requirements with regard to the characterisation of such claimed compounds according to his or her general knowledge. For this reason, the Board of Appeal considered the subject matter as having been insufficiently disclosed. The patent was finally revoked due insufficient clarity and support (T 1151/04). This case was cited in a later appeal against Bayer-Schering dealing with reach-through claims (T 1063/06).

Reach-through claims

Claims of this reach-through type have been the subject of much controversy over the past few years. On the one hand, a reach-through claim might be considered an appropriate reward for a patentee for its innovative findings and research expenses. However, competitors often criticise reach-through claims as functional and overly broad, resulting in an undue burden for a person skilled in the art.

In 2001 the European Patent Office (EPO), the US Patent Office (USPTO) and the Japanese Patent Office carried out the Project B3b Report on Comparative Study on Biotechnology Patent Practices, in order to compare their treatment of reach-through claims. All three reached similar conclusions concerning the patentability of the exemplary claims they had studied. In 2004 the EPO commented on these types of claim as follows: "[reach-through] claims which attempt to obtain protection for chemical products and their uses, by defining the product in terms of a screening method used to test its biological activity or binding to a biological target… This is an attempt to obtain protection, which has not been invented… Claims of the above type cannot be granted… which are not allowable primarily by reason of lack of clarity, support and sufficient disclosure."

This understanding of broad and functional claims which reach through to future inventions was established in EPO case law in the following years and found its way into the EPO's Guidelines for Examination: "In general, claims directed to merely functionally defined chemical compounds that are to be found by means of a new kind of research tool (e.g. using a new screening method based on a newly

Arwed Burrichter
Senior Partner
COHAUSZ & FLORACK
Germany
Tel: +49 211 90 490 0
Fax: +49 211 90 490 49
aburrichter@cohausz-florack.de

Arwed Burrichter is a senior partner with the law firm COHAUSZ & FLORACK. He is a renowned and highly experienced European and German patent attorney. Having obtained a PhD in chemistry from the University of Southern California, Los Angeles, Dr Burrichter prosecutes and litigates patents in the fields of pharma, general chemistry, polymer chemistry and biochemistry, and advices on strategic IP decisions.

> "The Federal Court conceded that applicants may be allowed to make certain generalisations if these take account of a legitimate interest in covering the scope of the invention"

discovered molecule or a new mechanism of action) are directed to future inventions, for which patent protection under the EPC is not designed. In the case of such 'reach-through' claims, it is both reasonable and imperative to limit the subject-matter of the claims to the actual contribution to the art (see T 1063/06)."

The German view

In the case at hand the German Patent and Trademark Office (GPTO) considered that the claims were insufficiently disclosed to be carried out by a person skilled in the art without an undue burden. It argued that the claim provided no specified guidance as to how to discover such inhibitors. Obviously, the technical teaching of the main request would require further scientific studies. There was also significant legal uncertainty, because it was not clear how far before the filing date already-known diabetes compositions would be encompassed by the claim. Due to an alleged lack of enablement, the GPTO maintained that the patent was limited to auxiliary 1ac with claim 1 as follows: "Oral use of inhibitors of dipeptidyl peptidase (DP IV)-enzyme activity for lowering blood sugar levels of glucose under the known characteristic glucose-concentrations in the serum of a mammalian with diabetes mellitus, wherein said DP IV inhibitors are alanyl-pyrollidine, aminoacyl-thiazolidine, N-valyl-prolyl or O-benzoyl hydroxylamine."

Patent Court decision

The patentee appealed to the Federal Patent Court of Germany. The court understood the solution to the technical problem to lie not in the explanation of the mode of action, but rather in the provision of the specific means by which blood-sugar levels could be reduced by the inhibition of the DP IV enzyme. The Patent Court held that the invention was not disclosed in a sufficiently clear and complete manner to be carried out by a person skilled in the art. It held the view that the claim of the main request claimed the use of inhibitors, which were characterised only by a functional feature (the interaction with DP IV). This would cover a large number of compounds, which were defined by their functional rather than by their compositional features. The Patent Court further agreed that no appropriate instructions to identify these inhibitors had been provided, meaning that there was insufficient disclosure. It held that a research programme would be needed in order to determine such compounds, which was unacceptable. The generalised wording of the patent claim was so broad that the claimed scope of protection would reach beyond the actual contribution of the invention to the prior art.

In its decision, the Patent Court underlined the lack of enablement and confirmed the GPTO's decision, explicitly highlighting the EPO's decision in its reasoning.

A major issue in the appeal proceedings was the question: "Whether a claim does not fulfil the requirement of enablement because it includes – due to its functional characterisation of applying compounds according to the teaching of claim – both, compounds of the prior art as well as future compounds."

In this regard, the patentee requested the Patent Court to allow an appeal to the Federal Court of Justice under Section 100(2) of the Patent Act, to ensure uniform case law or further development of the law. The Patent Court granted this request.

Federal Court of Justice decision

The Federal Court considered the Patent Court and EPO decisions but finally delivered a contrary judgment, setting aside the Patent Court's ruling.

For the Federal Court, the invention was the application of DP IV inhibitors. This approach differed from the interpretation followed by both the Patent Court and the EPO. It understood the technical teaching as the inventive use of DP IV inhibitors, not as the provision of specific compounds for the inhibition of DP IV. Although a number of DP IV inhibitors were known before the filing date, they had been taught and used exclusively for other purposes.

The Federal Court conceded that applicants may be allowed to make certain generalisations if these take account of a legitimate interest in covering the scope of the invention. The court underlined that the circumstances of the individual case will be decisive. It argued that chemical compounds can be defined by scientific nomenclature or their structure. However, if this kind of definition is unsuitable to characterise the teaching disclosed, the characterisation may be provided by functional definitions of the feature, to ensure adequate protection of the invention. Therefore, the invention is sufficiently disclosed if it provides a person skilled in the art with at least one example of an experimental method. The Federal Court further stated that the description of the patent should clearly describe how a person skilled in the art could determine such DP IV inhibitors without an undue burden. The requirement of disclosure does not require that the description contain all conceivable variants of the components which are encompassed by the functional characterisation. In this particular case, the generalised wording was permissible under the condition that no protection was sought beyond what appeared in the description – which was not discovered by the Federal Court – and the examples appeared to the person skilled in the art to be the most general form of the technical teaching.

The Federal Court thus confirmed the admissibility of a functional depiction of a group of compounds in a use claim. It did not see a problem with the fact that the claim encompassed compounds not yet available. Insofar as use of an invention goes, it is acceptable if compounds are encompassed that have not yet been made available to the public.

The opportunities

The Federal Court recognised the innovative idea in the case of dipeptidyl-peptidase inhibitors, and that this would encourage further innovation. It demonstrated that it was not afraid to depart from the EPO's standard rejection of functional claims in order to provide appropriate protection. The claim discussed above is not a typical reach-through claim; however, this decision concedes broader rights than EPO case law. In Germany, this case indicates that patents claiming compounds defined by their function are possible, although they might reach through the use of future compounds. The possibility of obtaining this type of protection may be particularly attractive to innovators.

The decision offers encouragement for applicants that wish to apply for patent protection in important pharmaceutical markets such as Germany. In view of recent developments, applicants working in the field of fundamental research and drug discovery programmes would be well advised to explore the possibility of obtaining reach-through coverage for their inventions in Germany. ■

COHAUSZ & FLORACK
Bleichstraße 14
40211 Dusseldorf, Germany
Tel: +49 211 90490 0
Fax: +49 211 90490 49
www.cohausz-florack.de

Corinna Lueg
Technical Expert
COHAUSZ & FLORACK
Germany
Tel: +49 211 90 490 0
Fax: +49 211 90 490 49
clueg@cohausz-florack.de

Corinna Lueg obtained a graduate degree in pharmacy from the University of Münster, Germany. She received her PhD in medicinal chemistry with a focus on drug development (University of Münster, Germany). Dr Lueg joined COHAUSZ & FLORACK in 2013 and is currently training as a patent attorney.