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French Autorité de la Concurrence Fines Sanofi €40.6 Million for Denigrating Competing Generics

On May 14, 2013, the French Autorité de la Concurrence (Autorité) issued a decision imposing a fine of €40.6 million on French company Sanofi-Aventis France (Sanofi) for an abuse of dominance in the market for the cardiovascular drug clopidogrel. This is not the first time the French competition authority has addressed the issue of an originator's defamation of competing generics companies' products, and highlights that this is a key area for the Autorité to ensure and facilitate generic entry. For example, in December 2007, the Autorité ordered Schering Plough by way of an interim measures order to stop making denigrating comments to physicians and pharmacists and to publish a statement in two medical magazines confirming the bioequivalence of the relevant generic drugs that had been permitted on the market and the possible substitution by pharmacists as soon as they were listed as generic drugs. The decision also makes clear that the Autorité is willing to define markets narrowly to be limited to the pharmaceutical in question in relation to issues involving life cycle management and generic entry.

The Products Concerned

Plavix is a clopidogrel brand drug which prevents relapses in cardiovascular diseases and is very widely prescribed in cases of Acute Coronary Syndrome (ACS). It is the fourth best-selling drug in the world and, in 2008, was the number one reimbursed pharmaceutical in France based on total reimbursements made by the French social security agencies.

The Context: Opening to Competition From Generics in 2008

Sanofi's patents for Plavix expired in 2008, opening the clopidogrel market to competition from generics. However, Sanofi obtained further patents on salts used in the composition of Plavix, which expired in 2013, leading competing generics manufacturers to use different salts in order to avoid patent infringement.

Moreover, a combination of Plavix and aspirin remains patent protected until 2017, and is specifically indicated for the treatment of ACS. Therefore, Sanofi is the only manufacturer authorized to sell this combination of Plavix and aspirin until 2017.

The French authorities had approved generics using different salts, finding them bioequivalent, and issued marketing authorizations for a number of generic versions at the beginning of 2009.

Finally, Sanofi also manufactures its own generic of Plavix (Clopidogrel Winthrop), which is thus the only generic version of clopidogrel using the same salts as Plavix.

The Commercial Practice Concerned

The Autorité found that Sanofi had set up a commercial strategy to counter the entry of generics of Plavix. According to the Autorité, the strategy consisted of systematically denigrating and discouraging the use of competing generics.

According to the decision, Sanofi implemented this strategy through its team of medical representatives who visited with physicians and with pharmacists:

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- **At the prescription stage**: Sanofi representatives denigrated competing generics to physicians, to ensure that they would insert a "nonsubstitutable" mention when prescribing Plavix or its Winthrop generic product;
- **At the substitution stage**: Sanofi representatives denigrated competing generics to pharmacists, with the aim of avoiding substitution for Plavix, or at least only for its Winthrop generic.

In addition, the decision found that Sanofi representatives issued threats of legal liability vis-à-vis physicians and pharmacists if they prescribed the generics companies' products.

Sanofi had tried to justify its communications to physicians and pharmacists by arguing the following:

- The difference in the salts used by the generics raises issues regarding the generics' efficacy and innocuousness. However, according to the decision, French public authorities had confirmed the inaccuracy of Sanofi's insinuations in a letter to Sanofi and instead authorized the generics as bioequivalent, despite the use of different salts;
- The generics companies did not have an authorization to market their products as a combination with aspirin for ACS treatment. Sanofi sought to raise doubts about the compatibility of the different salts used by generic products and aspirin. However, according to the decision, it was possible to prescribe the generics alongside aspirin, a treatment having the same efficacy in ACS treatment.

Sanofi Held a Dominant Position in a Market for Clopidogrel

The Autorité found that Sanofi enjoyed a dominant position in the French market for clopidogrel sold in pharmacies, in which Sanofi has a market share of about 60 percent through its brand-drug Plavix and its own Winthrop generic. The Autorité thoroughly investigated alternatives to Plavix within the relevant ATC 4 category, which is typically the relevant market definition, and which has been accepted by the Autorité in prior cases when assessing whether pharmaceutical companies hold a dominant position in the analysis of life cycle management strategies. However, based on the facts of this case, the Autorité defined a narrower market because it considered that there are no substitutes to clopidogrel and because the importance of the pharmaceutical's brand meant that prescribers and patients would not consider any substitutes.

Denigrating a Competitor's Product Can Constitute an Abuse of Dominant Position

The Autorité, basing its decision on Article L.420-2 of the Commercial Code, as well as Article 102 TFEU, found that an originator's statements concerning the quality of a generic competitor's products vis-à-vis physicians and pharmacists can constitute an abuse of a dominant position if the statements are inaccurate and have the effect of maintaining or strengthening a dominant position. According to the decision, the denigrating statements created an illegitimate doubt on the efficacy and innocuousness of the competing generics and, along with threats of legal liability, were anticompetitive. The Autorité stated that the only acceptable commercial strategy for Sanofi in this case would have been to emphasize the difference in salts. Implying that this difference in salts could have consequences on health and legal liability when the French authorities had already granted marketing authorizations and had confirmed by letter to Sanofi the bioequivalence of these generic products constituted an abuse of dominant position.

The Effects Analysis

In assessing whether Sanofi's statements had the effect of maintaining or strengthening a dominant position, the Autorité looked at the substitution rate (or "generification" rate) of Plavix with generics compared to trends of other molecules using projections of the French health care authorities.

The Autorité found that the substitution rate for Plavix was:

- Lower than projected; and
- Lower when compared to the substitution trend of other drugs in general.

This effect was key in the decision. In 2010, the Autorité had refused to grant interim measures in this case because the Securité Sociale studies showed normal substitution rates for Plavix. Updated studies on effects led the Autorité to find an anticompetitive effect because the entry of competing generics was significantly slowed.

Tackling Obstruction of Generic Entry Through Strategies of Misrepresentation

The Sanofi decision is in line with earlier cases of the Autorité, which focus on obstruction of generic entry through defamation of generic products and their bioequivalence. For example, in the case of Schering Plough the Autorité found that the direct interference with and obstruction of the launch of a competitor's product based on inaccurate statements fell outside competition on the merits. In the Sanofi decision, the Autorité paid special attention to the fact that these statements were inaccurate and that Sanofi had full knowledge that they were inaccurate given the marketing authorizations and the letter received by Sanofi from the French authorities, which confirmed the efficacy of generic products with different salts, as well as the possibility to use them in conjunction with an aspirin treatment for ACS.

The full text of the decision is here.