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A Q&A with Ingrid Vandenborre and Michael Frese

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14 October 2024

Credit: Skadden, Arps, Slate, Meagher & Flom LLP

The latest edition of GCR's **Guide to Life Sciences** is edited by Skadden, Arps, Slate, Meagher & Flom partner Ingrid Vandenborre and counsel Michael Frese. In a Q&A with GCR Insight, they discuss the European Commission testing out novel theories of harm in the pharmaceuticals sector, merger control post-*Illumina/Grail* and an increasing number of disparagement cases and deal reviews centred on potential competition concerns.

What are the key competition issues affecting clients in the life sciences sector right now?

Frese: The life sciences sector has been a focus area for European competition authorities for a long time. Unlike in other sectors, where the European Commission often takes the lead in enforcement, we see a lot of groundbreaking judgments and developments originate at national level. On the conduct side of things, we see the commission pursue theories of harm that are almost unique to the life sciences sector. Of course, there are traditional theories of harm that are applied across multiple industries, but we are increasingly seeing patent settlement cases, excessive pricing, competitive disparagement and more recently, research discontinuance identified as key issues in the pharmaceuticals space. These are theories of harm that we have not encountered in other sectors.

This year has also seen the conclusion of a rare cartel case in the industry – only the second since the 2001 vitamins case. This shows that the commission continues to be very active in enforcing against anticompetitive conduct in this space.

Another important recent development is the ECJ's long-awaited judgment in the Perindopril appeal in June 2024. This case concerned an allegation of anticompetitive patent settlements in which an originator concluded settlement agreements with a number of generic companies, some of which (but not all) involved cash payments. On appeal at the lower-tier EU court, large parts of the commission's investigation were confirmed, but there was one exception: one of the generic companies reached a licence agreement instead of a cash transfer, which required it to pay royalties to the originator. The General Court said that this was not an anticompetitive settlement agreement and annulled the case, but the ECJ has now overturned that decision, indicating that these kinds of agreements qualify as anticompetitive 'by-object' infringements. The court also concluded that granting a patent licence in some markets in exchange for the licensee agreeing not to enter or challenge patents in other markets may be unlawful market sharing. This indicates that the commission has a lot of support from the court in pursuing an aggressive agenda in the pharmaceuticals space.

Vandenborre: When it comes to merger control, things are a little different. The European Commission and member states have sought new ways to review below-threshold deals, but the *Illumina/Grail* judgment has halted liberal interpretations of the statutory framework. The judgment indicates that the ECJ – at least with regard to merger control – does not support the commission's approach to expanding its jurisdiction to review below threshold acquisitions. This is a sharp contrast to the court's confirmation of the commission's expansive approach when it comes to restrictive conduct. It would appear that the commission is testing out novel theories of harm first in pharmaceuticals, and while these theories of harm are unlikely to remain limited to the pharma sector, that is where the cases currently are.

Just to dwell on the implications of the Illumina/Grail judgment for a moment, it is clear that the commission's approach to Article 22 referrals has created a lot of uncertainty and it remains to be seen whether the ECJ's judgment will fix this. The commission has issued a statement following the judgment, saying that it looks forward to accepting referrals from member states that have jurisdiction to review transactions. As several European countries take a more flexible approach in determining jurisdiction – some have even expanded their jurisdictional basis for review – it will remain important to consider potential reviews in the European Union.

Frese: In terms of advice for clients, if you look at the novel theories that the commission is pursuing – whether these involve patent settlements, denigration or research discontinuance – it remains crucial to assess ordinary course of commercial arrangements based on the potential impact on competition. The recent enforcement cases show that even practices that are completely in line with patent law, price regulations or other regulatory systems could potentially be considered contrary to EU competition law, and this is something to remain very vigilant about.

You mentioned the Illumina/Grail judgment. In September, the ECJ annulled the European Commission's decision to accept a referral from member states to review Illumina's acquisition of Grail, despite failing to meet notification thresholds. Can you expand a bit more on the judgment's potential impact on deal reviews in the life sciences sector?

Frese: To take a step back, in March 2021, the commission published new guidance in which it shifted its approach to the referral mechanism set out in Article 22 of EUMR. It decided to encourage referrals of concentrations by member states to the commission to deal with a perceived enforcement gap, enabling review of so-called 'killer acquisitions' involving large companies seeking to acquire a small target with competitive potential that does not necessarily meet the turnover thresholds. The commission's new guidance specifically notes that the pharmaceuticals sector would likely be a key focus area for its application. This was made clear in Illumina's acquisition of Grail, the first application of the new approach to Article 22.

Illumina's planned acquisition did not meet the notification thresholds under EUMR, nor did it meet notifications thresholds under any of the EU member states' regimes. However, the French Competition Authority had concerns about the deal and raised these with the commission – and what the commission did was quite surprising to everyone in the industry. It relied on an almost-forgotten provision in EUMR called the Dutch Clause, which enables member states to refer deals to the commission for review. The clause is so named because it was introduced at the initiative of the Dutch government at the time, which did not have a merger control regime. If there was a deal that really impacted trade in the Netherlands, the then-government wanted to be able to refer it to the commission for review. The commission has never really encouraged referrals, but in this case – even though there is a merger control regime in France and the thresholds were not met – it accepted the referral and invited others to join based on its new referral policy. On that basis, the commission reviewed the deal and prohibited it, but the deal was nevertheless implemented pending the review, so gun-jumping fines and interim measures were also imposed.

However, Illumina disagreed with the commission's notion that it had jurisdiction to review the deal, so it appealed and the higher court's decision was issued on 3 September 2024. The ECJ was very clear: under circumstances where a member state has a merger control regime and the thresholds are not triggered, there is no basis under the EUMR to refer the deal to the commission for review. The court took a strict stance and supported legal certainty – when Illumina was planning for this deal, it had no expectations that it could be subject to review by the commission, given that none of the thresholds were met.

Vandenborre: We have been debating what this means going forward. The commission has stated that it expects to continue to accept referrals. In some cases – *Adobe/Figma*, for example – referrals have relied on member states with jurisdiction to review, but not exclusively. It is not the case that all past Article 22 cases are without basis. Indeed, this is the case for *Illumina/Grail*, but not for all referral matters. The commission will probably be looking to member states that do have jurisdiction. Many member states have already looked to lower their thresholds for review in anticipation of the judgment, to ensure that they have broader review capabilities. Member states also have call-in powers for transactions that do not meet their notification thresholds.

Companies will therefore still have to assess the risk of referral. Perhaps member states that have been more relaxed about taking jurisdiction on a market-share threshold basis – like Spain or Portugal – or on a *de minimis* basis – like Germany or Austria – may reconsider their approach, even under their existing thresholds, and others can introduce or expand application of call-in powers for deals that are below mandatory notification thresholds. However, it is certainly the case that while there is definitely scope for member states to take jurisdiction, the commission would have no legal basis to pro-actively drive referrals. Moreover, it will be difficult for the commission or member states to determine which member states the transaction may have an impact on – which is still a requirement for referral.

It will be a trial-and-error approach to see to what extent regulators have rights in 'in-scope' referrals, and whether this will be sufficient to address the perceived gap in current legislation for killer acquisitions that the commission has identified. The outgoing EU competition chief Margrethe Vestager repeated this at a conference, saying that addressing the gap will be a bit of a conundrum and that it's a task for the next commissioner, not for her. However, they will have to address it somehow, and some unpredictability for companies may remain as we see how this develops.

Thermo Fischer/Olink **closed earlier this summer after an in-depth probe by Germany's Federal Cartel Office that took into account future competition. Do you expect this to become an increasing focus during deal reviews in the life sciences sector?**

Frese: *Thermo Fischer/Olink* is a good example of authorities considering future developments, such as potential competition, in their merger reviews. Traditionally, most investigations in the life sciences industry have been focused on horizontal overlaps. To a large extent, this is still the case, but we are seeing the commission increasingly looking at vertical deals and more novel theories of harm in other industries. Of course, the case in point is *Illumina/Grail*, which was a vertical deal that was blocked. As discussed, the commission had no jurisdiction to review that deal, but it does show that the commission is really focused in terms of substantive assessment.

Thermo Fisher/Olink wasn't reviewed by the commission, but by the German Federal Cartel Office and the UK Competition and Markets Authority. The case was cleared, but the authorities were very focused on potential competition and on the parties' internal documents to determine the extent to which they were tracking and responding to each other's product development. Both parties were active in supplying technologies that could be used for proteomics discovery and analysis, which is the study of proteins and their potential use for biomedical and clinical applications. However, the parties used different technologies, so the competition authorities examined to what extent these were complementary or substitutional. They concluded that they were complementary and that customers would buy these technologies independently from each other.

In July, the European Commission accepted commitments from Vifor Pharma to address potentially anticompetitive product denigration. A parallel CMA investigation is still pending. These sorts of investigation have gained more attention in recent years – do you expect them to become more prevalent?

Vandenborre: These cases have put disparagement on the agenda. There's still a pending case against Teva on similar conduct, although this is not a pure disparagement abuse case as the commission is examining both the misuse of the patent system and disparagement. It is worth mentioning that the commission's investigation into Vifor Pharma ended with commitments, not infringement findings – they cannot be scrutinised by the courts or set a clear precedent. The same is true for the commission's recent excessive pricing case. The legal community is calling for some jurisprudence that can test this properly, but because this is so limited, we must look back to previous cases for now or at national level.

The commission launched its investigation into Vifor Pharma in June 2022 and commitments were accepted in July 2024. The formal investigation was meant to address concerns that Vifor, which is an originator for intravenous iron treatment, restricted competition by disparaging its competitor Pharmacosmos, which was another originator – not a generic. This is an interesting aspect in and of itself, as it concerns rival originator products, whereas previous investigations have tended to focus on competition between originators and generics. The CMA launched an investigation into the exact same conduct in parallel in January 2024, probably coordinating closely with the commission. The case was initiated by complaints from Pharmacosmos as opposed to being initiated by the authorities themselves. It also had support from the UK Prescription Medicines Code of Practice Authority, which found that Vifor had made disparaging statements about the safety of Pharmacosmos' drug Monofer under the Code of Practice for pharma companies.

It is likely, given this recent action, that companies will be more concerned about how they engage in advertising, although we are already seeing in our practice that this is very challenging. Where do you draw the line between illegal disparagement and distinguishing your own product legitimately? Many companies have questions about what the specific problematic conduct is and what the best course of action would be. The commitments are not very helpful in answering these questions because they seem pretty broad in terms of what these companies will not undertake, so it's hard to draw clear lessons from them.

The only real court-confirmed disparagement case we've had at EU level (despite there being lots at member-state level, particularly in France) is *Hoffman-La Roche*, where it was ruled that coordination between competing pharmaceuticals companies to communicate misleading information may amount to a restriction of competition. However, this was really about misleading information, which is different from disparagement.

When it comes to an originator blocking a generic, disparagement comes into play where a company does not give the full information or disincentivises prescribing physicians. When it is an originator blocking an originator, like in *Vifor*, things are a bit different. Since you're not really blocking a generic, you're basically restricting communications about your product because of a competitor that is not dependent on you for entry or for anything else. This case is much more far reaching in that sense than some previous cases.

Frese: *Vifor* also goes further than *Hoffman-La Roche*, which was a market-sharing arrangement in essence. One of the companies sold a drug for ophthalmic indication and another sold a similar drug that was used off-label for an anti-cancer treatment with completely different prices, and there was misleading communication that was considered anticompetitive.

The European Commission issued a rare cartel decision in the pharmaceuticals sector last year. Why do you think cross-border cartels in that sector are so rare? Do you expect more cartel investigations in this sector?

Frese: With only one previous pharma cartel decision in the 2001 vitamins case, it is indeed very rare to have cartel investigations in this industry. Why is that? Well, on one hand, it is a heavily regulated industry, with marketing authorisations and pricing and reimbursement controls. Even if companies were planning to collude, it is a very difficult industry to do this cross-border. This is key, because the commission's jurisdiction depends on whether a deal effects trade between member states. Since many aspects of competition in the pharmaceuticals sector take place at national level, this makes it more difficult for the commission to investigate.

On the other hand, we do see some activity by national competition authorities in the cartel landscape. For example, in February 2022, the Belgian Competition Authority adopted a settlement decision, in which it fined two pharmaceuticals companies for participating in a cartel involving flu vaccine sales to pharmacists. In 2021, the Spanish National Markets and Competition Commission also fined two pharmaceuticals suppliers for market sharing. You do see some cartel investigations in this industry, but they typically happen at national level because these markets are national in scope. That said, abuse of dominance investigations tend to form the majority of the commission's enforcement actions in the pharmaceuticals sector, more so than cartels.

However, the commission recently adopted a settlement decision involving a product named SNBB, which is an input material to produce an abdominal antispasmodic drug. The commission imposed a relatively modest fine compared to some of the eye-popping fines it has previously imposed, totalling €13.4 million between five pharmaceuticals companies. The decision signals that cartel detection and enforcement in this sector is not purely a national issue.

What is crucial here is that there was a leniency application. One of the six companies involved actually stepped forward and confessed to cartel conduct, so it did not receive a fine. The commission found that the cartel involved the coordination and fixing of minimum sales prices to distributors and generic drug manufacturers, as well as quota allocations and the exchange of commercially sensitive information, which are very traditional cartel allegations. This shows – as does the 2001 vitamins case – that even though cross-border cartel investigations in the pharmaceuticals industry are rare because of market dynamics, the commission is willing to undertake them.

Vandenborre: The key point is that it will not necessarily always be the commission that looks at cartel investigations: member states have been and will continue to be involved. I don't think that companies consider these investigations to be rare, or they assume they're not at risk. Where the commission is involved, this is usually because the investigation coincides with some other anticompetitive conduct, or because it involves a raw material, or because the conduct's impact goes beyond the national market.

The third edition of the GCR Guide to Life Sciences is now live.

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