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Denigrating Competitors: To What Extent is it Permissible under Article 102 TFEU (France)?

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I. Introduction

This article examines the recent decision from the French Competition Authority (hereinafter referred to as the 'Autorité') concerning abusive practices aimed at preventing generic competition to Sanofi-Aventis France's blockbuster Plavix® (hereinafter referred to as the '*May 2013 Sanofi Case*'). In that decision, the Autorité fined Sanofi-Aventis France and Sanofi (together referred as 'Sanofi') more than €40 million for having 'denigrated' competing generics in the French market of the cardiovascular clopidogrel treatment sold by pharmacists for ambulatory care, in order to favour sales of Sanofi's original product and 'self-generic' Clopidogrel Winthrop®.[1]

The Autorité considered that Sanofi has abused its dominant position in the French market of clopidogrel prescribed by ambulatory care, and therefore has breached Article L.420−2 of the French Commercial Code, as well as Article 102 of the Treaty on the Functioning of the European Union (TFEU). In 2010, the Autorité issued a first decision on this case, whereby it had dismissed a request for interim measures and decided to proceed with the investigation on the merits of the case.[2] The *May 2013 Sanofi case* is now subject to an appeal before the Paris Court of Appeal.

Key Points

- For the first time, a dominant company was fined for denigrating a generic competitor with the aim of preventing its entry onto a market.
- The analysis of the context in which the practice was undertaken, as well as the large body of evidence the investigation found were the key components of the Autorité's analysis;
- The allegations made by the dominant firm were found to be denigrating on the basis of a detailed assessment into whether they consisted of objective observations or unsubstantiated assertions and whether they had actual or potential effects on the market concerned.

II. Summary of the *May 2013 Sanofi case*

Plavix® is a drug used to prevent relapses of serious cardiovascular diseases. Its active ingredient is called clopidogrel. Plavix® stands as a blockbuster in the pharmaceutical industry; it is the fourth best-selling drug worldwide and in 2008 it represented the highest amount of a drug reimbursement by the national public healthcare system: €625 million. Sanofi-Aventis France, a subsidiary of the Sanofi group and French leader of the pharmaceutical industry, began to market Plavix® in France in February 1999. The first clopidogrel generic competitors of Sanofi were launched at the beginning of October 2009.

The patent protecting this drug in Europe, in particular its active ingredient, clopidogrel, expired in July 2008, thus allowing other pharmaceutical laboratories from that date to market the drug under their own brands, as generic versions of Plavix®. However, Sanofi filed complementary patents in order to extend the initial protection (i) with respect to the salt used in Plavix® until February 2013 and (ii) with respect to the indication for the treatment of acute coronary syndrome in dual therapy until February 2017.

Yet, the variations in salts and therapeutic indications of Plavix®'s generic competitors have no impact on the bioequivalence and substitutability of these drugs. The French Health Security Agency of Healthcare Products pointed out that, in particular, the variation in salt does not prohibit a medicine being classified as generic and therefore does not constitute an obstacle to substitutability by pharmacists. Thus the clopidogrel generics were listed in the directory of generic medicines, which allowed

* Case Handler, *Autorité de la concurrence* (French competition Authority). The views expressed in this article are personal and do not represent the position of the *Autorité*.

1 Autorité, decision no. 13-D-11 of 14 May 2013.

2 Autorité, decision no. 10-D-16 of 17 May 2010.

them to be substituted for Plavix® by pharmacists,[3] unless the prescriber explicitly excluded this possibility with the sentence 'non-substitutable' on the prescription, on a case-by-case basis.

However, Sanofi had been spreading incorrect allegations over Plavix®'s generics (except for its 'self-generic', Clopidogrel Winthrop®). Results from the investigation have shown that from September 2009 to January 2010, Sanofi-Aventis had put in place a global and structured communication strategy aiming at driving Plavix®'s generics out of the market. It was found that Sanofi insinuated that the differences in salts and therapeutic indications could lead to the health professional's liability should medical problems or issues arise from the use of the Clopidogrel Winthrop®'s competitors' generics.

The investigation has led to numerous testimonies by doctors and pharmacists as well as feedback from the national health insurance fund for employees and information provided by pharmacists' associations that all indicate that Sanofi had been spreading doubts about Clopidogrel Winthrop®'s generics efficacy.

The Autorité decided that the behaviour of Sanofi met the relevant standard for finding an abuse of dominant position on the market for clopidogrel prescribed in the context of ambulatory care, as the commercial communication put in place by the laboratory relied on unsubstantiated facts rather than on objectively determinable considerations, thus inserting doubts in health professionals' minds on the efficacy and innocuousness of generic competitors of Plavix®. Finally, the Autorité found that Sanofi's practice had an impact on the market, thus maintaining or strengthening its dominant position, especially as the substitution rate of Plavix® dramatically decreased shortly after the launch of its competitors' generics on the market.

III. Analysis of the *May 2013 Sanofi case*

First, the Autorité had to define the relevant market in which Sanofi would be dominant. It is interesting to note that the Autorité insisted on the fact that within the pharmaceutical sector, the essential criteria to define a relevant market is the prescriber's perception. The Autorité thus defined a narrower market than it used to with regard to generic entry cases it had previously. In fact, the Autorité considered that there are no substitutes to clopidogrel and that due to the importance of the brand, prescribers and patients would not have considered any other substitutes. Therefore, clopidogrel constituted an indispensable molecule in cardiovascular treatments and was prescribed heavily, even though its price was high. The Autorité thus concluded that the relevant market was the French market of clopidogrel distributed by pharmacists for ambulatory care.

Secondly, Sanofi was found to be dominant in this market on the basis of several factors, including the company's market share (approximately 50 per cent, both in terms of sales and revenues); the fact that on the French market Sanofi was the leader of the pharmaceutical industry, with a revenue on the active ingredient clopidogrel of €2.7 billion; Sanofi was the owner of Plavix®'s patent that had allowed it to commercialise the product since 1999 and thus provided Sanofi an enormous notoriety; finally, contrary to the generic companies, Sanofi had employed a large network of medical visitors exclusively trained to visit doctors for commercial purposes.

A. A highly sensitive context

An analysis of the context in which the practice was carried out, as well as the types of evidence and indications the investigation had found, were key to the Autorité's analysis in that case.

In France, the context was highly sensitive as health professionals and in particular prescribers were not sufficiently informed about generics in general and the public was already suspicious about them.

First, despite the fact that prescribers are allowed to mention drugs by their international denomination, the majority of French doctors would rather use the drugs' commercial names, thus directly impacting the volume of commercialisation of certain drugs, as was the case for Plavix®. The Autorité also found in 1999[4] that prescribers did not always have complete and precise information on drugs, but rather knew about the more famous medicines or the ones they had been told about by medical visitors sent by pharmaceutical laboratories. In 2011, the French minister of labour still raised concerns about doctors' ignorance over drugs.[5]

Secondly, health professionals were not aware of the regulations applicable to generics. For instance, the Autorité has found that prescribers did not know how the authorisation to be put on the market was granted to generics. Because of the absence of knowledge about the generics' legal framework as well as a substantial lack of skill realting to drugs, it was impossible (or at least very difficult) for health professionals to be able to formulate their own objective opinion on the bioequivalence and

3 See Article L.5125–23 of the Public Health code.

4 Autorité, opinion no. 99-A-05 of 17 February 1999.

5 According to a study dated 2011, 50 per cent of prescribers were using information received during medical visits to update their knowledge on drugs.

substitution of Sanofi Clopidogrel Winthrop® by competitive drugs.

Medical visits also played a key role in that context, allowing Sanofi to manipulate health professionals' minds in order for them to directly prescribe Clopidogrel Winthrop® or to mention 'non-substitutable' on the prescriptions. According to Sanofi, the variations in salts and therapeutic indications were dangerous for the patients and its substitution with drugs other than Clopidogrel Winthrop® would directly impact the patients' health.

The health professionals' ignorance about generics combined with their high level of aversion to risk was taken into account by the Autorité when analysing Sanofi's behaviour in the market. In particular, the Autorité has noted that mistrust vis-à-vis new generic drugs launched on the market could only be overcome by clear, precise, and objective information which was supposed to be given by medical visitors and pharmaceutical representatives to health professionals. However, Sanofi did not provide complete or clear information on Clopidogrel Winthrop®'s competitive drugs but rather used strategies of misrepresentation in order to tackle obstruction of a generic entry onto the market.

B. Qualification of the anticompetitive practice as a 'denigrement'

Sanofi's communication strategy fell within the scope of Article L.420−2 of the French commercial code (and of Article 102 TFEU) as the Autorité qualified the practice as 'denigrement' towards Clopidogrel Winthrop®'s competitors. The Autorité has already rendered decisions that focused on the obstruction of generic entry through 'denigrement' of generic products and their bioequivalence. However, the Autorité was only issuing pronouncements concerning interim measures, and therefore it was not very precise about the analysis on 'denigrement' regarding generics in the pharmaceutical sector.[6] The *May 2013 Sanofi case* marks the first time the Autorité has fined on the merits a pharmaceutical laboratory for abuse of its dominant position by having denigrated its generic competitors in order to exclude them from entering the market.

B1. A decision based on numerous testimonies and documents found by the investigation services

In order to qualify the practice as 'denigrement', the Autorité took into account not only the particular context surrounding the communication strategy described above (see Section II. A), but also looked into several documents and pieces of evidence the investigation has been able to uncover. In fact, in such a context, a large body of corroborating evidence made it possible to establish the practice of 'denigrement'.

The Autorité was able to base its decision on numerous corroborating factors: (i) testimonies from a large panel of independent prescribers and pharmacists with no attachment or relationship whatsoever to any laboratories; (ii) documents written by a couple of pharmacists' associations before the proceedings against Sanofi took place and distributed to their members in order to reassure them about Plavix®'s generics competitors; (iii) testimonies from a large panel of representatives of the independent national health insurance fund for employees which were corroborating the testimonies by doctors and pharmacists. None of those health professionals had any interest in incriminating Sanofi. In addition, the Autorité could base its decision on several public statements made by Sanofi itself. All those testimonies and documents were corroborative of the official communication that Sanofi itself relayed to health professionals.

Those elements, combined with the fact that Sanofi's statements were found to be inaccurate, constituted the basis upon which the Autorité qualified the practice as 'denigrement'.

B2. 'Denigrement' consists of creating an illegitimate doubt in health professionals' minds

Sanofi's communication strategy had two sides. First, the laboratory had been communicating directly with generic laboratories and health authorities, emphasising, before the launch on the market of Plavix®'s generic competitors, the patent difference as regards the variation in therapeutic indications. However, Sanofi did not contest the market authorisation granted to the generics nor did it warn health officials on claimed risks of safety or efficacy.

In addition, Sanofi had put into place a commercial communication strategy towards health professionals, in particular doctors and pharmacists, aimed at deterring them from the generic substitution process. As explained before, the laboratory would use medical visitors and pharmaceutical representatives to achieve its goal. Sanofi's strategy took place at two important levels: (i) at the prescription stage, by convincing doctors to write 'non-substitutable' on the prescriptions in order for Plavix® to be sold instead of its generics (pharmacists

6 Autorité, decision no. 07-MC-06 of 11 December 2007; *Autorité*, decision no. 09-D-28 of 31 July 2009.

must substitute the original drug by a generic when it exists, except when the doctor writes 'non-substitutable' on the prescription); (ii) at the retail level by convincing pharmacists only to substitute Plavix® with Clopidogrel Winthrop®.

It results from the numerous testimonies and documents found by the investigation services that medical visitors and pharmaceutical representatives from Sanofi-Aventis spread, at the national level and to doctors and pharmacists, views casting doubt on the efficacy and innocuousness of generic competitors of Plavix®. Substantial feedback provided by the national health insurance fund for employees established that doctors were greatly influenced by this communication.

Contrary to what could happen in other sectors such as telecommunications, the mere fact that the dominant company—Sanofi—had been disseminating partisan, one-sided and sometimes incomplete information was sufficient to qualify the behaviour as 'denigrement'. It is interesting to note that Sanofi's communication was actually based on objective elements differentiating its own drugs and generics with the ones launched by its competitors, such as the variations in salts and the difference in therapeutic indications. However, Sanofi did not communicate clearly on the exact patents' scope of Plavix®, nor did it base its allegations upon verified medical or scientific justifications. It was thus impossible for a doctor or a pharmacist not to prescribe or sell a drug other than Plavix® or Clopidogrel Winthrop®.

In fact, in the context described above, and because Sanofi was clearly aware of disseminating incorrect allegations about its competitors' generics, the Autorité concluded that Sanofi's communication strategy had the effect of creating illegitimate doubt in health professionals' minds such that they consequently had no choice but to substitute Plavix® by Sanofi's self-generic Clopidogrel Winthrop® or to mention 'non-substitutable' on prescriptions, thus excluding the possibility for Plavix® to be substituted by any other generics.

It stems from the above that a pharmaceutical laboratory that has put forward in the frame of a communication strategy not only qualities but differences in its competitors' products, which can only be understood as substantial, in the particular context described above (see Section III. A), necessarily aims at creating objective doubt over the qualities of the laboratory's competitors' drugs in the minds of health professionals. In the Autorité's views, this behaviour reveals that the laboratory's goal was to mislead health professionals about generic competitors and can thus be qualified as anticompetitive 'denigrement'.

C. The effects analysis and the link between the dominant position and the anticompetitive practice

In order for the Autorité to qualify the 'denigrement' as an abuse of a dominant position, it had to verify that Sanofi's behaviour had the effect of maintaining or strengthening its dominant position on the market of clopidogrel distributed by pharmacists for ambulatory care.

As mentioned above, the practice has impacted health professionals' behaviour as they heavily prescribed or sold Plavix® or Clopidogrel Winthrop®, thus excluding Sanofi's generic competitors from the market. The analysis of the effects has revealed that a lot of health professionals were particularly suspicious about other generics despite any objective considerations with which to support these suspicions.

Furthermore, in order to assess the link between Sanofi's dominant position and the anticompetitive practice described here, the Autorité insisted on the fact that thanks to Sanofi's huge notoriety it already had in the market of clopidogrel (Sanofi was the market leader), it could easily take the role of the health authorities by spreading incorrect and faulty allegations among health professionals.

Finally, the Autorité has found that Sanofi's practice has had a potential and actual effect on the market for clopidogrel. In fact, Plavix®'s substitution's rate constantly decreased shortly after generic drugs were launched on the market (approximately five months after the first generic had been launched on the market). Moreover, at the same time, Sanofi's self-generic of Plavix®, Clopidogrel Winthrop®, was able to achieve a substantial market penetration rate. In fact, the Autorité found that Sanofi's own generic version of Plavix® had managed to obtain 34 per cent market share,that is, four times more than Sanofi's market share in generics in France. The practice therefore had a serious influence on the structure of the market and the evidence in the Autorité's file confirmed the existence of economic harm.

IV. Conclusion

The Autorité concluded that there had been an abuse of a dominant position by Sanofi in the market of clopidogrel prescribed for ambulatory care, which took place from September 2009 to January 2010, a period of five months, even though the effects of the practice were longer. The Autorité reached this decision by assessing the extent to which the undertaking's wrong allegations were based on non-objective differences and unsubstantiated assertions,

the effects the communication had on the structure of the market, whether this would be potential or actual, and finally the level of trust market participants put into the company, which could include the level of notoriety of the dominant undertaking.

It is interesting to note that the European Commission had already pointed out in its pharmaceutical sector inquiry released in 2009 that the potential anticompetitive behaviour of originator laboratories could indeed consist in adopting a very aggressive commercial strategy during the launch of a generic medicine. However, it is the first time in Europe that a national competition authority has found an abuse of a dominant position as a 'denigrement', based on the merits of a case, in the pharmaceutical sector.

Pharmaceutical companies should therefore be particularly cautious in their disseminating information with health professionals, especially when generics are at stake. That said, the highly sensitive context in which the practice has been implemented, as well as the large body of evidence that the investigation has found, have indeed led to the Autorité's decision in this case. The practice at stake had had a serious effect on the market, thus allowing the Autorité to impose a fine of €40.6 million.

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