Abuse of Dominance in the Pharma & Biotech Sectors

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Abstract

In 2009, the much-debated EU Pharmaceutical Sector Inquiry lifted the "red tape" from the EU pharmaceutical and biotech sectors and has provided the basis for an increased scrutiny of these sectors under European competition law. In practice, this has been the starting point for a number of important proceedings and recent decisions that lie at the interface of competition law, intellectual property law, pharmaceutical R&D, market approval procedures, pharmaceutical life cycle strategies and access to healthcare.

The aim of the paper is to discuss the recent developments in the EU concerning the application of the abuse of dominance rule in the Pharma and Biotech sectors. In certain aspects the latest case law development from the EU Commission, EU Courts, but also from national competition authorities and courts, is rather unique. It goes beyond what we have seen hitherto regarding the use of the prohibition of abuse of dominance in the Pharma and Biotech sectors in the EU, as well as what we have seen from other jurisdictions having similar prohibitions. Possibly, the reason for this rather new line of case law is that pharmaceutical firms are utilizing business practises that were uncommon twenty years ago. Business practises that, at least by certain commentators, should be regarded as benign, while these practises have been considered to amount to abuses by the European competition authorities and courts. It is these cases and business practises I would like to analyse further.

The point of departure of the paper is a short description of the business and patent practises of the pharma and biotech sectors. I will present an overview of the "pharma business", focusing on the practises and conduct that now have been identified as allegedly anticompetitive as a violation of Article 102 TFEU. The issues raised in the Inquiry will be discussed, with reference to the case law that has developed since the Inquiry was published. In particular, the cases and investigations in the EU regarding shutting out a competing technology and buying out a number of competitors that had developed cheaper medicines will be analysed. In other words, the paper will scrutinize not only competitor buy-outs (combined with pay-for-delay and other settlement agreements), e.g. the recent *Servier* decision by the EU Commission, but also misuse of the patent systems (e.g. the *AstraZeneca* case), the misuse of courts (or vexatious litigation, see for example the *ITT Promedia* and, to some degree, *AstraZeneca* cases) and, in general, the pharma companies' alleged misuse of the regulatory system. The Italian *Pharmacia/Pfizer* case is of relevance here, where the Consiglio di Stato in 2014 stated that Pfizer had actually misused its intellectual property rights, and that it was irrelevant whether the divisional patent and the relevant SPC were or were not legitimately requested and obtained, since the scope of patent law is different from that of competition law. Thus, even though acting within the legitimate boundaries of intellectual property law, Pfizer was still abusing its dominant position according to the Court.

It seems clear that patent strategies, such as defensive patenting, patent flooding, strategic patenting, with the aim of excluding competitors, and business strategies such as "evergreening", may, according to European antitrust authorities and courts, have anticompetitive effects and/or lessen the competitive process and the incentive to innovate. Thus, these rather common business/patents strategies may violate the competition law prohibition of abuse of dominance, and this will be discussed in the paper. The question raised and discussed is whether, and when, these strategies are anticompetitive and violate the rule against abuse of dominance.