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German court reverses decision on pemetrexed dipotassium (Eli Lilly v Actavis)

Thorsten Bausch (Hoffmann Eitle) · Thursday, April 2nd, 2015

With its judgment of March 5, 2015 (I-2 U 16/14), the Higher Regional Court (HRC) Dusseldorf reversed the first-instance decision and has now come to same conclusion as did the High Court of Justice for England and Wales (here) by holding that pemetrexed **dipotassium** does not fall within the equivalent scope of protection of EP1 313 508 claiming pemetrexed **disodium** (in a combination formulation with vitamin B12 or a pharmaceutical derivative thereof). The facts of the case have been set out in the above-referenced blog by our colleagues at Bristows, to which we wish to refer.

In the above-mentioned High Court decision, a significant factor was the prosecution history. Justice Arnold summarized the prosecution history as follows: “Lilly attempted to obtain broader claims, first to an antifolate and secondly to pemetrexed, but the examiner objected to those claims. In particular, the examiner objected that the amendment to introduce claims to pemetrexed lacked support in the description and therefore constituted added matter. The description contained textual support (but not supporting data) for broad claims to an antifolate, but it did not even contain textual support for claims to pemetrexed. Rather than argue the point, Lilly opted for narrow claims to pemetrexed disodium in order to obtain rapid grant of a patent.” When pondering to what extent prosecution history can be an aid to claim construction, Justice Arnold moreover stated: “[...] consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement. [...] I consider that the present case provides a good illustration of this.”

The German courts have consistently refused to consider the prosecution history when construing a patent claim. The main arguments have been that Art. 69 EPC conclusively enumerates the description and the drawings as the basis for interpreting the claims and that the prosecution history is not sufficiently accessible for the public (although it is questionable whether this is still true in an age of online registers). For the first time in its judgment “*Okklusionsvorrichtung*” (Aga v. Occlutech; [here](#)), the Federal Court of Justice (FCJ), however, indicated in an *obiter* remark that to construe a claim, one may consider earlier versions of this claim such as in the published application or the granted claim if it was later limited in opposition proceedings or otherwise. The HRC Dusseldorf applied this new approach in the “*Drospirenon*” decision (judgment of September 13, 2013; I-2 U 23/13), albeit only with regard to a comparison between the granted claim and a later limited claim. The court expressed doubts as to the appropriateness of a comparison with the claim of the published application.

In the here introduced “*Pemetrexed*” judgment, the HRC Dusseldorf has taken the position, as did Justice Arnold, that any protective scope having been given up during prosecution – for whichever reason – cannot be claimed back later as an equivalent scope of protection. On the other hand, the Court maintained that the file wrapper cannot be used for interpreting the claim. In the Court’s view, it is clear in the present case from the description that the patentee originally intended a broader scope of protection. The description sets out that the side effects of antifolates as a class can be reduced by administering vitamin B12 in combination. By claiming only one very specific salt form of one antifolate, the skilled person would consider all other salt forms to be deselected and thus outside the equivalent scope of protection.

Thereby the Court applied the “*Auswahlentscheidung*” concept (i.e. selection decision concept) which also goes back to the above-mentioned FCJ decision “*Okklusionsvorrichtung*“. If it is clear from a patent that the patentee in its patent claim selected from alternatives, a not selected alternative cannot be covered by the equivalent scope of protection either since its identification would not be guided by the teaching of the patent claim. For example in the “*Okklusionsvorrichtung*” decision, the alternative made use of by the attacked embodiment was not claimed, but disclosed in the description. Since “*Okklusionsvorrichtung*” this legal concept of a selection decision has been applied and further developed in several further cases, such as in the FCJ judgment of September 13, 2011, X ZR 69/10 “*Diglycidverbindung*“; HRC Dusseldorf judgments of November 7, 2013, I-2 U 29/12 – “*WC-Sitzgarnitur*” and January 3, 2013, I-2 U 22/10, “*Regenschirm*“, to name only a few.

With the “*Pemetrexed*” judgment, the HRC Dusseldorf has added another aspect to this legal concept. To be excluded from the equivalent scope of protection due to a selection decision, the Court holds, it is sufficient if the alternative is disclosed generically, provided it was known to be covered by the generic term on the priority date. As pemetrexed dipotassium was known as one possible salt form of an active ingredient in the class of antifolates, claiming pemetrexed disodium constitutes a selection decision against pemetrexed dipotassium.

This raises the question of whether it would have helped Eli Lilly to remove before grant the parts of the description discussing the general concept of using vitamin B12 to reduce the side effects of antifolates. The HRC Dusseldorf seemed to believe so since it mentions this option when considering whether its decision would unfairly disadvantage the patentee.

As a final remark, the “*Pemetrexed*” judgment seems to indicate that the HRC Dusseldorf has not finally closed the book on comparing the asserted patent claim to the claim version published with the application. The Court merely mentions that this legal question could remain unanswered since it is not relevant for the decision. Given how strongly the Court argued that one should not be allowed to claim back as equivalent something that was given up during prosecution, and that not all descriptions disclose as much as EP ‘508, such a comparison may become relevant in the future.

The HRC has not granted leave to appeal this case to the FCJ but Eli Lilly already announced that it will petition the FCJ to accept the case.

With this, I extend my best wishes for the Easter holidays.

Clemens Tobias Steins

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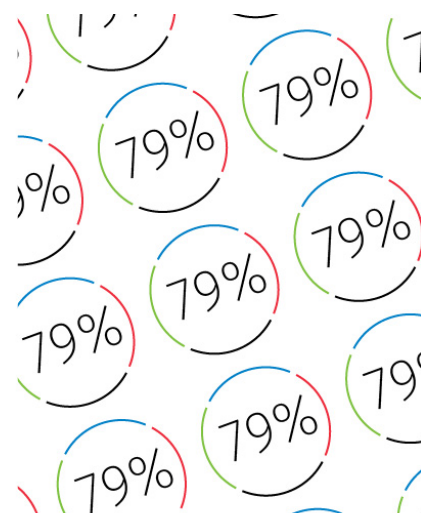
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This entry was posted on Thursday, April 2nd, 2015 at 4:35 pm and is filed under literally fulfil all features of the claim. The purpose of the doctrine is to prevent an infringer from stealing the benefit of an invention by changing minor or insubstantial details while retaining the same functionality. Internationally, the criteria for determining equivalents vary. For example, German courts apply a three-step test known as Schneidmesser's questions. In the UK, the equivalence doctrine was most recently discussed in *Eli Lilly v Actavis UK* in July 2017. In the US, the function-way-result test is used.">Equivalents, Germany, Scope of protection

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