The strategies in view of the approval of generics and the rules of competition defense

Decision 13-D-11 of the French Competition Authority in the case Sanofi-Aventis (Plavix®)

Background

The generic clopidogrel based medicinal products that were approved starting from July 2008, when the basic patents of this product expired, showed two differences with respect to Plavix® that was the reference medicinal product: the generics contained a clopidrogel salt different from the one used for Plavix® and could not include, among their approved indications, the treatment of acute coronary syndrome in combination with acetylsalicylic acid.

These differences were due to the fact that both the clopidogrel salt used for Plavix® as well as the indication in question were protected by specific patents until February 2013 and February 2017 respectively.

It is known that the European regulation provides that the different salts of an active ingredient shall be considered the same active ingredient, unless they have significantly different properties with regard to safety and/or efficacy and that the authorization of generics with exclusion of indications of the original medicinal product that are still protected by patents is also permitted.

In this situation, the French Competition Authority ruled about a matter regarding the information that the company that holds the marketing authorization of the reference medicinal product can provide, where appropriate, to healthcare professionals, before the launch of the generic medicinal product.

Information versus abuse

In this case, the French Authority considered that Sanofi-Aventis had designed and implemented a communication strategy specifically designed to generate confusion regarding the properties of the generics and therefore it achieved that the penetration of the generics in the market was much lower than the normal level of penetration.

Without entering into an analysis of the decision, which is not relevant for our remarks, we must highlight two aspects. In the first place, we would like to draw the attention to the type of procedure chosen by the generic company that filed the complaint. To file a complaint against an information or promotional campaign on the basis of the competition defense rules is possible, and may be more attractive than filing a complaint before the ordinary courts or before self-regulatory systems. The decision of the French Authority is a precedent to bear in mind.

In the second place, the rules that prohibit the abuse of a dominant position or unfair conduct must always be taken into account when considering the strategies to adopt in the event of changes in the market structure. To defend the position that has been achieved thanks to innovation and to the own efforts is legitimate, but the line between abuse and disloyalty can be very fine; and the reading of this Decision proves that some administrations are willing to enter into this discussion.