

Can a decision to make a licensee pay royalties fall foul of European competition law?

Summary

Following arbitration proceedings a licensee (Genentech) has been ordered to pay substantial royalties to a licensor (Hoechst) in respect of sales of a drug which was allegedly manufactured using a "patented" technology.

The European patent in question has already been revoked by the European Patent Office (EPO), so clarification from the Court of Justice of the European Union (CJEU) has now been sought as to whether the order (to pay the royalties) is appropriate under EU competition law.

Dispute

This dispute originates from a licence agreement executed on 6 August 1992 which permitted Genentech to use a cytomegalovirus (CMV) enhancer, with a view to manufacturing and using proteins for research purposes.

In return, Genentech agreed to pay a single non-reimbursable royalty of DM 20,000 (about USD 12,000 in 1992) as costs for the issue of the licence and an annual fixed royalty of DM 20,000 for research purposes.

In addition, the agreement stipulated that Genentech should pay running royalties of 0.5% of net sales of any finished goods incorporating a product under licence.

Genentech (which became part of the Swiss group Roche) developed Rituximab (trade name Rituxan) and this drug became one of Roche's top-sellers. Genentech did not identify Rituxan as a licensed product, nor did it pay the running royalties.

In 2008, Genentech terminated the agreement and filed actions in the U.S. for patent invalidity and non-infringement. A finding of non-infringement was affirmed by the Court of Appeal of the Federal Circuit.

The situation in Europe differed somewhat.

The European patent under license had been revoked by the EPO on 12 January 1999 (the patent was opposed by an unconnected third party).

However, during arbitration proceedings the Arbitrator found that infringement was still possible because, in his view, the essence of the agreement was that royalties

would be payable to the licensor during the entirety of the agreement, even in the event that the patent was subsequently held to be invalid. It was not explicit in the agreement but, in coming to this view, the Arbitrator considered that the commercial object of the agreement (which was interpreted under German Civil Law) was to avoid any lawsuit on the validity of the U.S. patents during the period of the agreement, and therefore that the parties had foreseen that running royalties were payable based on the manufacture of Rituxan.

Genentech asserted that the Arbitrator's decision contravenes European competition law because it sentences a payment of royalties for a technology that is not now patented and is freely accessible to others. Whilst this may be true it is also arguable that Genentech was given a head start over its competitors by gaining early access to that technology, and that this head start may have led to the commercialisation of a blockbuster drug quicker than any of its competitors.

In our view the order to pay the royalties seems a little unjust. It may be fair for a licensor to claim royalties that a licensee did not pay prior to a final and binding decision on a patent's validity, but to claim royalties post that decision does not seem quite right. On the other hand, Genentech did have the option to terminate the agreement in 1999 when the European patent was revoked. The fact that it did not do so gives some weight to the Arbitrator's argument that the commercial object of the agreement was to protect the validity of the U.S. patents. If this turns out to be the crux of the issue then there may be some merit in the order for Genentech to pay the royalties.

There was also a side issue as to whether the sale of Rituxan would have actually infringed the patent in any event. This was due to the fact that the European patent in question covered a CMV enhancer, but Rituxan itself does not include the enhancer. The Arbitrator held that Genentech had used the enhancer under licence in the recombinant synthesis of proteins in order to manufacture Rituxan, and thus had to pay royalties on that use under the terms of the licence agreement.

It will be interesting to see the decision of the CJEU as it could impact other scenarios, such as validity and scope of claw-back clauses.

This matter was referred to the CJEU on 23 September 2014, and the decision is unlikely to issue for quite some time. We will report further when we have news.