STRATEGIC ALLIANCES IN THE PHARMA SECTOR: AN EU COMPETITION LAW PERSPECTIVE

BY CHRISTIAN RITZ & BENEDIKT WEISS[1]

1 Christian Ritz, LL.M. (USYD), Partner, Antitrust & Competition/ Compliance & Investigations; Benedikt Weiss, LL.M. (Aberdeen), Senior Associate, Antitrust & Competition (both Hogan Lovells International LLP Munich/ Berlin).

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Strategic alliances in the pharma sector present distinct challenges under EU competition law. While often pro-competitive, these collaborations require a careful assessment under Article 101 TFEU, especially where they involve coordination between actual or potential competitors. This article focuses on purely contractual alliances and outlines the key antitrust considerations for such partnerships. It discusses the relevance and limitations of safe harbors under the Horizontal Guidelines, the R&D Block Exemption Regulation (R&D-BER), and the Technology Transfer Block Exemption Regulation (TT-BER). It also addresses typical antitrust considerations in the context of strategic alliances, such as information exchange, exclusivity provisions and the need for antitrust compliant governance. Where appropriate, the article also contrasts the EU's stricter approach to competitor collaborations – particularly on information sharing – with the more permissive U.S. "rule of reason" standard. Finally, it provides practical recommendations to ensure that strategic alliances remain compliant with EU competition law while promoting innovation and patient access.

I. INTRODUCTION

Strategic alliances have become an increasingly popular form of collaboration in the pharma industry.[2] Typically, but not exclusively, these alliances are formed between smaller biotechnology companies and larger pharma companies and are characterized by close collaboration throughout the entire product lifecycle, from clinical development to market access and commercialization. By pooling complementary resources and expertise, such collaborations aim to accelerate innovation, reduce costs and optimize go-to-market strategies. The collaborations that facilitated the rapid development and commercialization of COVID-19 vaccines are a perfect example of this model in practice.[3] More recent examples are collaborations between biotech/pharma and AI-focused companies, as well as cooperation related to mRNA technologies.

Strategic alliances vary in structure, ranging from purely contractual collaborations to equity-based joint ventures. They are often global in nature and involve a high degree of cross-border collaboration. While strategic alliances can bring significant pro-competitive benefits, such as increased innovation and improved patient access, they are subject to strict antitrust requirements and require appropriate antitrust safeguards.

Given the importance of the EU market – particularly for the commercialization of alliance products – compliance with EU competition law is non-negotiable. This article therefore focuses on the EU competition law perspective on strategic alliances. Due to a visible trend in favor of purely contractual alliances, it is limited to these, while equity-based partnerships, such as joint ventures, are outside the scope of this article.

II. THE EU COMPETITION LAW FRAMEWORK FOR STRATEGIC ALLIANCES

EU competition law does not provide a dedicated framework for the assessment of strategic alliances. Instead, general competition law rules apply. Whether and to what extent a strategic alliance fulfils the requirements of EU competition law therefore depends largely on the nature of the cooperation, its setup, and the existence of appropriate antitrust safeguards for its execution. In certain cases, additional regulatory approvals may be required. The following is an overview of the main competition law requirements for strategic alliances:

A. Regulatory Approvals

The first question for any strategic alliance is whether it requires regulatory approval. This is more commonly an issue in equity-based alliances (e.g. joint ventures), as they may fall within the scope of the EU regulatory clearance triad, EU merger control regimes, foreign direct investment ("FDI") rules, and the EU's Foreign Subsidies Regulation (FSR).[4]

- **Merger Control:** The EU Merger Regulation[5] and the national merger control regimes of the EU Member States provide for a formal review and clearance process by competition authorities for alliances that constitute a concentration within the meaning of the applicable merger control regimes provided that certain notification thresholds are met. These regimes aim to prevent the creation of monopolies or the strengthening of dominant positions that may impede effective competition.[6]

- **Foreign Direct Investment ("FDI"):** FDI is a separate review and approval regime that differs from Member State to Member State. Although the EU does not operate a centralized FDI screening regime, the FDI Regulation[7] establishes a framework for cooperation between the Commission and Member States to screen investments that may affect security or public order.[8]

- **Foreign Subsidies Regulation ("FSR"):** The FSR is a third regime that empowers the Commission to investigate subsidies granted by third countries that distort competition in the internal market. It applies ex ante to mergers, public procurement, and also includes

2 See https://www.bcg.com/publications/2022/innovation-power-of-alliances or https://www.contractpharma.com/exclusives/the-evolution-of-strategic-partnerships-in-the-pharma-industry/ (both last accessed on 17 April 2025).

3 See e.g. European Commission Communication on the EU Strategy for COVID-19 vaccines, COM(2020) 245 final, 17 June 2020; see also Druedahl, Minssen & Price, in: "Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships."

4 See Regulation (EU) 2022/2560 of the European Parliament and of the Council of 14 December 2022 on foreign subsidies distorting the internal market ("FSR").

5 Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings ("EU Merger Regulation").

6 See Article 2(3) of the EU Merger Regulation.

7 Regulation (EU) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union ("FDI Regulation").

8 See Article 1(1) of the FDI Regulation.

an ex officio tool for other market situations. Notably, the FSR covers foreign financial contributions made up to five years prior to 12 July 2023.[9]

Although filing obligations under the above regimes are rare for purely contractual alliances, exceptions exist.

- For example, even purely contractual alliances may require merger control clearance in certain jurisdictions (e.g. Brazil). While there are currently no similar rules in the EU or its Member States, certain exclusive licensing agreements may result in a notifiable concentration if these licenses constitute a business with a market turnover and the transfer of such licenses will transfer the turnover-generating activity (provided that the merger control turnover thresholds are met).[10]

- FDI and FSR should always be considered when the cooperation involves sensitive technologies (e.g. biotechnology) or significant financial contributions (e.g. government funding of clinical trials). Notably, the FSR also explicitly recognizes an ex officio review of foreign subsidies, which can be initiated independently of a concentration, for example on the basis of a complaint by a competitor.[11] The practical consequences of such a review can be significant, as it allows the EU Commission to investigate non-EU financial contributions received by alliance partners up to five years prior to 12 July 2023.[12]

In practice, the applicability of these regimes can have significant impact on project timelines. It should be clear early in the project planning whether filings are required, as under most regimes the collaboration cannot begin until regulatory clearance has been obtained (so-called "standstill obligations"). This is particularly important as failure to comply can result in "gun-jumping" violations with significant fines.

B. General Competition Law Framework

As there is no dedicated antitrust assessment framework for strategic alliances, general competition law rules apply. Article 101 TFEU plays a key role as it prohibits agreements that are restrictive of competition unless they qualify for an exemption. While strategic alliances that foster innovation and enable or accelerate access to medicines may be pro-competitive or sometimes even indispensable[13], they may still involve restrictions of competition in research and development or commercialization that require closer scrutiny.

- One specific concern in the context of strategic alliances is often the potential restriction of competing innovation efforts, such as the discontinuation of overlapping (late stage) clinical trials. This was also highlighted just recently in the European Commission's 2024 ex-post evaluation of acquisitions in the pharma sector, which raised concerns about innovation competition being dampened by horizontal collaboration.[14]

- As strategic alliances require a large amount of coordination at many levels, a typical additional risk is exchange of competitively sensitive information. EU competition law is particularly stringent on the exchange of competitively sensitive information even within an otherwise pro-competitive collaboration.[15] Notably, this diverges from US antitrust law, which applies a more permissive "rule of reason" approach to pro-competitive alliances, especially also when it comes to exchange of competitively sensitive information.

C. Responsibility for Antitrust Compliance

On a practical note, it is the sole responsibility of the alliance partners to ensure compliance with global antitrust laws, including EU competition law. They are expected to carry out a self-assessment under Article 101 TFEU that confirms that the cooperation is in line with EU competition law.[16]

9 See Article 1(1) FSR.

10 See para. 24 of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.

11 See Article 9(1) FSR.

12 See Article 53(1) FSR.

13 This market access consideration is reflected in paras. 33 and 138 of the Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (2023/C 259/01) – ("Horizontal Guidelines").

14 See p. 14 of the Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector leading to the discontinuation of overlapping drug research and development projects available at https://op.europa.eu/en/publication-detail/-/publication/6eacab93-b129-11ef-acb1-01aa75ed71a1/language-en (last accessed on 17 April 2025).

15 See e.g. para. 369 of the Horizontal Guidelines.

16 See paras. 1 and 2 of the Horizontal Guidelines.

To assist with such self-assessment, the EU Commission has issued guidelines that provide useful guidance. These guidelines[17] are complemented by regulations such as the R&D Block Exemption Regulation ("R&D-BER")[18] or the Technology Transfer Block Exemption Regulation ("TT-BER")[19], which set out the conditions under which certain types of cooperation are permitted.

- The R&D BER provides a safe harbor for joint research and development activities, subject to market share thresholds and other conditions (e.g. access to joint R&D results, no hardcore restrictions, etc.).[20]

- Similarly, the TT-BER provides a safe harbor inter alia to technology licensing agreements provided they stay within defined market share thresholds and other conditions (e.g. no hardcore restrictions, etc.) are met.[21]

The practical challenge is that strategic alliances often do not fit neatly into these "pre-defined buckets" of collaboration that EU competition law considers to be in line with antitrust requirements.[22] A self-assessment tailored to the specific characteristics of the individual strategic alliance is therefore essential.[23] In the next section, we take a closer look at the typical antitrust considerations for the antitrust assessments of strategic alliances.

III. KEY ANTITRUST CONSIDERATIONS FOR STRATEGIC ALLIANCES

There are a number of antitrust considerations surrounding strategic alliances that need to be carefully managed. The following is intended to provide a non-exhaustive overview of these considerations:

- **Competitor collaboration:** A foundational question is whether the alliance partners are actual or potential competitors. This shapes the applicability of safe harbors (e.g. market share thresholds)[24] and affects the intensity of compliance efforts (e.g. safeguards for information exchange)[25]. In practice, this often involves a comprehensive analysis of potential competitive overlaps in the product portfolios or pipelines of the alliance partners, which can be particularly challenging for early-stage or multi-indication assets where future success and competitive dynamics are uncertain. Notably, market delineations required for this exercise may not always correspond to the view of the business teams.

- **IP and know-how strategies:** In purely contractual alliances, the alliance partners work together while maintaining their independence. They have a commercial interest in preventing their alliance partner from using or having access to their proprietary know-how or IP. Counter-intuitively, depending on the nature of the alliance (e.g. in a joint R&D collaboration), EU competition law may require that the alliance partner be granted effective access to the joint R&D results (foreground) and, in some cases, even to background know-how.[26] For this reason, antitrust considerations should not be disregarded when it comes to the design of IP and know-how arrangements or more generally the definition of IP strategies in strategic alliances.

- **Exclusivity arrangements:** Alliance partners may have a commercial interest in preventing each other from engaging in competing activities during the alliance or even beyond. However, territorial exclusivities, field-of-use restrictions or non-competes may conflict with EU competition law. Knowing the limits is absolutely essential to ensure an antitrust-compliant collaboration. For example, restric-

17 E.g. Horizontal Guidelines or Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements ("TT-Guidelines").

18 Commission Regulation (EU) 2023/1066 of 1 June 2023 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements ("R&D BER").

19 Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements ("TT-BER").

20 See para. 73 of the Horizontal Guidelines and Articles 1 et seqq. of the R&D BER.

21 See para. 40 of the TT-Guidelines and Articles 1 et seqq. of the TT-BER.

22 As a more general point, this is also acknowledged in para. 4 of the Horizontal Guidelines.

23 Para. 4 of the Horizontal Guidelines.

24 See e.g. para. 87 of the EU Horizontal Guidelines.

25 See paras. 368, 370 and 406 et seqq. of the Horizontal Guidelines.

26 See Articles 3 and 4 of the R&D BER.

tions on competing R&D activities may be permitted during the term of a joint R&D effort but not beyond that.[27] Similarly, restricting active sales in certain territories may be permissible under certain conditions, whereas restricting the alliance partner in making sales to customers (e.g. hospitals) who have not been actively targeted ("passive sales") may pose antitrust risks.[28] It is thus crucial to reconcile the typical commercial interests surrounding exclusivity arrangements with applicable antitrust requirements.

- **Market access and commercialization:** Coordination on market access and commercialization strategies, such as dossier preparation, reimbursement negotiations or pricing, is essential to maximize commercial potential in a strategic alliance. At the same time, this is an area where the antitrust risk exposure is particularly high. Under EU competition law, the permissible extent of such coordination depends largely on the nature of the strategic alliance and its governance structure (particularly with respect to joint decision-making).[29] Appropriate safeguards (e.g. guidelines, firewalls, clean teams, etc.) should be put in place to ensure that information is exchanged in line with competition law. Although market access may be a distant prospect at the outset of an alliance, its antitrust requirements should be considered as early as possible to ensure compliance with competition law throughout all phases of the collaboration.

- **Monitoring relevant changes:** Strategic alliances in the pharma sector can last many years, from early clinical development to actual marketing of the products. During this period, market conditions and dynamics may change significantly. Monitoring changes relevant from an antitrust perspective is crucial. For example, a collaboration that started as a non-competitor collaboration may become a competitor collaboration over time.[30] In addition, some safe harbors under EU competition law are time-limited, requiring a reassessment after a certain period.[31] Changes to the alliance, such as to commercialization plans, distribution structures (e.g. co-marketing instead of co-promotion), or the addition of new assets, may have antitrust implications that warrant a reassessment.[32] It is therefore important to closely monitor such changes and to be aware of their antitrust implications.

IV. PRACTICAL RECOMMENDATIONS FOR STRATEGIC ALLIANCES

To minimize antitrust risks, it is essential to adopt comprehensive antitrust compliance measures for both setup and execution of a strategic alliance. We summarize key considerations in this respect below:

- **Alliance Setup:**
    - Conduct early-stage antitrust self-assessments to understand the antitrust risk exposure and to ensure antitrust compliance from the outset.
    - Clearly define governance and decision-making structures to correctly set the scope of permissible coordination.
    - Ensure that contractual terms in the cooperation agreements align with the safe harbors provided by EU competition law.
- **Alliance Execution:**
    - Establish clear protocols for handling competitively sensitive information and implement necessary safeguards such as clean teams or firewalls.

27 See e.g. Article 8(a)(ii) R&D BER.

28 See e.g. Article 8(d) and (e) R&D BER or Article 4(c) TT-BER.

29 See e.g. Article 8(c) R&D BER.

30 See e.g. Article 6(4) R&D BER.

31 See e.g. Article 6(2) and (3) R&D BER.

32 See e.g. Article 4(3) TT-BER.

- Regularly train employees on competition law compliance, emphasizing the EU's strict stance on information sharing.

- Periodically review the alliance frameworks to adapt to relevant changes or evolving regulatory and business dynamics.

V. CONCLUSION

Strategic alliances between pharma companies – especially those involving joint R&D and subsequent commercialization – can bring significant pro-competitive benefits, but also raise complex challenges from an antitrust compliance perspective.

In the global context, EU competition law plays an important role, as the EU is a key market for innovative medicines. Particular attention must be paid to the EU's strict approach to information sharing. If the collaboration involves competitors, appropriate safeguards must be put in place.

Overall, early involvement of legal teams, careful structuring, and ongoing antitrust compliance guidance are key to ensure the lasting success of these cross-border partnerships.

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