• France: The Autorité de la Concurrence fines Sanofi-Aventis € 40 600 000 for denigrating Generic Versions of branded Drug Plavix

On 14 May 2013, following a complaint from the generics manufacturer Teva Santé, the Autorité de la concurrence (the Autorité) imposed a fine of € 40 600 000 on Sanofi-Aventis for having implemented a strategy of denigrating the generic versions of its branded drug, Plavix, vis-à-vis pharmacists and doctors, with the goal of limiting their entry on the market and favoring Sanofi-Aventis' Plavix as well as its own generic version Clopidogrel Winthrop. It found that Sanofi–Aventis had abused its dominant position, thereby infringing Article 102 TFEU as well as the corresponding French provision.

A prior decision was handed down by the Autorité in 2010, dismissing Teva Santé's request for interim measures while deciding to proceed with the investigation on the merits of the case. This is the first time that a competition authority fines this particular type of originator practice aimed at generics.

Plavix is a 'blockbuster' prescribed to prevent complications from atherothrombosis. It is the fourth best-selling drug worldwide and was the first drug in France in 2008 in terms of reimbursement costs for the public health care system (€ 625 000 000).

Even though the patent protecting the drug, in particular its active ingredient, clopidogrel, expired in Europe in July 2008, Sanofi-Aventis filed complementary patents in order to extend the initial protection (i) to the salt used in Plavix (hydrogen sulfate) until February 2013 and (ii) to the indication for the treatment of acute coronary syndrome (ACS) in dual therapy until February 2017. These complementary patents do not however call into question the bioequivalence of the clopidogrel generics, which allowed them to be listed in the directory of generic medicines. Pharmacies could thus dispense generics for all prescriptions of clopidogrel, including of Plavix, (generic substitution), unless the prescribers, the doctors, explicitly excluded this possibility.

The investigation showed that, from September 2009 to January 2010, the time of independent generic launch, Sanofi-Aventis put in place a global and structured communication strategy vis-à-vis health professionals. The core of this strategy was to emphasise the above patent-related differences, however irrelevant for generic substitution, to deter doctors and pharmacists from the generic substitution process. Sanofi-Aventis' medical visitors and pharmaceutical representatives insinuated that these differences could lead to the health professionals' liability should medical problems arise from the use of the competitors' generics. At the prescription level, Sanofi-Aventis thus convinced doctors to avoid generic substitution by inserting the indication 'non substitutable' in their Plavix prescriptions. In case prescriptions nonetheless allowed generic substitution, Sanofi-Aventis also discouraged pharmacists from substituting Plavix with generics other than its own generic medicine, Clopidogrel Winthrop.

Sanofi-Aventis did not match its health hazard claims, aired in its communication campaign, with any regulatory action, for example by contesting the market authorization granted to these generics or otherwise alerting health officials on claimed risks of safety or efficiency.

Overall, the Autorité established that this conduct fell outside the scope of competition on the merits (see, e.g., AstraZeneca e.a./Commission, C-457/10, paragraph 129) and constituted an abuse of Sanofi-Aventis' dominant position on the market for clopidogrel prescribed in the context of ambulatory care. The Autorité found that the impugned behaviour met the relevant standard for a finding of abuse, as the commercial discourse of the pharmaceutical company relied on unsubstantiated assertions rather than objective considerations and that it was liable to restrict (and had in fact restricted) competition. In addition, the causal link between Sanofi-Aventis' dominance and the abuse was clear by virtue, in particular, of the brand-name recognition and the confidence placed by health professionals in the pharmaceutical company's assertions.

Finally, the evidence in the file showed the existence of economic harm. Sanofi-Aventis' abusive conduct led to an atypical generification process (sharp rise followed by a steady decline rather than stabilization of the share of generics), falling short of the health care system's target of a 75% generic penetration rate by end 2010 (it stood instead at 64.6%), which corresponds to a shortfall in savings for the public health insurance system that it estimates at € 38 000 000. Even within the generics segment, Sanofi-Aventis' practices allowed it to obtain a 34% market share with its own generic of Plavix, four times the average market share enjoyed by its other generic drugs.

See press release in French and in English