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CLIENT MEMORANDUM

Excessive Prices of Medicines and Antitrust Laws: Should Pharmaceutical Companies Really Begin to Worry?

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Direct control of prices under competition law in the absence of some form of anticompetitive conduct (e.g., market collusion or exclusionary practices) raises numerous problems. Many have argued in particular that excessive pricing by a dominant firm is self-defeating as it typically attracts new entrants (save perhaps in markets where barriers to entry are particularly high or in statutory monopoly situations), so that regulatory intervention for this type of behavior is not warranted in the first place. More importantly perhaps, defining a legal test to determine beyond what level a price becomes "excessive" raises considerable practical difficulties, and, assuming one could effectively articulate such a test, it would become equally (if not more) difficult for a regulator to design an adequate remedy to properly address such a concern in the long term.

Those issues probably explain why there has been little regulatory intervention on the basis of excessive pricing. In Europe, the few cases where dominant firms were sanctioned for having charged high prices are now relatively old. Some observers actually thought that such cases were a bit "old fashioned" and that, absent unusual circumstances, this line of case law did not survive the so-called modernization of competition law whereby the enforcement activity is primarily focused on "exclusionary" abuses by dominant firms (aiming at excluding rivals), as opposed to so-called "exploitative" abuses (aiming at extracting monopoly rents through the use of market power).

However, over the last few months, control of excessive prices has made a significant comeback on the forefront of the antitrust news in Europe, especially in the pharmaceutical sector.

In the UK, there are no fewer than two pending investigations, and one final decision that is subject to appeal, on this issue. All those cases seem to concern products that are not subject to strict price regulations, either because they have been "de-branded" or because they have been off-patent for a number of years.

- Just a few weeks ago, the Competition and Markets Authority (the "CMA") fined Pfizer £84.2 million and its distributor Flynn Pharma £5.2 million for charging excessive prices for Phenytoin sodium capsules, a drug used to treat epilepsy.[1] The CMA has also ordered the companies to reduce their prices. Pfizer and Flynn Pharma announced that they would be appealing the decision to the UK Competition Appeal Tribunal.

- In March 2016, the CMA launched a formal investigation against Actavis UK, in connection with its distribution of Hydrocortisone tablets, which are used as the primary replacement therapy for people whose adrenal glands do not produce sufficient amounts of natural steroid hormones (adrenal insufficiency). The CMA announced that the case concerns "a suspected breach of competition law in the pharmaceutical sector" under antitrust rules covering the abuse of a dominant position. The CMA announced just a few days ago that it issued a statement of objections against the company.[2]

- In October 2016, the CMA announced the opening of new investigations, following suspicions of excessive prices in the supply of certain pharmaceutical products, including to the UK's National Health Service.[3] The CMA did not specify what drug was at issue or what company was targeted, but Canadian producer Concordia International has confirmed that it is under investigation.

Although the CMA has been particularly active on this front in Europe, this is not a purely British phenomenon. There also has been a case on excessive prices in Italy, involving the manufacturer Aspen, which was fined more than €5 million for increasing the price of a cancer drug.[4] Aspen allegedly achieved such price increase by adopting an aggressive negotiating strategy with the Agenzia Italiana del Farmaco, including threats to stop supplying the medicine on the Italian market.

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1 https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs

2 https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs

3 https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-conduct

4 http://www.agcm.it/en/newsroom/press-releases/2339-a480-price-increases-for-cancer-drugs-up-to-1500-the-ica-imposes-a-5-million-euro-fine-on-the-multinational-aspen.html

Also, a recent speech by Margrethe Vestager, European Commissioner for Competition, suggests that the European Commission is also considering taking action in cases of excessive prices.[5]

Commissioner Vestager noted that people's health often relies on a drug sold by only one company. "That can be because the company has a patent. But it can also be that no one else is interested in coming in to the market" due to low levels of demand. "That isn't a problem in itself, if prices stay at a reasonable level. But there can be times when prices get so high that they just can't be justified. After all, people rely on these medicines for their health, even their lives. The best answer is often to adjust regulation, or to give the health systems that buy those medicines better bargaining power. But as the recent action by the British and Italian competition authorities shows, there can be times when competition rules need to do their bit to deal with excessive prices," she suggested.

This new trend is troubling in many respects. The problems identified above, which led the regulators to adopt a cautious approach with respect to excessive prices, are as acute as ever. Should the enforcement activity in this area of the law continue to develop at its current pace, pharmaceutical companies will face extremely challenging issues in their day-to-day activities, all resulting from the considerable legal uncertainty that this line of case law will create.

First, pharmaceutical companies will struggle to identify the circumstances under which they may be regarded as "dominant" on a given product and geographic market. Market definition is particularly tricky in the pharmaceutical sector, where, at least in Europe, the relevant market may be defined at a therapeutic level, at a molecular level, or even at a dosage-form level. Second, as mentioned above, determining beyond what level a price becomes "excessive" is an almost impossible task.

Those issues arise in a global context, where innovation needs to be properly rewarded with respect to innovative products and where margins are typically very low in the generic industry, and where buyer power is often very significant.

One can of course understand that certain pricing policies with respect to specific products may have raised questions from various stakeholders, in particular in an industry where tax payers often bear the ultimate burden of high prices. However, as acknowledged by Commissioner Vestager herself, there is much to be said, in terms of legal certainty (and indeed efficacy), in favor of *ex ante* price regulation as opposed to an enforcement policy that can hardly be based on legally practicable criteria.

This seems to be yet another example of competition law being used as a means to tackle certain shortcomings in certain areas of the law that would best be addressed by other forms of state intervention.

In this regard, it is interesting to compare the interventionist stance that European agencies seem to be taking with the approach that prevails in the United States, where the prices charged for certain pharmaceutical products can also give rise to quite a bit of controversy.

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[5] Chillin' Competition Conference, Brussels, 21 November 2016 – Protecting consumers from exploitation.

As a matter of fact, U.S. antitrust authorities investigated a number of situations involving significant price increases, including in particular the recent EpiPen case, which concerned a product distributed by the generic company Mylan. However, it appears that in this case, the price increases were associated with a form of allegedly illegal conduct other than a violation of U.S. antitrust rules.

Mylan indicated in October 2016 that it had agreed to pay $465 million to the Department of Justice and other government agencies to settle allegations of anticompetitive conduct with respect to its EpiPen device, used to provide emergency treatment for severe allergic reactions.[6] Mylan had been under investigation since 2014 following steady price increases from about $100 per pack in 2008 to about $600. However, the price increases were reviewed in light of the allegation that Mylan had misclassified EpiPens as a "non-innovator multiple source drug" for the purposes of the Medicaid Drug Rebate Program, and as a result overcharged Medicaid for them.[7]

Similarly, the ongoing investigations concerning the pricing policies of Turing Pharmaceuticals seem to be looking not at price increases as such but at certain possible distribution restrictions that in turn allowed the price increases to occur.[8]

But absent any form of collusion or attempt to monopolize, there is no basis in U.S. antitrust law to sanction excessive prices. Given the complexity of the issues identified above, this seems to be a sound position that European regulators should carefully reflect upon before opening again the Pandora's box of price regulation through competition laws.

If you have any questions regarding this memorandum, please contact David Tayar (+33 1 53 43 4690, dtayar@willkie.com), William H. Rooney (212-728-8259, wrooney@willkie.com) or the Willkie attorney with whom you regularly work.

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6 http://www.nytimes.com/2016/10/08/business/epipen-mylan-justice-department-settlement.html?_r=0

7 *Cf.* http://www.grassley.senate.gov/sites/default/files/constituents/2016-10-11%20CEG%20to%20DOJ%20(Mylan%20Settlement).pdf

8 http://www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html