Key Takeways

Skadden

Antitrust in Life Sciences: A Dialogue With Anna Vernet

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On March 26, 2024, Skadden hosted a discussion on key developments in antitrust enforcement in the pharmaceuticals and life sciences sectors.

Ingrid Vandenborre, co-head of Skadden's European antitrust practice, was joined by **Anna Vernet** (head of unit at the Directorate-General Competition (DG COMP), Antitrust: Pharma and Health Services, European Commission (EC)), **Catherine Higgs** (global head of competition law and legal director for UK & Ireland Pharma, GSK), **David Parker** (managing director, Berkeley Research Group (BRG)) and **David Sevy** (executive vice president, Compass Lexecon). The event was co-organized by BRG, Compass Lexecon and *Global Competition Review*.

The Pharmaceutical Sector Continues To Be a Priority for Competition Enforcement in Europe

On January 26, 2024, the EC published a report providing an overview of the enforcement of EU antitrust and merger rules by the EC and the national competition authorities (NCAs) in the pharmaceutical sector between 2018 and 2022. In her keynote speech, Ms. Vernet highlighted what she considered to be the key findings of the report and pointed out that the pharmaceutical sector continues to be a priority for competition enforcement in Europe.

In the period covered by the report, the European Competition Network (ECN) adopted 26 antitrust decisions in the sector. Of those cases, nine have resulted in commitments decisions. The remaining 17 cases have resulted in prohibition decisions by competition authorities, leading to the imposition of fines totaling €780 million. Ms. Vernet explained that over time, enforcement has shifted from Article 101 conduct cases to abuse of dominant cases under Article 102 TFEU. Over the period covered by the report, approximately:

- 50% of the total cases concerned abuse of dominant cases;
- 31% concerned cartel activity;
- 11% concerned vertical restraints (including retail price maintenance and exclusivity arrangements); and
- 8% concerned pay-for-delay agreements.

Ms. Vernet explained that in the period covered by the report, the EC reviewed more than 30 pharmaceutical sector transactions, four of which were problematic and cleared with remedies to address the EC's concerns, while one merger was abandoned. She noted that compared to other sectors, the intervention rate in the pharma sector is high, but noted that none of the cases were referred to a Phase II investigation and all were resolved in the Phase I process.

Key Takeaways
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Enforcement Trends in the Pharmaceutical Sector

Ms. Vernet identified a number of key enforcement trends:

- **A decrease in the occurrence of pay-for-delay agreements:** Ms. Vernet explained that the number of pay-for-delay cases has decreased, with *Teva Cephalon*, which is currently on appeal before the European Court of Justice, as the only decision adopted in the period covered by the report. She observed that the EU courts have confirmed and harmonized the legal test in *Generics UK*, and that more recent pay-for-delay cases are more complex.
- **A rise in disparagement abuses:** Ms. Vernet noted that investigations of disparagement in the pharmaceutical industry have been on the rise. She acknowledged that the French competition authority has pioneered enforcement in this space, with the Belgian and Italian authorities following suit. She noted that the preliminary ruling of the European Court of Justice in *Hoffman La Roche* provides some guidance on the legal principles to apply to these cases, even if the case concerns an infringement of Article 101. Ms. Vernet identified the relevant conduct as involving misleading information and communications about safety that are of such a nature that it may discredit a competitor's product, thereby reducing competitive pressure. She also noted that disparagement cases may concern competition between originators, or between originators and generics manufacturers, and can be extended to off-label use. Ms. Vernet noted that guidance on what constitutes disparagement will come from the European Commission, and also pointed to the proposed legislation on comparative advertising in pharmaceuticals currently being discussed in the European Parliament, which will also bring some clarification on problematic conduct in this space.
- **Excessive pricing — particularly relevant in the pharmaceutical sector:** Ms. Vernet noted that the number of excessive pricing cases appear higher in the pharmaceutical sector than in other sectors — the report references seven cases. Ms. Vernet noted that the reported cases involve major price hikes (from 200-300% to 2000-3000%) and high margins (80-90%). When querying the link between excessive pricing cases and the protection of innovation, Ms. Vernet observed that these cases concern medicines that have been off-patent for a long time.
- **Enforcement against low pricing strategies:** Ms. Vernet noted that the report shows that the network is also actively investigating and enforcing more traditional Article 102 cases, such as exclusivity rebates, loyalty inducing rebates and other cases, such as predatory pricing.
- **Misuse of patents and vexatious litigation:** Ms. Vernet noted the absence of decisions concerning patents-related abuses by dominant companies over the period covered by the report, but referenced the ongoing EC investigation into divisional patent strategies, and referred to developments at the national level in relation to vexatious litigation.

Article 22 EUMR and Below Thresholds Mergers

The panel then discussed the role of Article 22 of the EU Merger Regulation, which allows member states to request the European Commission to examine certain acquisitions, even where they do not meet EU or national merger control thresholds, and how this is perceived from the industry's perspective. Ms. Higgs noted that a first priority for companies when assessing the viability of a merger and the regulatory requirements is legal certainty, and that Article 22 has removed a degree of certainty from merger discussions. Ms. Higgs noted that the likelihood of the EC calling in a merger under Article 22 substantially informs companies' merger discussions. The increased importance given by authorities to nascent/innovation markets and high deal valuations also were raised during the discussion. In this context, Ms. Vernet confirmed that the date for the finalization of the Commission's anticipated killer acquisition study has not been identified yet.

Forward-Looking Assessment of the Relevant Market

The panel also discussed the forward-looking nature of the EC's assessment, with a particular reference to the EC's findings in relation to the *Illumina/Grail* transaction. Ms. Higgs noted that as an in-house counsel supporting the company's internal assessment, the first step in assessing future markets is to look at the company's own assessment as reflected in their internal projections and through discussions with the product teams, who will have the best view on the competitive outlook of the market. However, Ms. Higgs further noted that companies are concerned with what this sort of far forward-looking assessment means in terms of the distribution of the burden of proof. Competition authorities devise certain theories of harm and postulate what, from their perspective, the future will look like, which in turn means companies often face an immense burden of proof when attempting to disprove these possible theories of harm. Conversely, it is difficult for companies to propose an alternative hypothesis with the requisite level of proof for it to be acceptable to the authorities. She added that this level of disparity regarding the distribution of the burden of proof is amplified, as the market assessment becomes increasingly forward-looking.

Key Takeaways
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When asked whether there is "too much" speculation about market assessment, Ms. Vernet noted that the analysis should always be case specific. Noting the difference between the *ex ante* and *ex post* nature of merger and antitrust assessment, respectively, Ms. Vernet acknowledged that in merger reviews looking at internal documents is a key step for competition authorities to understand the parties' rationale.

Mr. Parker noted that while it is difficult for authorities to predict how a specific market will develop over time with certainty, especially in innovative markets, the forward-looking assessment of the market becomes increasingly relevant for authorities when discussing how to devise remedies.

Ms. Higgs added that, in the specific case of pharma, the transparency of the product developments gives way to some predictability in this type of assessment — product development takes many years, clinical trials are lengthy and publicly available, there are no sudden product launches and this product development will be reflected in internal documents.

EU vs. National Enforcement in the Pharma Sector

In light of the report's emphasis on proceedings initiated by member states, Ms. Vernet highlighted that antitrust enforcement in the pharma sector is not solely the EC's responsibility, but rather a shared competence with member states. She pointed out that National Competition Authorities (NCAs) carry out approximately 90% of antitrust enforcement across all sectors, a fact also attributable to the EC's relative size (Antitrust and Merger departments of DG COMP) compared to some national NCAs. Ms. Vernet also noted the national nature of pharmaceutical markets, which means that the EC is not always best placed to assess a case. In that context, she concluded, it is reasonable to expect the NCAs to continue playing a major role in leading antitrust enforcement in the pharma sector.

Differential Pricing in the Different Member States

When asked whether companies should anticipate differential pricing (regulated, nonregulated and national reimbursement considerations) in the different member states to be a material factor in terms of enforcement, Ms. Vernet noted that this requires a case-by-case assessment but that differential pricing is not inherently problematic. Ms. Vernet also confirmed the relevance of price differentials during the market definition stage. She added that an assessment of any case in the pharma sector heavily relies on national regulation, pricing and reimbursement rules. Ms. Vernet also acknowledged that the varied regulatory approaches of member states in this sector add to the complexities of the EC's review. Ms. Higgs added that price differential can drive parallel trade and can be an issue in some markets but that the existing case law on parallel trade offers companies the framework to navigate these complexities.

Mr. Sevy concluded the discussion by highlighting the complexities involved in evaluating excessive pricing cases, particularly the practical application of the legal test outlined in the *United Brands* judgment, in respect to relevant cost measurement or the assessment of fair product-level prices and margins in the case of multiproduct firms. He also shared insights on the enforcement of disparagement conduct, emphasizing the necessity for solid proof that the communication in question is indeed distortive rather than the mere reflection of available versus unavailable scientific evidence regarding risks attached to alternative treatments.

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