

## Key Takeaways

# Assessing Innovation in Life Sciences: Towards a Robust Economic Framework

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Earlier this year, Skadden hosted a discussion on the role of innovation in European competition law and merger control investigations in the life sciences industry.

**Ingrid Vandendorre**, co-head of Skadden's European antitrust practice, was joined by **Ulla Schwager**,<sup>1</sup> head of unit for Antitrust: Pharma and Health Services at the European Commission's (EC) Directorate-General for Competition; **Moritz Suppliet**, economic analyst at the EC's Directorate-General for Health and Food Safety; **Jo Seldeslachts**, professor at KU Leuven and senior research fellow at DIW Berlin; **Gosia Majewska**, assistant professor at ESSEC Business School; and **Bogdan Chiritoiu**, president of the Romanian Competition Council.

The 19 May 2025 event was moderated by **Adina Claiici**, managing director at the consulting firm BRG and visiting professor at the College of Europe, and co-organized by BRG and *Global Competition Review*.

## The Life Sciences Sector: A Continued Competition Enforcement Priority in Europe

In her keynote speech, Ms. Schwager noted that according to the September 2024 *Draghi Report*, the European Union is falling behind in some innovation markets, such as biologicals and orphan drugs. Despite the existing scientific progress, unmet medical needs remain. She emphasized the need to foster innovation and find the right balance between fair pricing and companies' incentives to innovate.

Ms. Schwager pointed out that there are several initiatives and proposals in the pipeline to reform the pharmaceutical framework in the EU, such as the Biotech Act, and a host of policy measures and strategies to start up and scale up production, as well as funding measures for companies to bring innovative products to the market.

Turning to case practice, Ms. Schwager commented that innovation considerations are present in many recent behavioural cases in the life sciences industry. Examples include the:

- Recently adopted *Vifor* commitment decision — on disparagement practices.
- Ongoing *Zoetis* investigation — on alleged anticompetitive product discontinuation.
- Series of "pay-for-delay" investigations.

Similarly, in the area of merger control, both *Illumina/GRAIL* and *Novo Holdings/Novo Nordisk/Catalent* showcase the European Commission's (EC's) focus on innovation considerations, according to Ms. Schwager.

This focus is reflected in the EC's approach to market definition and the framework provided by the EC's 2024 Market Definition Notice. For pipeline products, the EC may conclude these products belong to an existing relevant product market or form

<sup>1</sup> Ms. Schwager spoke in her personal capacity, and the views she expressed do not necessarily reflect the positions of the European Commission.

## Key Takeaways

# Assessing Innovation in Life Sciences: Towards a Robust Economic Framework

a new product market. Ms. Schwager referred to *Novartis/GlaxoSmithKline Oncology Business* (M.7275) and *AbbVie/Allergan* (M.9461) as examples of where the impact of a concentration was extended to competition in pipeline products. In addition, the EC may look at early stages of research, which may serve multiple purposes and, in the longer term, feed into various products. The EC calls these “innovation spaces.”

The EC’s focus on innovation is also reflected in the substantive merger assessment. Ms. Schwager mentioned *Dow/DuPont* (M.7932) as a case in point.

The four-stage assessment of innovation theories of harm in horizontal merger cases is:

1. **First stage:** Assessment of actual competition between the parties’ existing marketed products.
2. **Second stage:** Assessment of potential competition between one party’s existing marketed and pipeline products at advanced stages of development, and the other party’s pipeline products at advanced stages of development.
3. **Third stage:** Assessment of innovation competition in relation to the parties’ earlier stage pipeline products, *i.e.*, the potential discontinuation, delay or redirection of the overlapping pipeline projects.
4. **Fourth stage:** Assessment of innovation competition in relation to the capability to innovate in certain innovation spaces, *i.e.*, any structural reduction in the overall level of innovation.

Ms. Schwager noted that the EC’s assessment is focused on:

- The closeness of competition among the merging parties’ pipeline drugs, but also with competing drugs (therapeutic indication, mode of action, mode of delivery, line of treatment).
- How promising the merging companies’ pipeline drugs are.
- The overall number of competing marketed and pipeline drugs in the market.

To assess innovation effects, the EC relies on historic market data, scientific data on the relevant diseases (such as clinical guidelines), feedback from both market participants (such as medical experts and key opinion leaders) and competitors, as well as information provided directly from the merging companies, including internal documents.

Ms. Schwager noted the following cases as examples of EC intervention:

- *Novartis/GlaxoSmithKline Oncology Business* (M.7275 – 2015): therapies to block cell proliferation
- *J&J/Actelion* (M.8401 – 2017): insomnia medication

- *Takeda/Shire* (M.8955 – 2020): inflammatory bowel diseases
- *AbbVie/Allergan* (M.9461 – 2020): inflammatory bowel diseases

Ms. Schwager also noted the *J&J/TachoSil* case (M.9547 – 2020) on hemostatic patches, which was withdrawn in Phase II.

As far as EC cases on innovation competition are concerned, Ms. Schwager noted that cases *Dow/DuPont* (M.7932) and *Bayer/Monsanto* (M.8084) are still the key precedents.

In terms of evidence relied upon in these two cases, Ms. Schwager referred to:

- The industry context (*e.g.*, consolidation trend).
- The launches of new active ingredients.
- Patent applications and citations.
- The research and development (R&D) expenditures of merging parties and competitors.
- Integration plans and internal documents.

Ms. Schwager also commented on the EC’s recent case practice in vertical mergers, where the focus is on input foreclosure impacting innovation efforts downstream. Ms. Schwager mentioned *Novo Holdings/Novo Nordisk/Catalent* (M.11486 – 2024), in which the EC investigated the risk of input foreclosure both for actual and potential competitors.

She noted that in that case, the EC had undertaken a comprehensive market reconstruction and was able to clear the transaction unconditionally, as the investigation showed that:

- There was sufficient spare capacity in the market.
- There were credible alternatives.
- Customers could switch.

Ms. Schwager concluded by stating that the development of innovation theories of harm is largely case-driven and dependent on industry background.

## How Should Innovation Be Measured in Life Sciences?

Ms. Claiçi opened the panel for discussion, noting that in order to assess the success of competition enforcement to incentivize innovation, we should first agree on what exactly we mean by innovation and how to measure it.

Ms. Majewska noted that the aim of pharmaceutical innovation is bringing to market products that solve unmet needs. The road to these products is long and uncertain. The key question to ask is how life sciences companies decide to proceed from one stage of development to the next.

## Key Takeaways

# Assessing Innovation in Life Sciences: Towards a Robust Economic Framework

Mr. Seldeslachts added that the pharmaceutical industry is particularly suitable for the exploration of this question, as much of the underlying data is public, allowing policymakers and experts to assess at what stage of development a project is — starting from the pre-clinical stage and continuing onto the clinical trials to product launch.

Mr. Suppliet noted that innovation can be thought of as a process and outcome. Both can be measured:

- Process can be measured in terms of the time of each development phase, and it can be compared against R&D expenditure and number of trials, labs, among other metrics.
- Output can also be quantified in terms of, for instance, number of patents, new products on the market and new market authorizations. In some scenarios, like for innovative medicines, it is even possible to measure and compare innovation in terms of quality — *e.g.*, the quality of innovative medicines can be measured in terms of effectiveness and efficacy, as well as against other medicines/treatments. Some of the comparative evaluations can happen in the context of regulatory approval processes.

Mr. Chiritoiu framed innovation as a “defence.” For a national competition authority (NCA), innovation concerns are less central. This is because the bigger mergers go to the EC for review and because the purview of NCAs are national markets.

Companies’ innovation decisions are normally not made for the national markets. As a result, innovation restrictions are not linked to national markets, either. The merging companies may rely on innovation defences, but in practice these defences are seldomly decisive. A major uphill battle for companies relying on an innovation defence is that it requires an authority to accept short-term losses for potential future gains.

### How Should Innovation Be Incentivised?

Ms. Majewska noted that there is well-developed literature showing that the projected market size is very important for a company’s choice regarding development. She distinguished between “pull incentives” (future rewards) and “push incentives” (support for development costs).

While pull incentives reward success, in some contexts, they tend to benefit large companies that are able to spread risk across multiple projects. Push incentives are much more important for smaller companies. Incentives will need to be adjusted based on the product field and company.

Mr. Suppliet remarked that the role of the policymaker can be seen as using incentives to introduce solutions to address market failures. For example, some basic research projects are too distant from any market, so there is no way of monetising them. While

basic research can be essential for follow-up research and practical applications, for-profit companies may not want to invest in them. In such a case, policymakers and regulators can, for example, use push incentives to encourage and complement private investments. The state aid framework for research, development and innovation (RDI framework) tends to reflect this notion.

Mr. Suppliet further noted that pull incentives can be found in the proposed reform of the EU pharmaceutical legislation, with a tradeable exclusivity voucher for innovative antimicrobials and a range of suggestions to modify and modulate regulatory protection periods for innovative medicines.

Ms. Claiici asked about the impact of “counter pull incentives,” *i.e.*, the presence of an existing competing product in a company’s portfolio, and how that may influence the company’s R&D decisions. Ms. Majewska was less concerned about these incentives, noting that if a company started working on a project, it must have some potential beyond the existing product. Additionally, should that company choose not to develop a new version of an existing product, there is always the risk that a competing company may develop a similar product.

### Determining Market Definition in Innovation Markets

Ms. Majewska and Mr. Suppliet commented on the difficulty of determining market definition for innovation in life sciences. Ms. Majewska noted that very similar molecules can do very different things. It helps to classify products into their technology classes.

Mr. Suppliet suggested that it may make sense to look at the demand and supply side to understand the market functioning of innovation. On the supply side, it can be helpful to shed light on the technological closeness, on the similarity of innovation. At the same time, on the demand side, maybe supported through a Health Technology Assessment, effectiveness, efficacy and clinical outcomes can be compared across competing treatments with different technologies. As a simple example, generics and originators tend to feature an identical technology and are considered perfect substitutes while biosimilars and originators feature not necessarily identical technologies but can be considered perfect substitutes.

The features of the life sciences sector pose interesting questions about traditional market definition in innovations where one multipurpose technology, such as mRNA, can address areas as different as vaccines, oncology and respiratory diseases.

### How Should Closeness in Technology Markets Be Measured?

Mr. Seldeslachts presented his work on the impact of M&As (R&D projects) of small targets in the antidiabetics industry.

## Key Takeaways

# Assessing Innovation in Life Sciences: Towards a Robust Economic Framework

He summarized the main points as follows.

- The study focuses on M&As of small companies in the anti-infectives market (Malek, Seldeslachts & Veugelers, 2025).
- Each individual project is mapped into two distinct spaces:
  - **Product market:** defined by Mechanism of Action (MoA).
  - **Technology market:** defined by associated patent content.
- Important distinction: Product and technology markets are not the same.
- Projects are linked to specific patents, which contain rich technological information.
- Technological closeness is measured via keyword overlap in patent texts.
- Traditional firm-level indicators (*e.g.*, patent classes) are too coarse for project-level analysis.

Mr. Seldeslachts noted that technological closeness is a promising indicator for assessing competition. However, it may not always signal substitutability; it can also reflect complementarities that generate synergies between acquirer and target. Unlike in product markets, our conceptual understanding of competition in technology markets remains less developed. In our study, we find that projects that are technologically close tend to perform better following an acquisition. This pattern points toward complementarities and integration benefits, rather than substitution and project termination.

### What Should the Role of Competition Policy Be for the Life Sciences Sector?

Mr. Seldeslachts noted that the theoretical relationship between competition and innovation remains unresolved, with contrasting perspectives from Arrow and Schumpeter. This underscores

the need for empirical evidence. While there are various ways to measure competition, M&A activity can serve as a useful proxy for changes in competitive dynamics. Our study finds that, in general, M&As involving small targets tend to result in weaker innovation outcomes. However, when the acquiring firm is already an incumbent in both the technology and product markets, and when the acquirer and target projects are closely aligned in both dimensions, the acquisitions are associated with stronger innovation performance.

Ms. Majewska commented that it is important to have a lot of activity and that the number of R&D projects is correlated to the number of companies active in R&D.

Mr. Suppliet remarked that it can be difficult for firms and public policy to give a clear and straightforward answer to the question of which market form allows for the social optimum of R&D investments. The role for public policy could be to support a competitive business environment supportive of innovation, for example, by allowing for the appropriation of investments in R&D with a functioning intellectual property system or by addressing market failures. Competitive markets, enforced through competition policy, can help to encourage innovation and to distribute their benefits to consumers.

Mr. Chirițoiu noted that as entry strategies for new pharmaceutical products are not country-specific, NCAs may want to focus their efforts on practices that delay generic entry. More generally, he noted that if you move away from products with the same molecule, competition law intervention becomes less self-evident. Competition policy should be focused on the needs of patients. This could mean being mindful that small innovative biotechs may need to partner with larger companies.



From left to right: Bogdan Chirițoiu, Adina Claiici, Moritz Suppliet, Jo Seldeslachts, Gosia Majewska



From left to right: Bogdan Chirițoiu, Adina Claiici, Moritz Suppliet