



When is a MA deemed transferred in the context of license and supply agreements of medicinal products?

Judgment of the Supreme Court of 7 December 2021

Background

Two companies entered into a license and supply agreement of medicinal products. Under such agreement, the licensor granted a licence to use certain documentation to obtain a marketing authorisation (MA) in Spain and other territories to the licensee. In consideration for the granting of such rights, the licensee undertook to pay a down payment to the licensor subject to the completion of certain milestones. According to the agreement, one of such milestones was the effective transfer of the Spanish MA to the licensee.

In this case, the conflict did not arise between the companies, but rather between the Regional Treasury of Navarre and the Spanish Tax Authorities (AEAT). Once the public deed of transfer of the MA was executed, the licensor issued the invoice for the agreed down payment, which the licensee paid. The Regional Treasury of Navarre argued being entitled to the accrued VAT because the obligation to make the down payment was not due until the Spanish Medicines Agency (AEMPS) authorised the transfer of the MA. On the other hand, the AEAT claimed that the payment obligation arose upon granting the deed of transfer, and hence that it was entitled to collect the relevant VAT amount.

The dispute was brought before the Arbitration Board of the economic agreement between the State and the Autonomous Community of Navarre, which ruled in favour of the AEAT.

This decision was later confirmed by the Spanish Supreme Court.

The relevance of the contractual provisions and the actions of the parties

Both the decision of the Arbitration Board and the Spanish Supreme Court are mainly based on the literal wording of the agreement that was originally entered into by the parties. They highlight that, according to the agreement, the licensee would acquire the MA upon execution of the agreement. On the other hand, they stated that as per the public deed that was required for the transfer of the MA, the effectiveness of the transfer was conditional upon approval by the AEMPS. Considering that, according to the agreement, the acquisition would take place between the parties upon execution, the Arbitration Board and the Spanish Supreme Court interpreted the down payment clause as meaning that the transfer of the MA took place, at the latest, upon execution of the public deed before a Notary Public.

The fact that the invoice was issued and paid after the execution of the public deed clearly supports this decision.

In short, according to this Judgment, payment obligations arising from a transfer agreement of a MA arise and become enforceable at the time agreed by the parties regardless of the date on which the AEMPS authorises the transfer.