Royalty Pharma Collection Trust v Boehringer Ingelheim GmbH



Court

Chancery Division (Patents Court)

Judgment Date

8 October 2021

Where Reported

[2021] EWHC 2692 (Pat) [2021] 10 WLUK 90 Judgment

Subject

Intellectual property

Other related subjects

Contracts

Keywords

Contract terms; Contract terms; Germany; Infringement; Licensing agreements; Method claims; Overpayments; Patents; Pharmaceuticals; Royalties

Judge

Judge Hacon

Counsel

For the claimant: Andrew Lykiardopoulos QC, James Segan QC.

For the defendant: Adrian Speck QC, James Whyte.

Solicitor

For the claimant: Powell Gilbert LLP. For the defendant: Allen & Overy LLP.

Case Digest

Summary

On the proper construction of an amended pharmaceutical licensing agreement governed by German law, the proprietor of a European patent concerning the use of linagliptin for the treatment of diabetes was entitled to royalties arising

from the defendant's manufacture of products for which linagliptin was the active pharmaceutical ingredient. The defendant was, however, entitled to recover overpaid royalties pursuant to the original licensing agreement.

Abstract

The claimant claimed outstanding royalties from the defendant pursuant to a pharmaceutical licensing agreement, and the defendant counterclaimed for overpaid royalties.

In 2005, the defendant had entered into a written agreement with a company (P) granting it a non-exclusive licence under patents and patent licences owned by P. P's benefit under that original agreement was assigned to the claimant in 2011. The original agreement was amended on 19 May 2015. The agreements were governed by German law with provision for the English courts to have jurisdiction in the event of any dispute. The products sold by the defendant which generated royalties under the agreements were pharmaceuticals authorised for the treatment of type 2 diabetes whose active pharmaceutical ingredient (API) was linagliptin. All the linagliptin used in the products was manufactured by the defendant in Germany. Some linagliptin was formulated, labelled and packaged into products in Germany and some linagliptin was exported by the defendant to other countries. One of the patents licensed by the claimant to the defendant was the German designation of a European patent (patent 705) granted in 2014, entitled "Method for lowering the blood glucose in mammals". Patent 705 was a pharmaceutical use claim, within the meaning of the EPC, for linagliptin in the treatment of diabetes. The claimant claimed around €23 million from the defendant in outstanding royalties pursuant to the amended agreement. The defendant's counterclaim to recover overpaid royalties under the original agreement was admitted by the claimant.

The claimant contended that but for the licence under the amended agreement, the defendant's manufacture of linagliptin in Germany would have infringed patent 705, and that from the date of the amended agreement, royalties fell due on that manufacture until the date of the patent's expiry in April 2017. The defendant submitted that (1) on the agreements' proper construction, although the manufacture of "Product" gave rise to the payment of royalties, the manufacture of "Compound" did not: even if the formulation of linagliptin API into Product could have been a royalty-incurring act, the manufacture of the API itself could not; (2) the act of manufacturing linagliptin, as opposed to its sale in a territory covered by the licence,

did not give rise to an obligation to pay royalties; (3) the manufacture of linagliptin in Germany did not, in any event, infringe patent 705 because linagliptin was not earmarked in Germany for use in the treatment of diabetes; (4) no products made for export from Germany could have infringed patent 705

Held

Judgment accordingly.

Obligation to pay royalties - Where the words of a written contract were clear and unambiguous and there was an inner coherence to the document, there was a presumption under German law that the words reflected the common intent of the parties. The parties had shared a common intention that the amended agreement obliged the defendant to pay royalties if it carried out any act of development, manufacture, registration, use, import/export, marketing or offer to sell and/or sale of Product, which act, but for the licence, would infringe a valid patent claim. It followed that the manufacture of Compound was licensed because it fell within the licence granted to manufacture Product or, alternatively, because it fell within the defendant's licence to "develop" as required to manufacture or have manufactured Product in the field. In other words, acts of manufacture, not just sales, could incur an obligation to pay royalties. The amended agreement therefore required the defendant to pay royalties on the manufacture of linagliptin in Germany (see paras 93, 107-109, 126 of judgment).

Infringement of patent 705 - An EPC 2000 claim would be directly infringed if the alleged infringer carried out an act in Germany in relation to the product of the claim, where the product was sufficiently tied to the use specified in the claim such that the German law requirement of "earmarking" was satisfied. An API could, in principle, satisfy the requirement of earmarking in its unaltered state, without having been formulated into a medicament or labelled. If there was earmarking of the API for use for the relevant purpose at the time of its manufacture, the act of manufacture would directly infringe the claim. The API linagliptin manufactured by the defendant in the relevant period was suitable for use for the purpose specified in claim 1 of patent 705, and that manufacture would, but for the licence, have amounted to an infringing act. Contrary to the defendant's submission, an EPC 2000 claim might be infringed where there was an infringing act in Germany, such as the manufacture of a product, including where the product was destined for export. It followed that the defendant

was obliged to pay royalties by reference to sales of Product containing the linagliptin irrespective of where those sales took place (paras 230, 235-239, 241-243, 263-264).

Conclusion - The claimant's claim to unpaid royalties under the amended agreement succeeded, as did the defendant's counterclaim for overpayment of royalties under the original agreement (para.305).