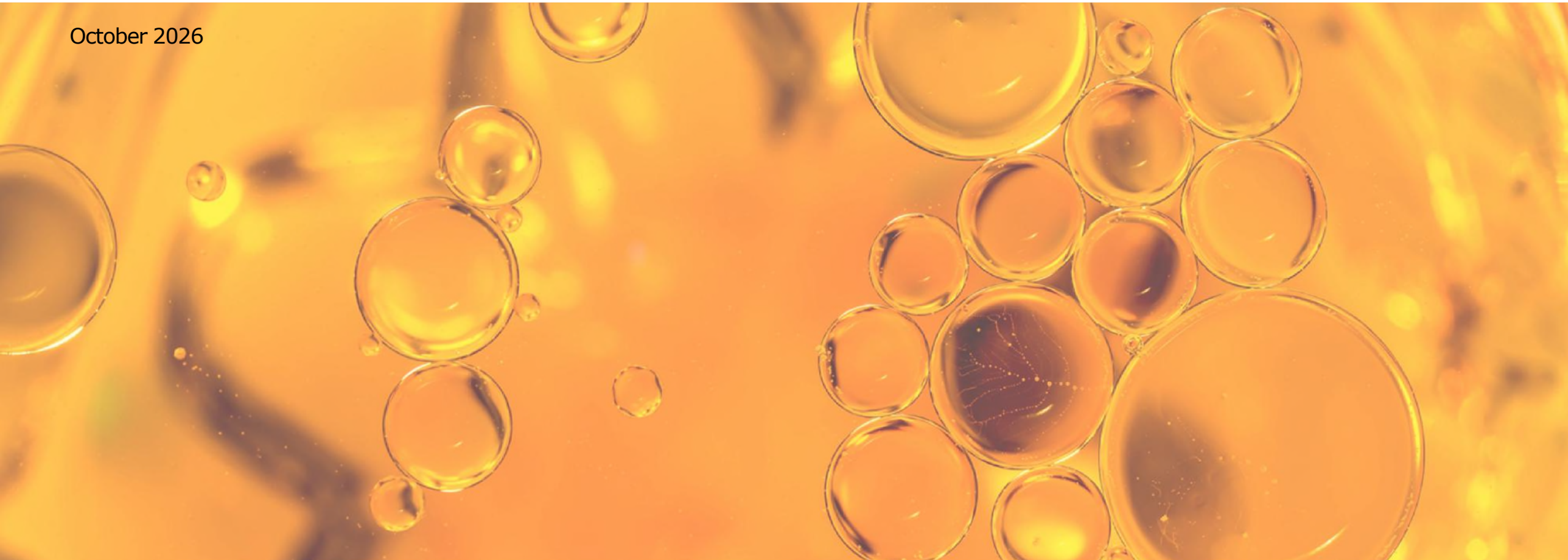


# Competition Before Competition

Beyond Prices & Market Share: How Regulators Now Look at Your Strategies in Life Sciences Markets

October 2026



# Introduction

Competition enforcement in the pharmaceutical and life sciences sector is often described through familiar doctrinal categories: disparagement, pay-for-delay, ecosystem foreclosure, killer acquisitions or follow-on damages.

Viewed individually, each represents a distinct branch of competition law. Viewed together, however, they reveal a broader shift in enforcement priorities.

Across pharmaceuticals, biologics and medical devices, European and UK authorities are increasingly focusing not simply on prices or market shares, but on the mechanisms through which competition is shaped before those outcomes materialise. Scientific communications, diagnostics, interoperability, intellectual property strategies and acquisition activity have become competitive variables in their own right. In parallel, the growth of private enforcement is changing the scale and duration of the legal exposure that can follow public intervention.

That shift is visible across an unusually diverse body of cases. Authorities continue to apply long-established legal principles, yet are doing so in response to increasingly novel fact patterns: (i) competition between originators rather than originators and generics, (ii) competition concerns centered on diagnostics and technological tools embedded in treatment pathways rather than only on promotional messages to healthcare professionals, (iii) licensing arrangements rather than cash settlements and (iv) below-threshold acquisitions examined after signing or years after closing.

The result is an enforcement landscape that can appear fragmented when viewed case by case. A different picture emerges when those developments are considered through the lens of competitive control. Many of the most significant recent matters concern one of four recurring themes: control over information, control over access, control over timing and control over market structure. Private litigation is analytically distinct. It concerns the financial, evidential and operational consequences that may follow once those forms of control attract public enforcement.

Against that background, this article considers five developments currently shaping competition risk across the life sciences sector in the European Union and the United Kingdom:

- 
- 1 Competition through information;**
  - 2 Competition through access;**
  - 3 Competition through timing;**
  - 4 Competition through market structure; and**
  - 5 Liability exposure.**

# 1. Competition Through Information

## Disparagement, Medical Communications and Biosimilars

France's Autorité de la concurrence established the framework in the 2010s. The theory is not limited to literally false statements. Authorities have treated selectively framed, incomplete or decontextualised safety communications as capable of abusive disparagement where they undermine an official regulatory assessment of equivalence or substitutability. The audience, a physician or pharmacist deciding whether to prescribe a substitute, is presumed to weigh an unresolved-sounding safety question more heavily than a confirmed regulatory equivalence finding<sup>1</sup>. The elements an authority has to establish are therefore evidentiary rather than purely legal: what was actually communicated, to whom, and whether it went beyond what the underlying regulatory record supported.

An important early illustration is the Italian Roche/Novartis (Avastin/Lucentis) matter. The AGCM sanctioned coordination concerning the dissemination of misleading safety messages about Avastin when used off-label in ophthalmology. The case was assessed under Article 101 TFEU and confirmed that coordinated communications about the safety of therapeutic alternatives may themselves constitute a restriction by object<sup>2</sup>.

The French proceedings concerning the same medicines followed a different route. In 2020, the Autorité de la concurrence treated alleged communications to healthcare professionals and public authorities as abuses of collective dominance under Article 102 TFEU and imposed fines totalling EUR444 million. The Paris Court of Appeal annulled that decision in full in February 2023. In June 2025, however, the Cour de cassation partially quashed the judgment and remitted the case. It held, among other points, that the Court of Appeal had not adequately examined potential competition after the relevant legislative changes, the possible exclusionary capacity of the communications, their context and the relevance of an alleged

objective. It also clarified that a dominant undertaking's speech is first assessed under Article 102, while any reliance on freedom of expression must then satisfy Article 10(2) ECHR. The proceedings therefore remain unresolved on remittal<sup>3</sup>.

Viewed together, the Italian and French proceedings illustrate that the legal qualification may differ while the underlying enforcement concern remains remarkably similar. The comparison is instructive. Italy addressed coordinated safety messaging as an agreement capable of restricting competition by object under Article 101. France examined communications and regulatory conduct as possible abuses by dominant undertakings under Article 102. The legal routes differ, as do the procedural outcomes. The common concern is nevertheless the same: scientific and safety communications may affect not only demand, but also the emergence or preservation of a therapeutic alternative.

The French litigation adds an important qualification. Regulatory legality and current substitutability do not necessarily exhaust the competition inquiry if the product may still exert potential competitive pressure.

The theory has since expanded beyond generic-substitution cases and safety messaging directed at therapeutic alternatives, in two directions. First, it has expanded beyond originator-versus-generic competition and into competition between originator products themselves. There is no bioequivalence finding to distort here. Any comparison has to be tested against clinical data and label wording instead, as in the Commission's Vifor decision on IV iron therapies<sup>4</sup> and its open investigation into Sanofi's flu-vaccine marketing<sup>5</sup>.

Second, and perhaps more consequentially, disparagement theories have increasingly become intertwined with patent and regulatory-cycle strategies. The Commission's Teva decision treated a "divisionals game" (staggered secondary patents, enforced and then strategically withdrawn to avoid an adverse precedent) and a disparagement campaign against a rival's therapeutically equivalent product as a single continuous infringement. The two conducts pursued the same commercial objective and reinforced each other's market effect<sup>6</sup>.

Biosimilars occupy a more nuanced position. Earlier generic-disparagement cases commonly rested on a straightforward premise: the competent authority had established bioequivalence, so communications suggesting otherwise contradicted a formal assessment. Biosimilars historically presented a more complex picture because interchangeability and substitution practices varied across Member States and clinical practice distinguished between treatment initiation and switching.

Much of the scientific uncertainty has narrowed. The joint EMA/HMA statement<sup>7</sup>, first issued in September 2022 and updated in April 2023, confirms that EU-authorized biosimilars are scientifically interchangeable with their reference products and with one another. It also preserves the distinction between scientific interchangeability and national rules on prescribing, switching and pharmacy-level substitution. Broad claims of non-equivalence are therefore harder to sustain, while questions of implementation and clinical management remain.

This explains why a direct safety-disparagement campaign about biosimilars generally would be harder to sustain today than it once was. The EMA/HMA position forecloses a blanket claim of clinical non-equivalence. It does not eliminate the narrower, genuine questions around monitoring a switch in an already-treated patient.

One current Italian investigation against Biogen illustrates the point<sup>8</sup>. The case does not concern a communications campaign questioning biosimilarity as such. Rather, it concerns a diagnostic test used to assess and monitor a clinically significant treatment risk. The practical significance of the issue is particularly apparent where physicians consider moving patients from a reference biologic to a biosimilar. Even where interchangeability is not scientifically disputed, decisions concerning treatment monitoring may still influence whether such a switch is made in practice. The investigation therefore suggests that, as regulatory consensus around biosimilarity has strengthened, competition concerns may increasingly migrate away from claims about equivalence itself and towards the clinical tools and processes embedded in treatment pathways.



## 2. Competition Through Access

### Ecosystems, Interoperability and Diagnostic Gateways

If disparagement cases concern control over information, ecosystem cases concern control over access. The question is no longer only what physicians, hospitals or purchasers are told. It is whether rivals can use the interfaces, diagnostics, software and workflows through which effective competition takes place.

Medical devices provide a useful illustration. Many purchasing decisions are taken by hospitals, procurement bodies or central frameworks with access to detailed comparative material. That may reduce the importance of classic prescriber-facing information asymmetries. It does not eliminate competition risk. The pressure point often shifts to interoperability, proprietary interfaces, service infrastructure and ecosystem design.

The most prominent current example is the Commission's investigation into Align Technology. The Commission is examining whether Align may have leveraged Invisalign clear aligners by restricting the use of competing intra-oral scanners in the Invisalign ordering process. Its official framing refers to tying and a restrictive interoperability strategy, including the alleged refusal to approve automated submission and to accept certain industry-standard scan files. No statement of objections or infringement finding has been issued, and Align disputes the allegations<sup>9</sup>.

Viewed more broadly, the investigation can also be read as an ecosystem-access case. Intra-oral scanners are the digital entry point into clear-aligner treatment. A restriction at that point may affect competition in scanners while reinforcing the position of the downstream aligner system. The gateway characterisation is an analytical reading of the Commission's concerns, not a separate legal test.

The Biogen inquiry provides a parallel from biologics. The AGCM's theory appears to be that a diagnostic embedded in the treatment pathway could be used to affect access to the medicinal product market next to it. Align and Biogen are factually distinct and both remain open. Yet the comparison is instructive. A product may be substitutable in pharmacological or technical terms while a companion technology makes switching operationally difficult.

Earlier aftermarket cases show why the existence of a closed system cannot itself establish an abuse. In 2021, the AGCM closed its investigation into the servicing of diagnostic-imaging equipment without finding an infringement. The case concerned access to service software, spare parts and technical information controlled by original-equipment manufacturers. Its outcome underscores that indispensability, refusal, foreclosure and objective justification must be established on the evidence, not inferred from system architecture alone<sup>10</sup>.

Access can also be mediated through professional and institutional channels. In February 2026, the Commission closed its Article 102 investigation into Edwards Lifesciences' Global Unilateral Pro-Innovation Policy after the policy was withdrawn. The Commission had examined whether the policy may have limited physicians' freedom to participate in clinical trials and scientific or educational activities supported by a competing TAVI manufacturer. The closure was expressly not a finding that the policy complied with competition law. The Commission concluded that its concerns had been addressed and that further action was no longer an EU priority<sup>11</sup>.

This theory differs from classic disparagement. No adverse statement about a rival's product is required. Foreclosure could instead arise through control over

clinical collaboration, trial participation, key opinion leaders or the channels through which a treatment is validated and adopted. Influence over the architecture of innovation may be as commercially significant as influence over the message.

No directly comparable UK decision has yet emerged. That absence should not be treated as a safe harbour. NHS procurement concentrates expertise and purchasing power, but it does not remove interoperability or ecosystem concerns. If access theories continue to migrate across life sciences, medical devices, diagnostics and digital health are likely to remain testing grounds.

The distinction that increasingly matters is therefore less the formal boundary between pharmaceuticals and devices than the architecture of the product offering. Some products can be purchased and used directly. Others depend on a technological, diagnostic or professional layer capable of becoming a competitive gateway. Earlier cases focused on the information reaching healthcare professionals and payers. Authorities are now also examining the infrastructure that determines whether rivals can reach them at all.

A further issue may become more prominent as these markets develop: cumulative access to data. Neither the Align nor the Biogen investigation is framed as a refusal to provide rivals with datasets. Yet connected scanners and diagnostic tools may generate data and experience that improve validation, performance and clinical acceptance over time. The automotive sector offers a useful analogy. EU competition and regulatory frameworks increasingly recognise that control of a connected product may confer not only control of an interface, but also a cumulative informational advantage that rivals struggle to replicate.

The comparison remains imperfect given the specific regulatory, confidentiality and clinical constraints surrounding health data. It nevertheless raises a broader question for future life-sciences ecosystem cases: whether access remedies focused on interoperability alone will always address the full competitive constraint where data, evidence and learning accumulate through use<sup>12</sup>.



### 3. Competition Through Timing

#### Patent and Regulatory-Cycle Strategies

Patent-related competition cases rarely concern permanent exclusion. Their economic significance more often lies in timing. A delay of months can preserve substantial revenue where prices fall sharply after generic or biosimilar entry. Competition law has therefore focused on circumstances in which intellectual property rights, regulatory procedures or settlements are said to influence when competition arrives.

AstraZeneca remains the doctrinal anchor. The Court of Justice upheld findings that misleading representations to patent offices in order to obtain supplementary protection certificates and the selective deregistration of marketing authorisations, which impeded generic reliance on the abridged procedure and affected parallel imports, could constitute abuses of dominance.

The judgment did not turn formally lawful regulatory steps into abuses as a category. It addressed a fact-specific use of public procedures that the Court regarded as outside competition on the merits<sup>13</sup>.

Teva is the clearest recent extension of that concern into divisional patent strategy. The Commission found that Teva staggered divisional applications, sought interim relief and withdrew challenged patents before reasoned validity decisions could issue. Combined with the disparagement conduct, the Commission characterised the practices as pursuing the same objective of delaying rival glatiramer acetate entry. The decision remains subject to judicial review and should not yet be treated as a settled general rule governing divisional filings<sup>14</sup>.

The Article 101 line addresses a different route to delay. In its June 2024 Servier judgments, the Court of Justice revisited patent settlements between an originator and potential generic entrants. The assessment turns on

whether the generic is a potential competitor and whether a transfer of value, viewed in context, can only plausibly be explained by the generic's commitment not to compete or challenge. The Court also held that the combination of the Krka settlement and licence arrangements could constitute market sharing by object. The judgments require analysis of the arrangement as a whole rather than a mechanical rule that every payment or licence is unlawful<sup>15</sup>.

The pending Italian Byooviz investigation tests the perimeter of that reasoning. The AGCM is investigating an alleged coordination among eight undertakings to delay the Italian entry of the ranibizumab biosimilar Byooviz. Its opening decision examines a 2022 agreement and the sequencing of launch rights, the possibility that an earlier US launch formed part of the commercial balance for delayed European entry. No infringement has been established, and the parties' commercial arrangements may be characterized differently in the course of the investigation<sup>16</sup>.

These cases now have a partial regulatory counterpart in the incoming EU pharmaceutical framework. The Council and Parliament reached a provisional political agreement in December 2025. Final compromise texts were published and endorsed at committee level in March 2026, but, as at 5 October 2026, the package remained subject to formal adoption and publication in the Official Journal. The expected model is entry into force in 2026 followed by a two-year application and transposition period<sup>17</sup>.

The agreed text would significantly widen the Bolar safe harbour. In addition to studies and activities needed to obtain a marketing authorisation, it would cover health technology assessment, pricing and reimbursement procedures and, subject to limits, the submission of procurement tenders.



The objective is to allow generics and biosimilars to complete a broader range of preparatory steps before patent or SPC expiry without authorising commercial launch during the protected period. Questions remain around third-party activities, territorial scope and the boundary between a protected tender submission and an infringing commercial offer<sup>18</sup>.

The framework would also decouple specified regulatory and market-access decisions from the patent or SPC status of the reference product. That is best described as a prohibition of regulatory patent linkage, not a general displacement of patent rights. Patent holders would retain the ability to enforce valid rights before competent courts. Regulatory, pricing, reimbursement and related authorities would not, however, treat an unresolved patent dispute as an independent ground for withholding the relevant administrative decision.

Whether this is a life-sciences equivalent of the Digital Markets Act is open to debate. The legal models are plainly different as the pharmaceutical package does not designate gatekeepers or create dominance-based conduct obligations. The comparison is nevertheless useful at the level of regulatory method. In both settings, the legislature supplements case-specific ex post enforcement with more prescriptive rules intended to address recurring access concerns.

The shift should not be overstated. The package does not codify the Article 101 or 102 tests developed in AstraZeneca, Servier or Teva. Nor would compliance with pharmaceutical regulation immunize a wider exclusionary strategy. Rather, the reform narrows certain procedural channels through which entry may be delayed while leaving patent courts and competition authorities to perform their distinct functions. It may reduce one category of dispute, yet relocate part of the conflict to the scope of the new safe harbour.

## 4. Competition Through Market Structure

### Below-Threshold Acquisitions and Structural Review

The first three developments concern the protection of existing market positions. Below-threshold acquisitions raise a different question: the acquisition of future market power before it fully materializes.

Life sciences sit at the centre of that debate because research pipelines and future capabilities may be strategically important long before they generate turnover.

Illumina/Grail became the emblematic case. Grail, which was developing blood-based cancer-detection tests, had no EU turnover and the transaction met neither EU nor relevant national notification thresholds. The Commission nevertheless accepted an Article 22 referral initiated by France, prohibited the transaction and imposed a gun-jumping fine after closing. In September 2024, the Court of Justice annulled the jurisdictional decisions. It held that Article 22 does not permit the Commission to accept a referral from a national authority that is itself not competent to review the transaction under national law<sup>19</sup>.

That judgment removed the central element of the Commission's 2021 below-threshold referral policy, but it did not eliminate all ex post risk.

What is filling the gap is more fragmented. *Towercast*-based ex post review remains available, allowing a national authority to examine a completed, non-notifiable transaction as a potential abuse of dominance, but only against an already-dominant acquirer, a profile that fits an established pharma or medtech incumbent far better than the kind of pre-revenue biotech target Article 22 was stretched to capture<sup>20</sup>. *Towercast* is therefore not a substitute merger-control filing route. It is an Article 102 backstop that can apply only where the acquirer is dominant and the acquisition itself forms part of an abuse.

National authorities have also explored a broader route under Article 101 TFEU, although *Towercast* itself concerned Article 102 only. In France, Decision 24-D-05 examined completed, non-notifiable business transfers in the rendering sector under Article 101 and the national equivalent. The Autorité accepted that acquisitions could, in principle, be assessed through that framework, but ultimately found no anticompetitive object and insufficient evidence for an effects analysis. In Belgium, the competition authority opened an Article 101 investigation into Dossche Mills' proposed acquisition of Ceres' artisanal flour activities before closing the investigation in July 2025. These matters do not establish that Article 101 has become a general substitute for merger control. They do show that some authorities consider both Articles 101 and 102 to be potentially relevant backstops. The boundaries of the Article 101 route remain unsettled<sup>21</sup>.

*Towercast* has already produced its first national-level application, and France offers a useful illustration of what dealmakers elsewhere in the EU should expect the mechanism to look like in practice. On 6 November 2025, the French Autorité de la concurrence fined Doctolib €4.665 million for abuse of dominance in the online medical appointment booking and teleconsultation markets, based in part on its 2018 acquisition of MonDocteur, then its principal competitor<sup>22</sup>.

Internal documents referred to MonDocteur as "competitor #1" and expressed an intention to eliminate it outright. The Autorité treated the acquisition itself as part of the abuse, while capping the penalty for that specific element at a symbolic €50,000 in recognition of the legal uncertainty that predated *Towercast*.

Doctolib is not a pharmaceutical or medical-device manufacturer. Its relevance is methodological. The decision shows what retrospective scrutiny may look like in a health-related market i.e: a transaction closed below thresholds, examined years later against dominance, intent, market development and foreclosure. For established pharma and medtech acquirers, the implication is not that every small acquisition requires a quasi-notification. It is that a contemporaneous record of rationale, efficiencies and the target's competitive significance may retain value long after closing.

A further lesson from Doctolib concerns evidence. Internal documents describing an acquisition as a means of eliminating a competitor featured prominently in the Autorité's analysis. In sectors subject to this level of scrutiny, transaction teams should assume that contemporaneous deal documents may one day be read alongside the economic evidence itself.

Foreign investment screening adds a separate layer. Its legal purpose is national security and protection of strategic interests, not the preservation of competition. Yet in life sciences it frequently captures the same transactions that attract merger-policy concern. France's authorisation of BC Partners' acquisition of Biogaran was accompanied by commitments to maintain headquarters and operations in France, safeguard employment, preserve the subcontracting model and ensure industrial, logistical and commercial continuity, with Bpifrance taking a significant minority position and board seat<sup>23</sup>.

The result is not that FDI screening has replaced merger control as the relevant checkpoint, but that the two now run in parallel, on entirely different legal bases, making life considerably harder for dealmakers. A single pan-European health-sector acquisition can face EU or national merger exposure, a residual Towercast risk, and multiple, uncoordinated FDI filings across several member states at once, each on its own timeline and criteria.



## 5. Liability exposure

### Follow-on Litigation as a Strategic Risk

Public enforcement is only part of the exposure. In life sciences, like in all other sectors, follow-on claims can outstrip the administrative fine and extend the consequences of conduct far beyond the underlying investigation. The Paris Court of Appeal ordered €150.7 million in damages over Sanofi's conduct that had drawn a €40.6 million fine more than a decade earlier<sup>24</sup>.

Recovery is not automatic. Even once liability is established, a claimant still has to prove causation and quantum separately.

The Netherlands offers a cautionary example, though on a different legal basis. A district court initially ordered AstraZeneca to compensate health insurer Menzis. The claim was not a competition-law follow-on action. It concerned AstraZeneca's enforcement of a patent that was later invalidated and rested on unjust enrichment, not competition law. The Court of Appeal of The Hague overturned that ruling in 2021. It held that AstraZeneca had acted lawfully and had not been unjustly enriched<sup>25</sup>. Sanofi and Menzis rest on different legal bases since one is a competition-law follow-on claim, the other a patent-enforcement tort claim. But both illustrate the same point. A favourable first-instance or authority-level outcome does not guarantee that damages will actually be recovered.

Who can actually bring such a claim? The question is not self-evident. It helps to separate claimants into three categories, rather than assuming patients belong among them by default.

**National health insurers and social security funds** are the most straightforward claimants. Under a reimbursement-based system, they bear the marginal cost of a delayed generic or disparaged biosimilar directly. That is precisely why CNAM's claim did not need to establish an individualised chain of causation running through millions of patients. The loss sits, already

aggregated and readily quantifiable, on the payer's own accounts. The Dutch Menzis litigation discussed above illustrates the same aggregation logic, even though it ultimately failed on a different legal basis.

**Competitors** form a second, more conventional category. This includes the generic, biosimilar or rival originator manufacturer whose product was denigrated or foreclosed. They plead lost sales and market share directly. This is the claimant type EU competition damages litigation was originally built around.

**Patients** and consumers are the harder case, and worth engaging with rather than assuming away. In tiers-payant systems, the patient typically bears no direct pecuniary loss from a delayed or disparaged cheaper alternative, since the insurer absorbs the overcost. That leaves individual standing on considerably thinner ground: a co-payment differential in systems with patient cost-sharing, or a non-pecuniary claim framed around impaired therapeutic choice. Neither has yet been tested in a health-sector follow-on matter.

The EU Representative Actions Directive gives qualified entities a procedural vehicle to bring such claims collectively<sup>26</sup>. But the vehicle's existence does not resolve what loss a patient claimant would actually be pleading, particularly where the payer with the cleaner claim has typically already litigated the same conduct, or remains free to do so.

On the evidence to date, the more likely pattern is different. Patient and consumer bodies are more likely to act as a secondary, pressure-oriented claimant category than as the primary route to recovery.

Limitation rules are moving in a claimant-favourable direction across the EU. The Cour de cassation, the Italian Corte di Cassazione<sup>27</sup> and the CJEU's

*Heureka* ruling both anchor the limitation period to the point a decision becomes final. They do not anchor it to a claimant's earlier, partial awareness of the facts <sup>28 29</sup>.

That extends realistic evidentiary exposure well past a decade from the underlying conduct. It has direct consequences for evidence management: retention of commercial and medical-affairs materials, and, hardest to preserve, the availability of field personnel whose testimony proved central to establishing liability in the founding cases.

A further procedural distinction, already visible across several of the matters discussed in this article, concerns the route by which public enforcement concludes. Recent life-sciences investigations have increasingly proceeded through Article 9 commitments rather than contested infringement decisions<sup>30</sup> <sup>31</sup>. Under this mechanism, a company offers commitments and the authority accepts them without finding that competition law has been infringed. The distinction matters for private enforcement. A final infringement decision can materially simplify a claimant's task. A commitments decision may provide useful factual indications and reshape commercial behaviour, but it does not establish liability. Procedural outcomes therefore influence not only the duration of exposure, but also the practical likelihood that a public investigation will generate follow-on damages actions in the first place.

Procedural vehicles are converging faster than the underlying case law. None has yet produced a mature body of health-sector precedent comparable to the founding French follow-on judgment.

In the UK, an opt-out collective proceedings regime now allows for claims to be brought on behalf of an entire class of consumers or businesses that may have suffered loss. This regime is in addition to the ability for potential claimants (such as the NHS) to bring individual claims for any alleged loss<sup>32</sup>.

The Netherlands offers the most developed infrastructure on paper. It has an opt-out collective-action regime. In practice, however, non-consumer claims more often use an assignment model instead: large numbers of individual claims are bundled and sold to a single claim vehicle, which then litigates them as one action<sup>33</sup>.

Germany, Italy and Spain show rising public enforcement intensity: dawn raids, opened investigations, excessive-pricing decisions<sup>34</sup>. None has yet produced a comparable body of follow-on damages precedent, even though cases are sharply increasing expectably in Italy. The litigation is more likely to follow the underlying enforcement activity than to lead it.

The one constant across jurisdictions is procedural rather than substantive. While national approaches to life-sciences competition law continue to evolve case by case, claimant-side procedural mechanisms are expanding in a more consistent direction. As a result, the matters most likely to generate significant private enforcement may not be those involving the most novel theories of harm, but those arising in procedural environments that make litigation easier, cheaper and more scalable.

# Conclusion

---

European and UK life-sciences competition enforcement is often presented as a collection of specialised doctrines: disparagement, ecosystem foreclosure, pay-for-delay, below-threshold review and follow-on damages.

Taken separately, each raises a distinct legal question.

Taken together, they reveal a broader shift.

Authorities are increasingly examining how competition is shaped before price effects materialise. Scientific communications can influence therapeutic choice. Diagnostic and technological gateways can determine whether a rival reaches patients. Patent, regulatory and settlement strategies can affect the timing of entry. Acquisitions can remove future capabilities before they generate revenue. Competition law is moving progressively upstream.

A final tension sits largely outside antitrust, yet increasingly shapes the environment in which competition policy operates. Many developments discussed in this article seek earlier entry, stronger price pressure and wider access to medicines. At the same time, policymakers are focused on the incentives that influence investment, launch and supply decisions.

The US most-favoured-nation pricing initiative illustrates that tension. In 2026, Amgen withdrew Repatha from supply under the Danish hospital tender. Reporting distinguished Amgen's public explanation, based on significant market changes and commercially unsustainable tender conditions, from market participants' attribution of the decision to the potential interaction between the Danish price and US reference pricing.

Repatha should not be treated as proof that lower European prices necessarily reduce innovation or that MFN policy will trigger widespread withdrawals. It is nevertheless a concrete illustration of cross-border pricing spillovers. A price negotiated in one market may affect revenue expectations and availability in another. That raises a question competition law cannot answer alone: how health systems can maximise competitive access while preserving incentives to develop, launch and continue supplying innovative treatments.

Ultimately, the most important question may no longer be where competition law ends and industrial policy begins, but how both can operate together. European and UK authorities are increasingly intervening at the point where competition is created rather than only where its effects are observed. For life-sciences businesses, competition law is therefore becoming part of a wider strategic framework encompassing intellectual property, market access, investment, launch sequencing and continuity of supply.

# Report authors



## Omblin Ancelin

Partner, Paris

**T:** +331 5329 1642

**E:** Omblin.Ancelin@simmons-simmon.com

**Recognized as Leading Partner,**  
Band 1 in HLS by [Legal 500 EMEA, 2026](#)



## Sarah Smith

Partner, London

**T:** +44 20 7825 4205

**E:** Sarah.Smith@simmons-simmon.com



## Riccardo Pennisi

Counsel, Milan

**T:** +3902 7250 5563

**E:** Riccardo.Pennisi@simmons-simmon.com

## How we can help

Simmons & Simmons' Antitrust and Competition practice has a longstanding, cross-jurisdictional pharmaceutical and medical devices sector focus, covering both enforcement defence and follow-on claims across France, Belgium, the Netherlands, Germany, Italy, Spain, the UK and Ireland.

Our team advises on the full spectrum of issues addressed in this article (disparagement and unfair-conduct investigations, patent-cycle and pay-for-delay strategy, medical devices and ecosystem-foreclosure theories, merger control and FDI screening for health-sector transactions, and the defence and pursuit of follow-on damages claims), for clients on both the claimant and defendant side.

If any of the developments discussed above raise questions for your business, our team would be glad to discuss them.

**Top 100 Global firm**  
consistently ranked by  
**Global Competition Review**

The team is praised for being "incredibly responsive and strategic" and having "strong attention to detail."

**Chambers and Partners**

# Footnotes

1 Autorité de la concurrence, Decision 13-D-11 (Sanofi-Aventis, 14 May 2013, EUR40.6m); Decision 13-D-21 (Schering-Plough, 18 December 2013, EUR15.3m); Decision 17-D-25 (Janssen-Cilag, 20 December 2017, EUR25m, reduced to EUR21m by the Paris Court of Appeal on 11 July 2019 and upheld by the Cour de cassation on 1 June 2022); CNAM v Sanofi, Paris Court of Appeal, 24 September 2025, [No. 19/19969](#) (EUR150,748,005).

2 Court of Justice, 23 January 2018, F. Hoffmann-La Roche and Others v AGCM, C-179/16, ECLI:EU:C:2018:25. The Court held that coordinated dissemination of misleading safety information concerning off-label use, aimed at reducing competitive pressure, may constitute a restriction by object.

3 Autorité de la concurrence, Decision 20-D-11, 9 September 2020; Paris Court of Appeal, Pôle 5, Chamber 7, 16 February 2023, RG No 20/14632; Cour de cassation, Commercial Chamber, 25 June 2025, No 23-13.391, partial quashing and remittal.

4 European Commission, Case AT.40577 - Vifor (IV iron products), commitments decision, 22 July 2024; UK CMA, Case 51377, commitments accepted 23 May 2025, including a GBP23 million ex-gratia payment by Vifor to the NHS.

5 European Commission, Case AT.40998, investigation opened June 2026 (Sanofi/CSL Seqirus); commitments offered 8 July 2026, market test ongoing.

6 European Commission, Case AT.40588 – Teva (Copaxone), Decision of 31 October 2024 (published 8 April 2025), €462.6m fine.

7 EMA/HMA, Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU, EMA/627319/2022, first issued 19 September 2022 (endorsed by CHMP 22 July 2022), updated 21 April 2023.

8 AGCM, Case A580, *Farmaci Sclerosi Multipla/Sandoz*, Decision to open investigation of 27 May 2026 against Biogen Italia S.r.l. and Biogen Inc.

9 European Commission, Case AT.40900, Align Invisalign, decision initiating proceedings and press release IP/26/1483, 30 June 2026: [https://ec.europa.eu/competition/antitrust/cases1/202627/AT\\_40900\\_1056.pdf](https://ec.europa.eu/competition/antitrust/cases1/202627/AT_40900_1056.pdf).

10 AGCM, Case A517, Mercati di manutenzione di dispositivi diagnostici, Decision No 28620 of 30 March 2021: [https://agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/41256297003874BD/0/B13F234DB1AF848FC12586DF00528DF4/\\$File/p28620.pdf](https://agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/41256297003874BD/0/B13F234DB1AF848FC12586DF00528DF4/$File/p28620.pdf) . The investigation, opened by Decision No 27007 of 31 January 2018, closed without a finding of infringement.

11 European Commission, Case AT.40755, Edwards Lifesciences, press release IP/26/412, 16 February 2026: [https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip\\_26\\_412/IP\\_26\\_412\\_EN.pdf](https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_26_412/IP_26_412_EN.pdf) .

12 European Commission, press release IP/23/2248, 17 April 2023, updating the Motor Vehicle Block Exemption Regulation Supplementary Guidelines; Commission Communication, Guidance on vehicle data accompanying Regulation (EU) 2023/2854 (Data Act), C/2025/5026, OJ C, 15 September 2025. The Commission cautions that the vehicle-data guidance is sector-specific.

13 European Commission, press release IP/23/2248, 17 April 2023, updating the Motor Vehicle Block Exemption Regulation Supplementary Guidelines; Commission Communication, Guidance on vehicle data accompanying Regulation (EU) 2023/2854 (Data Act), C/2025/5026, OJ C, 15 September 2025. The Commission cautions that the vehicle-data guidance is sector-specific.

14 Court of Justice, 6 December 2012, AstraZeneca v Commission, C-457/10 P

15 European Commission, Case AT.40588, Teva Copaxone, decision of 31 October 2024, C(2024) 7448 final; OJ summary C/2025/1680

16 AGCM, Case I868, opening decision of 21 May 2024 and press release of 6 June 2024, alleged coordination regarding ranibizumab / Byooviz: <https://en.agcm.it/dotcmsdoc/pressrelease/I868%20avvio%20EN.pdf> and <https://en.agcm.it/en/media/press-releases/2024/6/I868> .

17 Council of the European Union, 'The pharma package: new EU rules on medicines', recording political agreement on 11 December 2025: <https://www.consilium.europa.eu/en/policies/pharma-pack/>; Status on 10 September 2026.

18 Proposed Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, procedure 2023/0132(COD), final compromise text following the provisional political agreement of 11 December 2025, Article 85 and recitals 63–65, as published in March 2026

19 Court of Justice (Grand Chamber), 3 September 2024, Illumina and Grail v Commission, Joined Cases C-611/22 P and C-625/22 P

20 Case C-449/21, Towercast, Judgment of 16 March 2023.

21 Autorité de la concurrence, Decision 24-D-05 of 2 May 2024, practices in the rendering sector, non-lieu; Belgian Competition Authority, Dossche Mills/Ceres artisanal bakery activities, investigation opened under Article 101 TFEU on 22 January 2025 and closing decision published on 29 July 2025.

22 Autorité de la concurrence, Decision 25-D-06, 6 November 2025 (Doctolib), €4.665m total fine (€50,000 specifically for the predatory acquisition of MonDocteur under the Towercast framework).

23 French Ministry of Economy, FDI clearance decisions re Biogaran/BC Partners (January 2026) and Opella/CD&R (2025).

24 Autorité de la concurrence, Decision 13-D-11 (Sanofi-Aventis, 14 May 2013, EUR40.6m); Decision 13-D-21 (Schering-Plough, 18 December 2013, EUR15.3m); Decision 17-D-25 (Janssen-Cilag, 20 December 2017, EUR25m, reduced to EUR21m by the Paris Court of Appeal on 11 July 2019 and upheld by the Cour de cassation on 1 June 2022); CNAM v Sanofi, Paris Court of Appeal, 24 September 2025, No. 19/19969 (EUR150,748,005).

25 Rechtbank Den Haag, 14 October 2020 (Menzis v AstraZeneca); Gerechtshof Den Haag, 28 December 2021 (appeal judgment overturning the first-instance ruling).

26 Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers.

27 Corte di Cassazione civile, 28 February 2024, No. 5232.

28 Cour de cassation, Chambre commerciale, 30 August 2023, No. 22-14.094

29 Case C-605/21, Heureka Group v Google, Judgment of 18 April 2024.

30 European Commission, Case AT.40577 - Vifor (IV iron products), commitments decision, 22 July 2024; UK CMA, Case 51377, commitments accepted 23 May 2025, including a GBP23 million ex-gratia payment by Vifor to the NHS.

31 European Commission, Case AT.40998, investigation opened June 2026 (Sanofi/CSL Seqirus); commitments offered 8 July 2026, market test ongoing.

32 For example cases 1746/5/7/25 (T) 1747/5/7/25 (T) 1748/5/7/25 (T), the claims brought by the NHS relating to the EU Commission Decision in *Perindopril*.

33 Dutch Act on Redress of Mass Damages in Collective Action (WAMCA).

34 AGCM and CNMC excessive pricing decisions re Leadiant, 2022(AGCM: Case A524 / CNMC: Case S/0028/20); CNMC dawn raids, November 2023.

35 US Executive Order 14297, 12 May 2025; US HHS/CMS MFN targets, 20 May 2025; Euractiv, "US cholesterol drug withdrawn in Denmark, MFN pricing policy blamed", 6 March 2026.



[simmons-simmons.com](https://simmons-simmons.com)

© Simmons & Simmons LLP and its licensors. All rights asserted and reserved. This document is for general guidance only. It does not contain definitive advice. Simmons & Simmons LLP is a limited liability partnership registered in England & Wales with number OC352713 and with its registered office at CityPoint, One Ropemaker Street, London EC2Y 9SS, United Kingdom. It is authorised and regulated by the Solicitors Regulation Authority and its SRA ID number is 533587. The word “partner” refers to a member of Simmons & Simmons LLP or one of its affiliates, or an employee or consultant with equivalent standing and qualifications. A list of members and other partners together with their professional qualifications is available for inspection at the above address.