Is paying for a licensed but later invalidated patent contrary to Article 101 of the TFEU?

patentblog.kluweriplaw.com/2014/10/18/is-paying-for-a-licensed-but-later-invalidated-patent-contrary-to-article101-of-the-tfeu

Pierre Véron October 18, 2014

Pierre Véron and Amandine Métier, Véron & Associés

On 23 September 2014, the *cour d'appel de Paris*, in Genentech v. Hoechst and Sanofi Aventis Deutschland, Docket № 12/21810, decided to refer to the Court of Justice of the European Union the following question:

"Should the provisions of Article 81 of the Treaty, now Article 101 of the Treaty on the Functioning of the European Union, be interpreted as an obstacle to giving effect, in case of invalidation of the patents, to a licence agreement which imposes on the licensee royalties for the sole use of the rights attached to the patents under licence?"

Through this referral the court questions the compatibility with European Union competition law of an arbitral award, which ordered Genentech, the licensee, to pay more than €100,000,000 royalties to Hoechst, the licensor, for a patent held invalid in Europe.

The origin of the dispute lies in a licence agreement signed on 6 August 1992 between the German company Behringwerke, the licensor, (of which Sanofi-Aventis Deutschland, a subsidiary of Hoechst, is a successor) and Genentech, the licensee.

This license agreement relates to the use of enhancers for eukaryotic expression systems which had been identified in human cytomegalovirus (an enhancer is a DNA sequence that, when introduced into a cell that produces a drug, enables the cell to produce the drug at a much higher rate than would ordinarily be possible), the subject matter of European patent 0,173,177, US patent 5,849,522 and US patent 6,218,140.

The licence agreement was governed by German law and required that disputes be settled by arbitration in accordance with the rules of the International Chamber of Commerce ("ICC").

The 1992 licence agreement specified that in exchange for fixed annual payments, Genentech could practice the patents for research purposes; Genentech made corresponding payments from 1992 to 2008.

In addition, the 1992 license agreement required that Genentech pay an additional 0.5% running royalty on the sale of commercially marketable goods incorporating a "Licensed Product", being defined as "*materials (including organisms), the manufacture, use or sale of* ***which would, in the absence of this Agreement, infringe*** *one or more unexpired issued claims of the Licensed Patent Rights.*"

This additional running royalty has never been paid by Genentech.

On 12 January 1999, European patent 0,173,177 is definitely revoked by the European patent Office (decision T 0070/95).

Arguing that the development, manufacturing and sales of the top-selling drug Rituxan by Roche (Swiss group to which Genentech became a member in March 2009), for the treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin's lymphoma, known in Europe under the name MabThera, implement the technology the subject-matter of the license agreement, Sanofi asked for the payment of the additional royalty by letter of 30 June 2008.

Shortly thereafter, on 27 August 2008, Genentech notified Sanofi of its intent to terminate the Agreement on 27 October 2008.

On 24 October 2008, Hoechst started ICC arbitration proceedings (with a sole arbitrator) for the payment of royalties, pursuant to the license agreement.

Three days later, Genentech filed a complaint for a declaratory judgment of invalidity and non-infringement in the United States District Court for the Northern District of California and the same day Sanofi filed an infringement complaint in the United States District Court for the Eastern District of Texas.

The two U.S. court actions were consolidated in the Northern District of California, which granted a summary judgment of non-infringement on 11 March 2011, confirmed by the Court of Appeal for the Federal Circuit on 22 March 2012.

After having dismissed in a first arbitral award Genentech's claims as to the suspension of the arbitration, the non-arbitrability of the case and the nullity of the arbitration agreement, the arbitrator appointed by the ICC stated that Rituxan "*is produced with the help of the [patents-in-suit]*" and granted the request by Hoechst for communication of the financial reports relating to Rituxan in a second partial award of 9 June 2011

In a third partial award made in Paris on 5 September 2012, subject to the invalidation action brought before the *cour d'appel de* Paris, the arbitrator held Genentech liable with regard to Rituxan and the other products having the same properties and reserved the decisions relating to the evaluation of the quantum.

According to the decision of the *cour d'appel de Paris*, the arbitrator considered the commercial object of the agreement, interpreted according to Article 242 of the German Civil Code, which was to avoid any lawsuit on the validity of the U.S. patents during the period of validity of the licence agreement, and considered, consequently, that the parties had foreseen that "*while the licence agreement is in force, running royalties are due based on the manufacture of Rituxan even if, in the country of manufacture, the*

patent for manufacture of Rituxan were subsequently found to be invalid, and therefore if the manufacture of Rituxan were found not to have infringed the local patent in the sense of the right to patents in the country of grant and of manufacture".

As a consequence, in a fourth final award made in Paris on 25 February 2013 (and an addendum of 22 May 2013), also subject to the invalidation actions brought before the *cour d'appel de* Paris, the arbitrator ordered Genentech to pay to Hoescht €108,322,850 plus interests from 1998, as well as the costs for arbitration.

Genentech requested the *cour d'appel de* Paris to set aside the last three arbitration awards (handed down on 5 September 2012, 25 February 2013 and 22 May 2013) on the grounds that the recognition or enforcement of the award is contrary to international public policy according to Article 1520 of the French Civil Procedure Code.

According to Genentech, the decision of the arbitrator, who finds a breach of the licence agreement without finding any patent infringement, is contrary to Article 101 of the Treaty on the Functioning of the European Union, considering that the payment of unjustified royalties for the development and sales of rituximab in the territory of the European Union (Germany, France, Italy), is contrary to the principle of free competition and has a direct effect on the flow of trade between the Member States.

The *cour d'appel* notes that the parties agreed that the licence agreement would be interpreted and executed in accordance with the law of the Federal Republic of Germany and says that it "*is not contested that it authorises the licensor to claim royalties from the licensee until the termination of the agreement, notwithstanding the subsequent invalidation of the patents to which the granted rights were attached*";

This interpretation of the German law seems not to be fully correct, as if it is agreed that a licensor may claim the payment of royalties that the licensee did not pay until the moment the decision on invalidity is final and binding, it is no more the case after this decision.

This will be probably further discussed in this case.

But in view of this above-mentioned analysis, the *cour d'appel* concludes as follows:

"the arbitration award made the agreement applicable and considered that during the period of validity thereof the licensee was required to pay the royalties stipulated by the agreement even though the invalidation of the patents has a retroactive effect; the question therefore arises of knowing whether such agreement infringes the provisions of Article 81 of the Treaty, now Article 101 of the Treaty on the Functioning of the European Union as distorting competition within the internal market in that, by forcing the licensee to payment of royalties without cause by the effect of the invalidation of the patents attached to the granted rights, it inflicts a disadvantage in competition on the licensee;

Therefore, the question referred by the *cour d'appel de Paris* to the Court of Justice of the European Union the following question reads as follows:

"Should the provisions of Article 81 of the Treaty, now Article 101 of the Treaty on the Functioning of the European Union, be interpreted as an obstacle to giving effect, in case of invalidation of the patents, to a licence agreement which imposes on the licensee royalties for the sole use of the rights attached to the patents under licence?"

The reply to this question will be eagerly awaited in particular in France, where it is generally accepted in case-law that the royalties are due to the licensor until a final decision on the invalidity of the patent and are therefore not to be paid after such decision, even if the license agreement is not terminated.

Original French decision:
2014-09-23_CA_Paris_Genentech_c_Hoechst_RG_12-21810

English translation:
2014-09-23_CA_Paris_Genentech_c_Hoechst_RG_12-21810_Translation