Competition Merger Brief

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Cooper/Viatris (European OTC Business) – Divestiture remedy to unclog constipation and earwax competition concerns

Kathlynn Hinnekens, Hanna Perikangas, Dimosthenis Skarlatos

Introduction

On 3 May 2024, the European Commission ('EC') conditionally cleared the acquisition by Cooper Consumer Health S.A.S. ('Cooper') of the European over-the-counter ('OTC') business of Viatris Inc. ('Viatris' or the 'Target' and together with Cooper the 'Parties'), referred to below as the 'Transaction'.

Cooper and Viatris are both active in the development, manufacture, and commercialisation of finished dose pharmaceuticals ('FDPs'). Viatris is a US-based global healthcare company, formed through the combination of Mylan and Upjohn. Cooper, on the other hand, is a French healthcare company, which is controlled by the private equity firm CVC.[1]

The Transaction gave rise to various horizontal overlaps, the majority of which were found to be unproblematic. However, the Commission's investigation showed that the Transaction would have reduced competition in the markets for laxative enemas for infants in Portugal and for earwax removal products in Germany. Following divestiture commitments addressing these two markets, the Commission was able to clear the Transaction in Phase I.

This brief will describe the main learnings relating to market definition, the identified horizontal concerns, and the divestiture remedies offered by the Parties.

Defining the market for FDPs

When defining the relevant product markets for FDPs, the Commission typically takes into account the Anatomical Therapeutic Classification ('ATC') of the European Pharmaceutical Marketing Research Association,2 starting at the ATC3 level, where products are grouped by their intended use. However, the Commission has recognised that, depending on the product in question, it may be necessary to define the markets at a different level, for example, at ATC4 or even molecule level. FDP markets are generally national in scope due to the regulatory barriers, which result inter alia from national reimbursement systems.

The market investigation carried out in this case confirmed that the ATC3 level is not always the relevant product market. For example, there were strong indications that the ATC3 level "A6A – Drugs for constipation" should be further segmented, and specifically that, at least in Portugal, a separate product market could exist for laxative enemas for infants, given that laxatives with different routes of administration (oral vs rectal) and different galenic forms (e.g., enemas vs suppositories) are not easily interchangeable for infant patients.

The market investigation results similarly indicated for earwax removal products that the ATC3 level "S2D – Other Ear Preparations" (for all ear preparations that contain neither an antibacterial nor a steroid) did not correspond to the relevant product market, implying a narrower product market limited to earwax removal products (covering earwax removal drops and sprays), corresponding rather to the ATC4 S2D1 class.

Product market definition may also differ depending on the specificities of the relevant geographic market. For example, based on the evidence available, it appeared that in Portugal specifically, there is a preference for laxative enemas in the treatment of infant constipation, whereas this may not necessarily be the case in all Member States.

In a nutshell

Cooper's acquisition of Viatris' European over-the-counter business was approved under conditions. The Commission identified competition concerns in two specific markets: laxative enemas for infants in Portugal, and earwax removal products in Germany.

In these markets, the merged entity would have held very high market shares and only faced limited competition post-Transaction.

The Commission was able to clear the case in Phase I following clear-cut divestiture commitments, facilitating the entry of new rivals to maintain healthy competition.

[1] In addition to Cooper, a number of CVC funds' portfolio companies, including Recordati Industria Chimica E Farmaceutica S.P.A. ('Recordati'), are also active in markets that are horizontally and vertically related to those in which the Target is active in and were therefore also relevant for the competitive assessment.

[2] For OTC drugs the Commission typically also takes into account IQVIA's Consumer Health Classification ('CHC').

Horizontal concerns

The Parties' activities overlapped in various FDP markets. The majority of these overlaps were found non-problematic, considering factors such as limited combined market shares, limited increment, sufficient available alternatives or lack of closeness of competition.

However, the Commission found that the Transaction would raise serious doubts as to its compatibility with the internal market with regards to two specific markets, namely the markets for (i) laxative enemas for infants in Portugal, and (ii) earwax removal products in Germany.

In these markets, the merged entity would have held very high market shares and only faced competition from a very limited number of alternative players. Also, entry by new players on these markets was unlikely. As a result, the Transaction would have led to reduced choice for consumers and potentially higher prices.

In particular, in the market for laxative enemas for infants in Portugal, the Transaction would have constituted a three-to-two merger with a combined market share of the merged entity exceeding 90%. The only remaining competitor that would have been left on the market was small and unlikely to sufficiently constrain the merged entity post-Transaction. On this market, the overlap was not between Cooper and the Target, Viatris,, but rather between the Target's Bebegel product and a product offered by another portfolio company of Cooper's parent CVC, namely Recordati.[3]

In the market for earwax removal products in Germany, where brand recognition is considered important, the Parties' earwax removal brands (Cooper's Audispray and Viatris' Otowaxol) were the two main brands, and their combined market share would have been extremely high (up to around 90%), with a significant increment (20-30%). In addition, the other competitors in this market were all very small, with market shares below 3.5%.

The solution: divestitures

In order to address the competition concerns identified by the Commission, the Parties committed to divest Viatris' infant laxative medicine Bebegel in Portugal and Viatris' earwax removal product Otowaxol in Germany, thereby removing fully the overlap between the Parties in both relevant markets.

Both proposals involved the transfer of rights, titles, and interests in the respective products, enabling the purchasers to develop, manufacture, and use the products for sales and marketing in the respective national markets.

Following positive feedback from the market, the Commission concluded that the commitments would fully address its competition concerns and allow entry of new viable competitive rivals in the respective markets.

For both divestment businesses, the purchasers were assessed against the purchaser approval criteria set out in the commitments, including a requirement that they have a sales and marketing presence (and access to an appropriate distribution network in the relevant sales channels) in the respective markets. On 9 December 2024 the Commission approved InfectoPharm Arzneimittel und Consilium GmbH ('InfectoPharm') as the purchaser of the Oxtowaxol divestment business in Germany.[4] On 10 January 2025 it approved Grupo J. Uriach, S.L. ('Uriach') as the purchaser of the Bebegel divestment business in Portugal.[5]

Divestiture commitments are clear-cut remedies to address horizontal competition concerns, and, hence, typically preferred by the Commission, including in the pharmaceutical sector. The divestiture commitments proposed by the Parties in this case ensured that the Transaction would not result in anticompetitive harm for consumers in the markets for laxative enemas for infants in Portugal and for earwax removal products in Germany, thereby allowing the Commission to clear the Transaction in Phase I.

[3] In line with the Commission's established policy, for the purposes of competition assessment, all portfolio companies of a private equity group are considered as part of the same undertaking.

[4] Decision on the implementation of the commitments - Purchaser approval, 9/12/2024, C(2024) 8836 final.

[5] Decision on the implementation of the commitments - Purchaser approval, 10/0/2025, C(2025) 177 final.

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Competition Merger Brief

Eiffage / EQOS – Avoiding a (market) power surge along the track

Ana GHINEA, Otmane SBITRI, Andreas SOWA, Thibault SIRE

Introduction

On 16 October 2024, the Commission conditionally approved the acquisition of EQOS (Germany) by Eiffage (France).

The main overlap between the parties' activities concerned the installation and maintenance of catenaries and overhead contact lines for long distance train lines in Belgium.

Eiffage is active on this market through its subsidiary Duchêne, which is only active in the southern Belgian region of Wallonia.

EQOS entered this market in 2022 with the acquisition of Colas Rail Belgium ('CRB') from Bouygues and is present in both regions in Belgium: Wallonia and Flanders.

At the time, Bouygues decided to divest CRB in order to alleviate competition concerns – 'serious doubts' – expressed by the Commission with respect to its acquisition of Equans (M.10575 – Bouygues / Equans), namely that the acquisition may have impeded effective competition for the installation and maintenance of catenaries and overhead contact lines for long distance lines in Belgium. Because the combination of Eiffage and EQOS gave rise to serious doubts in relation to the same market, Eiffage offered to divest CRB again.

Installation and maintenance of catenaries and overhead contact lines

Catenaries and contact lines are overhead cables used to supply trains with electric current. The catenary serves as a stabilising cable to which the overhead line is attached in order to transmit electrical energy to the train.

Installation and maintenance services for catenaries and overhead contact lines over long distance railways are typically sourced through tenders by national infrastructure operators (e.g. Infrabel in Belgium). Differences in the technical aspects of railways between countries, as well as the need for service providers to comply with extensive national regulations explain why these markets are national in scope.

A transaction wired for trouble

The transaction would have combined two large players that competed closely in the already concentrated market for the installation and maintenance of catenaries and overhead contact lines in Belgium.

The new entity would have had a large market share (40-50%) and the transaction gave rise to a significant increment (20-30%).

Importantly, the results of the market investigation showed that the market was characterized by a shortage of qualified workers (i.e. linesmen) which translated into significant capacity constraints. As a result, not all players were able to participate in all tenders. In the vast majority of tenders, only four or less players participated.

The parties' bidding data showed that they were two of the four most frequent bidders over the past five years, competing head-to-head in Wallonia, where they were particularly close competitors, accounting for 70-80% of the projects in this region. Because of the shortage of qualified workers, entry and expansion were unlikely, which further limited the countervailing buyer power of the national infrastructure manager.

Accordingly, the Commission concluded that the proposed acquisition raised serious doubts in connection with the installation and maintenance of catenaries and overhead contact lines for long distance lines in Belgium.

In a nutshell

The acquisition of EQOS by Eiffage would have combined two large players competing closely in the already concentrated market for the installation and maintenance of overhead power lines for trains in Belgium.

To alleviate these concerns, Eiffage offered to divest the Colas Rail Belgium ('CRB') business that EQOS had acquired in 2022.

As this was the second time that CRB was divested in less than three years, specific safeguards were required to ensure the viability of that business and avoid qualified employees leaving the divestment business.

Preserving the viability of a divestment businesses sold for the second time

To address the Commission's serious doubts, Eiffage proposed a comprehensive remedy package consisting in the divestiture of the former CRB business regrouping EQOS' operations in the installation and maintenance of catenaries and overhead contact lines for long-distance lines in Belgium.

The remedy comprised the transfer of all essential, assets, personnel, as well as current and prospective customer contracts that were part of the business's ongoing operations.

Given this remedy would represent the second divestiture of the business within a 3-year span, and in view of the shortage of qualified personnel in the industry, additional safeguards were put in place to preserve the viability and competitiveness of the divestment business.

First, Eiffage introduced an extensive retention scheme covering not only key employees but also project leaders, site leaders, engineers, linesmen, etc. to provide them with a financial incentive to remain with the divestment business.

Second, Eiffage committed to not solicit key employees or linesmen from the former CRB business for a specified period of time and to replace any such personnel who might leave the divestment business before closing.

Finally, the requirements for the approval of the buyer of the divestment business by the Commission included the need for prior expertise in the railway infrastructure sector.

Conclusion

The remedy package offered by Eiffage fully addressed the Commission’s serious doubts and ensured that the divestment business would remain a credible and effective competitor to Eiffage.

On 18 December 2024, the Commission approved as a suitable purchaser Stadsbader, which is a construction group active in Belgium, with prior experience in the railway infrastructure industry. The Commission concluded that Stadsbader would be able to maintain and develop the divestment business as a viable competitive force in the future.

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JD Sports / Groupe Courir: Taking a step in the right direction

Agathe Célarié Roy, Basile Cotte, Jaroslav Kračún, Asimina Michailidou and Fabiola Zarrelli

Introduction

On 22 October 2024, the Commission conditionally approved JD Sports' acquisition of Groupe Courir ('Courir), (the 'Transaction').

Both JD Sports and Courir (the 'Parties') are multi-brand retailers of sports goods, focusing on sports footwear and to a lesser extent on sports apparel, selling online and in physical stores. JD Sports operates worldwide under various retail brands, e.g. JD Sports, Size?, Sprinter, Footpatrol, and Sport Zone (4 500 physical stores in 36 countries). Courir operates over 300 physical stores, located in Belgium, Denmark, France, Luxembourg, the Netherlands, Portugal and Spain.

The Commission had concerns that the transaction would have reduced competition in the **retail markets** for: **(i) lifestyle and performance sneakers and sports apparel** in certain local areas in **Portugal**; and (ii) **lifestyle sneakers** in certain local areas **in France**[1].

To address the Commission's competition concerns, the Parties offered to divest **all Courir stores in Portugal and several stores in France to Snipes**, a direct competitor for the retail of lifestyle sneakers and sports apparel.

Kicks and clicks

The Commission found that consumers are now taking sneakers beyond the sports field and into their everyday wardrobes, thus justifying a distinction between sneakers worn as a fashion statement (lifestyle sneakers) and those crafted for athletic use (performance sneakers). This finding was confirmed by the market investigation and reflected in the Parties' internal documents. These documents distinguish between the two categories and show that the Parties' main focus is the retail of lifestyle sneakers. As such, the Commission's investigation focused on the latter category lifestyle sneakers.

The Commission also explored how the local retail markets – not only for sneakers - are changing, as local stores and online sales lace together a new way to shop. In this industry, brand manufacturers distribute sneakers directly through their flagship stores and online, as well as via multi-brand retailers (such as the Parties) who negotiate nationwide supply contracts and suggest similar pricing across one country and online. However, the market investigation revealed a large majority of consumers prefer to shop in their nearby physical stores for fitting purposes, influenced by their location; urban consumers travel less, while consumers living in more remote areas travel further. While geographic proximity and local competition have traditionally defined the landscape for the retail of sports goods, the growing significance of online shopping has introduced new dynamics to the sneakers industry.

In this case, the Commission identified geographic proximity as a key competitive advantage, with retailers considering local competition when opening new stores. Therefore, the market for the retail of lifestyle sneakers was considered to be local, centred

In a nutshell

This is one of the few cases where the Commission assessed local markets, which also presented some national characteristics, such as recommended pricing and advertisement.

For the first time, in its assessment of local markets, the Commission took online sales into account in the relevant product market, and in the evaluation of local stores' market shares. Geographic proximity of stores and close similarity in product offering were also factored in.

To solve local competition concerns, an experienced buyer with an established national presence had to be found before approving the deal to keep competition strong beyond the local level.

[1] In the decision, these markets are referred to as 'leisure sports footwear' (lifestyle sneakers) and 'performance sports footwear' (performance sneakers).

around physical stores. However, with the rise of omnichannel strategies, online sales account for a non-negligible part of the sales in the sneakers industry. In-store and online channels have connections, with some consumers trying shoes in-store but buying online, or vice versa, highlighting an increasing integration. This shift in certain consumers' shopping habits means that in some markets, the Commission may need to reconsider how (local) retail markets operate. For instance, prices between in-store and online remain consistent, with multi-brand retailers monitoring pure online competitors, like Zalando and Amazon. In the sneakers industry, stores often act as showrooms to boost brand presence and loyalty.

In this case, the Commission followed a new approach, in line with the decisional practice of some national competition authorities (NCAs) (e.g. the Dutch NCA) which regularly look at local retail markets. Indeed, the Commission considered that in-store and online sales of multi-brand retailers were indissociable for lifestyle sneakers, reflecting their increasingly intertwined nature and impact on consumer behaviour. The growing influence of online sales is blurring the lines between in-store and online distribution channels, reshaping customers' experience. Therefore, although the markets were considered local in scope, online sales were included in the relevant product market and the turnover of both in-store and online sales was taken into account when calculating the market shares of the Parties and their competitors active in each area, as further detailed below.

Prior to this case, when assessing local retail markets, the Commission viewed in-store and online sales as separate markets, considering online sales too small to make a difference. Hence, most local retail cases focused mainly on physical stores' sales, including when calculating market shares. However, in line with the New Market Definition Notice, this case reflects a shift in market realities, brought about by digitalisation. Indeed, it is the first time that the Commission took into account online sales in its assessment of local retail markets, showcasing the growing importance of online purchases and their integration with in-store shopping.

Gauging market power one step at a time

Competitive pressure from online sales was reflected in the Commission's assessment of the transaction's effects at local level.

First, the Commission considered that a single methodology should be applied to all omni-channel players. To combine the online sales of competitors with those made in physical stores, the 'showroom effect' was taken into account, i.e. the lower the in-store share in a given area, the lower the online share in the same area.

Second, the Commission recognised that, given their significant impact on competitive dynamics, sales of pure online competitors should be factored into the market analysis.

Lastly, several adjustments were made, such as including sales from all multi-brand retailers whose vast majority of revenues come from sports goods to account for the competitive pressure exerted by retailers operating solely within a specific local area.

On this basis, market shares were calculated in both floorspace and revenues, together with shares based on number of stores. Given the difficulty in gathering precise data, the use of different metrics provided a more robust assessment of market power.

Considering the very high number of local markets assessed, the Commission developed a methodology taking into account the following factors: (i) market shares of the Parties, (ii) closeness of competition between the Parties, (iii) geographic proximity of the Parties' stores, and (iv) the presence and geographic proximity of close competitors in the local market, all measured in minutes from the Parties' stores.

Sneaker Sol(e)ution

Following the Phase I investigation, the Commission concluded that, as notified, the transaction raises serious doubts as to its compatibility with the internal market for the retail markets of (i) lifestyle and performance sneakers and (ii) sports apparel, in 19 locally affected markets in France and Portugal.

To address the Commission's serious doubts, the Parties offered to divest several Courir stores, which entirely removed the horizontal overlap between the Parties' activities in essentially all local areas raising competition concerns. In particular, the Parties' commitments provided for the divestment of 21 stores operating under the Courir brand - 15 in France and 6 in Portugal - to a single purchaser.

Taking into account that most sports goods multi-brand retailers have a national procurement strategy for their stores and nationwide marketing campaigns, it was necessary that the stores which were being divested to address competitive concerns at local level were sold to a single purchaser for each of France and Portugal. That way, the pre-transaction competitive dynamics could be replicated by a player with national procurement and marketing strategy. In addition, a number of other criteria were also important for the identity of a suitable purchaser.

First, the purchaser needed to be sizeable enough at national level to effectively compete with the new merged entity of JD Sports and Courir.

Second, the Commission's investigation revealed that supply contracts with brand manufacturers (e.g. Adidas, Nike, New Balance) were crucial for multi-brand sports goods retailers, such as the Parties, so as to be competitive and successful in the retail markets for sneakers, performance footwear and sports apparel. Hence, the Commission considered that the viability of the remedy would be strongly influenced by the identity of the purchaser. The latter needed to be significant in size and

adequately experienced so as to already have established distribution relationships with large brand manufacturers granting it access to the latest and trendiest sneakers.

In view of these requirements, the Parties committed to sell the divestment business to Snipes. Snipes is an established and experienced sneakers and sports apparel retailer, successful in both France and Portugal. Snipes had been identified as a close competitor of the Parties during the Commission's investigation. The Commission concluded after its market investigation that it is also capable to exert sufficient competitive pressure on the merged entity, and restore the competitive conditions, in the local areas where competition would be lessened. Snipes' significant market presence in the retail of sneakers and sports apparel in many countries in the EEA showed that it has the required expertise to purchase and further develop multiple stores in a given country.

In light of the strong link between the identity of the purchaser and the viability of the remedy, the Parties committed to sell the divestment business to Snipes already in the commitments and thus, the Commission assessed the remedy as a hybrid fix-it-first remedy. More specifically, compared to a usual 'fix-it-first' type of remedy, where the notifying parties identify a specific purchaser for the business they intend to divest during the merger review process and this purchaser is approved, together with the transaction agreements, in the Commission's decision conditionally clearing the merger, in a 'hybrid fix-it-first' scenario, the notifying parties identify the purchaser prior to the Commission's decision on the main transaction, but the suitability of the purchaser and/or the transaction agreements giving effect to the commitments are assessed in a separate decision on the implementation of the commitments (i.e. the Purchaser approval decision), which is adopted after the conditional clearance decision of the main transaction. Hence, during the market test of the remedy proposal, the Commission was able to gather feedback on the suitability of Snipes as a purchaser of the stores to be divested.

In this case, the hybrid fix-it-first nature of the remedy enabled the Commission to get comfort on both the remedy proposal and the suitability of the proposed purchaser at the time of drafting the conditional clearance decision. In addition, as part of the purchaser approval process, the Commission conducted a complete evaluation of the suitability of the divestment agreements. The Commission issued the purchaser approval decision a few weeks after the conditional clearance decision.

This case illustrates that although implementing a fix-it-first remedy within the limited timeframe of a Phase I investigation can be difficult, a hybrid solution may be more appropriate when the purchaser's identity is critical to the assessment of a remedy proposal. To get comfort on the purchaser's suitability prior to the adoption of the conditional clearance decision, the Commission worked closely with an independent advisor appointed by the Parties (and approved by the Commission). The appointment of independent advisors in merger investigations is done on a case-by-case basis and in rather specific circumstances where their independent expertise is required for the assessment of specific aspects of proposed remedies (but not to design the remedy, which is the responsibility of the notifying parties) prior to the appointment of a monitoring trustee. The role of the independent advisor in this case was to assist the Commission with the assessment of the suitability of Snipes as a buyer of the divestment business prior to the adoption of the conditional clearance decision in view of the need to get comfort on the buyer prior to the adoption of the conditional clearance decision. Following the decision, the independent advisor was appointed as the monitoring trustee of the divestment package.

As such, the Commission was able to accept the remedy proposal swiftly and conduct a comprehensive assessment of the related transaction agreements only after granting the conditional approval. The hybrid fix-it-first solution thus gave the Parties the requisite time to finalize the divestment transaction agreements, with the confidence that a suitable buyer had already been identified.

Conclusion

This case was interesting for several reasons. First, it tackled the competitive dynamics at both national and local levels within retail markets, including through a detailed local area analysis to assess the transaction's unilateral effects. Second, the decision clarified that online and offline sales are part of the same product market when it comes to retail sales of lifestyle and performance sneakers and sports apparel. This showcases the Commission's approach to adapting market definition compared to past cases, in line with its commitment, as set out in paragraph 14 of the revised Market Definition Notice, to be attentive to possible changes driven by trends such as digitalisation and consumer purchasing behaviour. Lastly, the transaction was approved with a hybrid fix-it-first remedy package that included an identified buyer in a Phase I decision.

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Competition Merger Brief

Novo Holdings/Catalent: Novo takes a big bite

Benedikt Herz, Daniel Irisarri Lolin, Cécile Manong, Hanna Perikangas, Dimosthenis Skarlatos, Zsolt Vertessy

Introduction

On 6 December 2024, the Commission unconditionally cleared the EUR 15.4 billion acquisition of Catalent by Novo Holdings and Novo Nordisk.

Both Catalent and Novo Nordisk are active in the pharmaceutical industry. Catalent is a contract development and manufacturing organisation ('CDMO'), which develops and manufactures drugs on behalf of pharmaceutical companies. It is headquartered in the US and operates a network of around 50 facilities across North America, Europe, Asia Pacific and Latin America. Novo Holdings is the controlling shareholder of Novo Nordisk, a Danish pharmaceutical company active in the treatment of chronic diseases and metabolic disorders including obesity and diabetes. As a result of the transaction, Novo Nordisk will acquire three of Catalent's production sites (in Belgium, Italy, and the US) and Novo Holdings will acquire the remaining sites.

In its investigation, the Commission assessed whether, post-transaction, Novo Nordisk's competitors would be able to access from alternative sources the CDMO services previously provided by Catalent. The focus of the Commission's investigation was the potential exclusion of Novo Nordisk's competitors by reserving Catalent's capacity to produce pre-filled syringes ('PFS') solely for Novo Nordisk's weight loss and diabetes drugs.

In this brief, we describe the market context in which the transaction took place and learnings related to the CDMO space, as well as the main issues assessed in the case.

Market context

By its nature and size, the transaction was somewhat unusual. It is not common for a pharmaceutical company to acquire a major multi-site CDMO with the aim of repurposing the CDMO's capacity for its own needs. As a result, the transaction attracted some public attention and questioning.

Transaction rationale

In the past few years, the demand for the latest generation of obesity and diabetes treatments has drastically increased. For Novo Nordisk, the transaction was a quick fix to meet this growing demand, by getting access to capacity and expansion potential more efficiently than by building internal capacity, thereby resolving a production bottleneck for its blockbuster diabetes and obesity medicine, Ozempic. In fact, Catalent already provided manufacturing services to Novo Nordisk for some of its Ozempic production. It additionally had manufacturing capabilities contracted out to other pharmaceutical companies as well as a significant potential for capacity extension in the form of floor space and qualified staff in its pre-existing facilities. Novo Nordisk therefore aimed to acquire that additional capacity and build new production lines on Catalent's sites.

Relevant market dynamics

Understanding the CDMO space was an important part of the Commission's investigation into the transaction, as it is a crucial piece of the pharmaceutical industry.

In a nutshell

The Commission unconditionally cleared Novo Nordisk's EUR 15.4 billion acquisition of Catalent.

The key question was whether the deal might limit rivals' access to important drug manufacturing services, especially for diabetes and weight-loss treatments.

However, after a careful review — including a market reconstruction and input from many industry players — the Commission found that the market will remain well-supplied by credible alternatives.

The case highlights the importance of thoroughly evaluating commercial and market dynamics, especially in innovative and fast-growing markets.

The CDMO space is very dynamic with many players operating globally. On the product development side, CDMOs are invaluable partners to small and medium pharmaceutical companies which often need to outsource some parts of the development of their medicine. At manufacturing level, CDMOs come into play to manufacture both products used in clinical trials and products ready for commercialisation. Outsourcing manufacturing is common regardless of the size of the pharmaceutical company, with small to medium players often not able to produce at commercial scale and larger ones looking to minimise their supply chain risks by qualifying alternative suppliers.

The manufacturing capabilities of CDMOs is large and ever-expanding. Indeed, CDMOs significantly stepped-up their manufacturing capabilities during the COVID crisis and were subsequently left with several idle production lines in the aftermath. This spare capacity has since been repurposed and expanded for a wide array of medicines including for new generations of products aiming to tackle another health crisis in the Western world: metabolic diseases.

In this space, Novo Nordisk and Eli Lilly are the market leaders, mostly due to their new generation GLP-1 receptor agonists, which primarily target diabetes and obesity. Both companies compete in this field and will likely soon face pressure from additional drug manufacturers, large and small. Indeed, innovators of all sizes, including AmGen, Pfizer, Zealand Pharma, and Altimmune, expect to enter the market in the coming years with the next generation of GLP-1 receptor agonists and other similarly acting products.

The Commission's investigation thus indicated that competition was or would likely be fierce both at the level of developing and manufacturing treatments for metabolic diseases and at the CDMO level.

Main theory of harm

Background

As mentioned above, the main relationship between Novo Nordisk and Catalent relates to Catalent being the supplier of (CDMO) manufacturing services to Novo Nordisk, for the production of its blockbuster obesity and diabetes drugs. The Commission therefore focused its assessment on that relationship.

The Commission received complaints with regard to the deal, notably raising foreclosure concerns whereby, after the merger, Novo Nordisk would stop or deteriorate the supply of manufacturing services to Catalent's other customers that compete with Novo Nordisk (because they market or are developing obesity and/or diabetes drugs).

The Commission applied the legal framework to assess vertical mergers, which comprises three cumulative conditions, i.e. (1) whether the merged entity would have the ability to engage in foreclosure, (2) whether it would have the incentive to do so, and (3) what would be the overall impact on effective competition on the market. The decision focused on the lack of ability and impact of foreclosure (conditions (1) and (3)), noting at the outset that the condition of the incentive (condition (2)) seemed probable in light of the deal rationale, which was for Novo Nordisk to make use of Catalent's manufacturing services to meet its own demand (as explained above).

Commission assessment

Various elements led the Commission to conclude that foreclosure concerns were unlikely, because of Novo Nordisk's inability to foreclose its competitors and of the unlikely impact of any foreclosure strategy on competition.

First, the Commission conducted a market reconstruction to build a picture of Catalent's current and future importance as a supplier, and the extent to which alternatives are available. Such exercises are helpful when reliable estimates of market shares are unavailable.[1] For this, the Commission contacted nearly 20 of the top competing CDMOs to assess their respective capacities for their manufacturing services. The market reconstruction had a high response rate and covered the vast majority of the supply for such services. The exercise revealed that Catalent's current and projected share of capacity was modest. Several other CDMOs would have spare capacity after the merger and could compete for Catalent's customers.

Second, in addition to the market reconstruction, the Commission contacted several hundred market participants to collect their views on the markets and the transaction. Overall, the Commission's investigation confirmed that there are several credible, good quality and sizeable alternatives to Catalent for the provision of manufacturing services. These rivals include Thermo Fisher, Vetter, Pfizer CenterOne, Rovi, INCOG or Corden Pharma. Many of these CDMOs were also identified as credible suppliers of manufacturing services on high-volume lines (lines producing large amounts of medicine), which may be particularly relevant to meet the significant and growing demand for obesity and diabetes drugs.[2]

Third, customers of manufacturing services can switch contract manufacturers. In many instances, customers have multiple CDMOs qualified for manufacturing their respective products, often in addition to in-house capabilities. Following its investigation, the Commission acknowledged that switching might take time (on average between 6 to 18 months depending on the stage of development or commercialisation of the product) and requires some investment (typically between EUR 1-7 million). That being said, market participants confirmed during the investigation that switching remains a viable option for customers of manufacturing services.[3] This should also be seen in the context of the significant revenues that many pharmaceutical products are expected to generate once

[1] Commission Notice on the definition of the relevant market for the purposes of Union competition law (OJ C, C/2023/6789, 22.2.2024), paragraph 112.

[2] The Commission noted in that regard that many players on the market made announcements on capacity expansions to cater for any increase in demand for manufacturing services for high-volume products.

[3] In that regard, the parties submitted that depending on contractual provisions, Catalent's customers can maintain production at Catalent's sites while qualifying an alternative supplier, allowing them time to switch and, for those that have a Phase III pipeline, the parties offered financial assistance to help cover switching costs.

marketed, and the likely low proportion that the cost of switching represents in the overall investment.

Overall, even though concerns were raised by some market participants, the Commission's investigation showed that Catalent is unlikely to have a strong position for the supply of manufacturing services. Therefore, the merged company would not have the ability to engage in a foreclosure strategy, and should this strategy be implemented, it would be unlikely to have an impact on competition.

Conclusion

The acquisition of Catalent by Novo Holdings and Novo Nordisk was an unusual example of a pharmaceutical company acquiring a CDMO to reserve its capacity (partly) for itself. It is therefore unsurprising that some of Catalent's customers were wary about the deals' impact on them. The Commission carefully assessed and weighed these concerns. For this assessment, a thorough market reconstruction and thorough investigation with customers and competitors was key. However, the Commission's investigation revealed that the CDMO market is competitive and dynamic – there are credible alternatives to Catalent, capable of providing the necessary manufacturing services to Novo Nordisk's competitors. The presence of these viable alternatives, alongside the ability to switch contract manufacturers, meant that the market would be able to absorb shifts in capacity without a detrimental impact on competition.

The Commission's investigation also took into account the need to preserve innovation. Many pipeline products are being developed for diabetes and obesity (as well as in other fields), so if the CDMO market were capacity constrained or if these pipelines could not be moved to alternative high-quality CDMOs, patients may ultimately have lost out on access to new, better, cheaper products. Fortunately, this is not the case. At the same time, Novo Nordisk explained that the acquisition would help it reach more patients living with diabetes and obesity by quickly gaining access to new manufacturing capacity in Europe and worldwide. The Commission's review thus shows that even large companies can gain scale through acquisitions, as long as effective competition is not harmed.