Competition Authority closes antitrust inquiry into patent settlement between originator and generic pharmaceutical companies

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AUTHOR

Eduardo Maia Cadete

Introduction

In September 2014 the Competition Authority opened an antitrust inquiry (Case PRC 2014/4) after receiving information from the health secretary of state regarding an agreement between the pharmaceutical companies Teva and its subsidiary Ratiopharm and AstraZeneca, under which Teva and Ratiopharm had agreed to withdraw the generic medicine Rosuvastatina Ratiopharm from the Portuguese market on February 25 2013 with immediate effect.

The authority issued requests for information to Teva, Ratiopharm, AstraZeneca and Infarmed (the national medicine authority) and conducted dawn raids of company premises, including those of AstraZeneca's affiliated companies Novastra, Stuart, Astra Alpha, Zeneca Epsilon and Mepha and the distributor Laboratórios Medinfar. The authority also questioned legal representatives from Teva, Ratiopharm and Medinfar and communicated the details of the case, as per Article 11 of EU Regulation 1/2003, to the European Competition Network and the competition authorities of other EU member states.

The antitrust inquiry was concluded in 2016 based on the findings outlined below, following a Competition Authority Council decision without the adoption of a statement of objections.

Main findings

The Competition Authority's inquiry primarily focused on Teva's decision to end its commercialisation of Rosuvastatina Ratiopharm following an agreement with AstraZeneca. Before the agreement was made, Teva had marketed Rosuvastatina Ratiopharm in Portugal with the active substance rosuvastatina and AstraZeneca had marketed two innovative medicines (Crestor and Visacor) with the same active substance.

In its decision, the authority acknowledged:

- the validity of patents and supplementary protection certificates under the applicable national and EU rules; and
- the fact that competition law does not affect IP rights.

Further, recalling the European Court of Justice (ECJ) decision in *Centrafarm* (Case 15/74), the authority stated that:

> *"Although the existence of rights recognized under the industrial property legislation of a member state is not affected by Article* [101] *of the Treaty, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that*

article. This may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement."

The authority concluded that competition law does not affect IP rights, including patents, although their exercise through an agreement between undertakings can potentially constitute a breach of Article 101 of the Treaty on the Functioning of the European Union (TFEU) and the equivalent national provision.

The authority's decision established that the holder of a patent has the right to enforce it judicially, and that the court may deem this right to be invalid due to unmet conditions. This point is even more relevant in the pharmaceutical sector, as generic companies frequently dispute – explicitly or implicitly – the patent rights of originator pharmaceutical undertakings.

Further, under Law 62/2011, disputes over the industrial property rights of reference and generic medicines are subject to mandatory arbitration. In such a procedure, the interested party (ie, the originator undertaking or patent holder) wanting to invoke the respective IP right and impede the launch of a generic medicine must lodge a written motion before an arbitration court within 30 days from the date on which Infarmed publishes notification of a request to launch a generic medicine. The undertaking that wishes to launch the generic medicine cannot start marketing the product in Portugal without a judicial reply.

The dispute resolution rules under Law 62/2011 increased the number of agreements aimed at settling such disputes. The Competition Authority restated that such agreements are not exempt from competition law rules, which are grounded in Sections 15 and 16 of the ECJ's judgment in *Bayer* (Case 65/86):

> *"In its prohibition of certain "agreements" between undertakings* [Article 101 of the TFEU] *makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind. It should also be noted that this assessment of such a settlement is without prejudice to the question of whether, and to what extent, a judicial settlement reached before a national court which constitutes a judicial act may be invalid for breach of Community competition rules. A no-challenge clause included in a patent licensing agreement may, in the light of the legal and economic context, restrict competition within the meaning of Article* [101 of the TFEU]."

In its decision, the Competition Authority stated the following:

> *"Being certain that undertakings have the right to terminate their disputes regarding patents, the truth is that when doing it, they have to comply with Competition rules... It is a PCA competence to assess the conformity of agreements between undertakings under Competition rules and... agreements which have as base an alleged or effective patent dispute are not immune to such control... To determine the lawfulness or unlawfulness of the agreement... one has to attend to the goal and extension of duties and benefits attributed to each party in the agreement at stake.*" (Sections 103 to 106.)

The authority provided guidance regarding agreements between originator and generic undertakings that may be deemed illegal (eg, where a generic undertaking is paid by an originator undertaking to halt its efforts to enter into or maintain itself in a market based on the fact that the generic medicine breaches the originator undertaking's patent rights). This situation differs from a framework in which the originator undertaking's patent is judicially enforced and deemed valid in court.

The authority adopted the following criteria to decide whether an IP settlement agreement is lawful:

- If a breach of patent rights is established by a court, the mechanism employed by the originator undertaking to evict the competitor from the market is legal, as it is based on patent rights.
- In cases where, by agreement between the parties, the generic undertaking decides not to challenge the patent based on a transfer of value of any kind by the originator undertaking – a scenario in which the generic undertaking's exclusion from the market is not based on the strength of the originator undertaking's IP right, but rather on the existence of an anti-

competitive agreement – the conduct continues to be unlawful, even if the originator undertaking successfully upholds the patent's validity in court.

The authority's main rationale for its approach was as follows:

> *"From the perspective of the innovative undertaking there is uncertainty regarding the possibility of entry of the generic in the market (potential competition). This potential competition is eliminated through the transfer of value to the generic undertaking and transformed into certainty of non-competition. This means that if the agreements related to patent disputes are not limited to regulate the patent breach, as it is known at the moment of the agreement, but is extended to future procedures yet unknown, then it becomes obvious that the will of the generic undertaking to cease its efforts to enter the market was not based on any assessment of a potential patent breach, but on the financial incentives granted by the innovative company."*

From an antitrust standpoint, the authority deemed that an agreement must be assessed based on the IP rights breached in order to assess whether the respective scope exceeds the judicial dispute, including if the generic undertaking was compensated for non-market entry.

Based on the criteria identified, the authority assessed the background of the settlement agreement established between Teva and AstraZeneca to determine:

- the validity of the supplementary protection certificate for AstraZeneca's product until June 30 2017;
- the pending judicial dispute between the parties that led to the settlement agreement; and
- the existence of an agreement whose scope was limited to the pending judicial dispute.

Based on these findings and the information retrieved at the undertakings' premises – including approximately 50 emails – no elements were found which:

- expanded the scope of the settlement agreement beyond the judicial dispute over IP rights; or
- included a financial incentive of any kind for the generic undertaking to withdraw its product from the market.

As a result, the authority found that Teva's decision to remove its product from the Portuguese market and the respective upstream IP settlement agreement did not breach antitrust provisions.

Comment

The Competition Authority's findings in the AstraZeneca and Teva antitrust investigation are the first in the jurisdiction to combine competition law rules and IP law in the context of a patent settlement between originator and generic pharmaceutical undertakings. Further, the decision provides ample guidance to economic agents regarding the requirements that must be fulfilled for such agreements to conform with competition law.

For further information on this topic please contact Eduardo Maia Cadete at Morais Leitão Galvão Teles Soares da Silva & Associados by telephone (+351 21 381 74 57) or email (maiacadete@mlgts.pt). The Morais Leitão Galvão Teles Soares da Silva & Associados website can be accessed at www.mlgts.pt.
