Kluwer Patent Blog

# The English High Court applies German law on EPC 2000 claims in Royalty Pharma v Boehringer

Florence Plisner (Bristows) · Tuesday, October 26th, 2021

On 8 October 2021, His Honour Judge Hacon (sitting as a Judge of the High Court) handed down his decision in an action brought by Royalty Pharma Collection Trust (**"Royalty Pharma"**) for approximately €23 million in royalty payments from Boehringer Ingelheim GmbH ("**Boehringer**") (*Royalty Pharma Collection Trust v Boehringer Ingelheim GmbH* [2021] EWHC 2692 (Pat)). The action relates to products sold by Boehringer containing the active pharmaceutical ingredient ("**API**") linagliptin for the treatment of type 2 diabetes. Boehringer manufactures the API in Germany. Some API is also formulated, labelled and packed into products in Germany, but some is exported by Boehringer to other countries.

Boehringer entered into a non-exclusive licence with Prosidion Limited in 2005. The agreement had a somewhat unusual governing law and jurisdiction clause in that it was governed by German law but provided that the Courts of England and Wales have jurisdiction over any dispute. The agreement was assigned from Prosidion to Royalty Pharma in 2011 and was amended in 2015 (but not with respect to the jurisdiction or governing law clauses). Royalty Pharma claimed outstanding royalties pursuant to the amended agreement. One of the patents licensed by Royalty Pharma to Boehringer was the German designation of EP 1 084 705 ("**EP 705**"), and it is this patent which formed the subject of the dispute.

**Boehringer's obligation to pay royalties under the amended agreement**

The first section of the decision centred on the interpretation of a clause of the amended agreement which states that royalties are payable by Boehringer "*on Net Sales of Product the development, manufacture, registration, use, import/export, marketing or offer to sell and/or sale of which, but for the Licence would otherwise infringe a Valid Claim*". Boehringer argued that manufacture of API was not a royalty-incurring act and that the relevant clause only related to the manufacture of formulated product. After extensively summarising the principles of German contractual law, and considering the substance of the negotiations leading to the agreement and the substance of the amendment, Hacon HHJ concluded that acts of manufacture of API could incur an obligation to pay royalties. The amended agreement therefore required payment of royalties on the manufacture of the linagliptin API in Germany, should this manufacture infringe EP 705 and subject to the issue of export.

**Would EP 705 be infringed absent a licence?**

Claim 1 of EP 705 is in the EPC 2000 form and covers a class of effectors of particular enzymatic activity for use in lowering the blood glucose level of mammals for the alleviation of diabetes.

The German courts have ruled that EPC 2000 claims correspond to purpose-limited product claims and can be directly infringed via an act in s.9(1) German Patents Act 1980. Case law further indicates that the subject-matter of such claims lies in the suitability of the substance "*for*" a certain medical use. In order to determine whether an infringer's product is "*for*" the treatment of the indication specified in the claim, the German courts have developed the doctrine of *sinnfällige Herrichtung*. If the product of the claim is sufficiently tied to (or "*earmarked for*") the use specified in the claim, the requirement of *sinnfällige Herrichtung* is satisfied.

Hacon HHJ held that, in principle, manufacture of an API could constitute an act of infringement of pharmaceutical EPC 2000 claims. No German court has previously reached this conclusion, but Hacon HHJ distinguished the case at hand from other *Bundesgerichtshof* ("**BGH**") case law in the pharmaceutical context, because the BGH case law referred to products which were old (i.e. the API was known at the priority date), whereas Boehringer developed linagliptin after the priority date of EP 705.

Hacon HHJ then considered whether an unaltered API can satisfy the requirement of *sinnfällige Herrichtung* without having been formulated into a medicament or having been labelled. German case law implies that an API can satisfy the requirement of *sinnfällige Herrichtung* by virtue of its inherent properties alone. Hacon HHJ considered *Östrogenblocker* and noted that *sinnfällige Herrichtung* will be satisfied at the time of manufacture if: (i) the API is suitable for use for the purpose specified in the claim; (ii) the manufacturer of the API has taken advantage of circumstances which ensure that use of the API for that purpose will take place (such prospective use being sufficient not occasional); and (iii) the manufacturer knows that the relevant circumstances are in place.

Given that the only authorised use of linagliptin is for the purpose specified in the claim (as part of a product containing excipients), this was a powerful factor in determining the circumstances were in place to ensure that linagliptin would be used for that purpose and that Boehringer knew it would be used exclusively for that purpose. Therefore, at the time of manufacture, the requirement of *sinnfällige Herrichtung* was satisfied in relation to the purpose specified in claim 1 of EP 705.

**Export and EPC 2000 claims**

Boehringer further argued that the act of manufacture can only infringe an EPC 2000 claim if the product is used in Germany. Hacon HHJ held, in line with obiter comments of the BGH in *Hydropyridin*, that an EPC 2000 claim may be infringed where there is a s.9(1) infringing act in Germany, such as manufacture, including where the product is destined for export.

Boehringer's manufacture of linagliptin API in Germany would therefore have infringed EP 705 but for the licence granted by the amended agreement. The acts of manufacture generated royalties under the amended agreement to be paid by reference to sales of product containing linagliptin, irrespective of where the sales took place.

**Would the decision have been the same under English law?**

It is interesting to consider whether the same decision would be reached if Hacon HHJ had had to apply English law rather than German law.

The seminal case on pharmaceutical use patents is the Supreme Court's decision in pregabalin. It should be noted that this decision addresses Swiss-type claims, which are seen by the English courts as purpose-limited process claims, whereas EPC 2000 claims are interpreted (in line with the German courts) as purpose-limited product claims. It is likely, however, that in this respect the analysis of the Supreme Court would be applicable to EPC 2000 claims as, similarly to Swiss-type claims, EPC 2000 claims have a purpose limitation which was the focus of the Supreme Court's infringement analysis. Therefore, it may also be deemed possible to directly infringe EPC 2000 claims via manufacture of an API, provided that the manufacture of that API is "*for*" the patented indication.

In order to assess whether the manufacture of the API is "*for*" the patented indication, it is an interesting exercise to apply the different tests as set out by the Supreme Court Justices in obiter remarks. Under Lord Sumption's "*outward presentation*" test, it is difficult to see how an unformulated API could ever be infringing as this test considers the physical characteristics of the product including its formulation, dosage, packaging, labelling and leaflet as decisive. This is interesting, as it is noted in the pregabalin judgment that this test derives from the jurisprudence of the German courts' "*sinnfällige Herrichtung*" test.

It is arguable that Lord Hodge and Lord Briggs' "*subjective intention*" test is more in line with the approach taken by the German courts in *Östrogenblocker* (applied by Hacon HHJ in the case at hand), which introduced a mental element based on foreseeability. If this "*subjective intention*" test were applied, it is easy to see how the facts of the present dispute, namely that the API was developed after the priority date of the patent and the API was only authorised for the patented indication, might lead the court to conclude that Boehringer's intention was for the API to be used for the patented purpose.

Perhaps this case highlights the fact that, as the German courts seem to have acknowledged, a more flexible approach is required to infringement of pharmaceutical use claims than a rigid "*only packaging will do*" or "*outward presentation*" test. The optimal approach should consider the wider circumstances surrounding manufacture of a potentially infringing product. The author notes that, in the UK, the analysis of indirect infringement as between Swiss-type claims on the one hand, and EPC 2000 claims on the other, is likely to be different because the former are construed as process claims and the latter as product claims. Several first instance cases have touched upon the issue of the indirect infringement of EPC 2000 claims and it will be interesting to see how the appellate courts deal with this issue and whether they attempt to reconcile the approach with that taken to Swiss-type claims or not.

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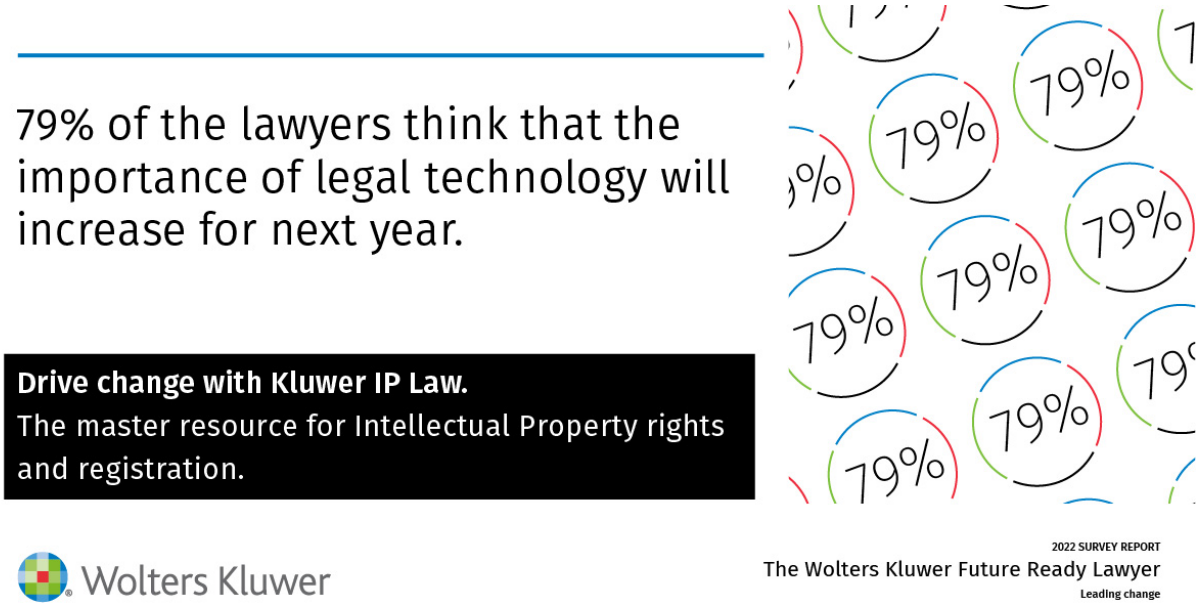


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