Coimisiún um Iomaíocht agus Cosaint Tomhaltóirí | Competition and Consumer Protection Commission

DETERMINATION OF MERGER NOTIFICATION M/25/008 – GOLDMAN SACHS / SYNTHON

Section 21 of the Competition Act 2002

Proposed acquisition by Skio Bidco B.V. of sole control of Stamina TopCo B.V.

Dated: 13 March 2025

Introduction

1. On 31 January 2025, in accordance with section 18(1)(a) of the Competition Act 2002, as amended (the "Act"), the Competition and Consumer Protection Commission (the "Commission") received a notification of a proposed acquisition whereby Skio Bidco B.V. ("Bidco") would acquire sole control of Stamina TopCo B.V. ("Stamina TopCo" (the "Target")), being the ultimate holding company of Synthon B.V. ("Synthon") (the "Proposed Transaction").[1]

The Proposed Transaction

2. The Proposed Transaction is to be implemented by way of a share purchase agreement (the "SPA") dated 15 December 2024 between the Sellers[2] and Bidco. Bidco is indirectly wholly owned by Skio Topco B.V. ("Skio Topco") and according to the Parties prior to completion of the Proposed Transaction, Skio Topco will be owned by certain investment funds managed by Goldman Sachs & Co LLC[3] ("GS & Co"), certain entities that are indirectly wholly owned by The Goldman Sachs Group Inc ("GS Group Inc") and a Luxembourg special purpose vehicle[4] which is itself indirectly wholly owned by (i) the funds managed by GS & Co and (ii) the entities owned by GS Group Inc. Therefore, following implementation of the Proposed Transaction, Stamina Topco, and indirectly Synthon, will be owned and controlled by investment funds and entities managed by Goldman Sachs.[5]

[1] Bidco, Stamina TopCo and the Goldman Sachs Group Inc. are referred to collectively in this determination as the "Parties".
[2] Stamina Investment S.À R.L., Nijmegen Investment S.À R.L., Quint Essence B.V., Stamina Manco I B.V., Stamina Manco II B.V. and Stichting Administratiekantoor Stamina II.
[3] According to the merger notification form, the investment funds are managed by Goldman Sachs & Co LLC and/or its affiliates.
[4] Skio Aggregator S.à.r.l. ("Skio Aggregator").
[5] GS Group Inc and its affiliates are referred to as "Goldman Sachs" throughout this determination.

The Undertakings Involved

The Acquirer – Skio Bidco B.V. (Goldman Sachs)

3. Bidco[6], an acquisition vehicle formed for the purpose of the Proposed Transaction, is [redacted], which in turn is indirectly owned by funds managed by GS & Co[8] ("GS & Co Managed Funds") and/or its affiliates and entities that are indirectly 100 % owned by GS Group Inc[9] ("GS Balance Sheet Entities"). According to the Parties, prior to completion of the Proposed Transaction it is proposed that GS & Co Managed Funds and GS Balance Sheet Entities will [redacted].[10]

4. GS & Co is wholly owned by GS Group Inc.[11] Goldman Sachs is a global investment banking, securities and investment management firm that provides a range of banking, securities and investment services worldwide to a substantial and diversified client base that includes corporations, financial institutions, governments and high-net-worth individuals.

5. Table 1 below provides a list of Goldman Sachs's portfolio companies that are currently active in the State.

Table 1: Goldman Sachs portfolio companies active in the State

Company	Sector
[redacted]	[redacted]

[6] [redacted].
[8] Goldman Sachs & Co. LLC is a New York, United States, incorporated entity.
[9] The Goldman Sachs Group, Inc. is a Delaware, United States, incorporated entity.
[10] Merger notification form, p. 4.
[11] GS Group Inc and its affiliates are referred to as "Goldman Sachs" throughout this determination.
[12] [redacted].

Source: The Parties

6. Table 2 below provides a list of Goldman Sachs's portfolio companies that are currently active in the pharmaceutical sector in the State.

Table 2: Goldman Sachs portfolio companies active in the pharmaceutical sector in the State

Company	Pharmaceutical Sector
[redacted] [Portfolio Company 1]	Specialty pharmaceuticals
[redacted] [Portfolio Company 2]	Contract Research Organisation ("CRO") and biopharmaceutical services
[redacted] [Portfolio Company 3]	CRO services; pharmaceutical and biotechnology
[redacted] [Portfolio Company 4]	Software company that provides clinical trial support

Source: The Parties

7. The Parties provided the following description of the business activities of [Portfolio Company 1][13]: "[[Portfolio Company 1]] *develops, manufactures, and markets pharmaceutical goods mainly for the following therapeutic areas:* [redacted] ... *[Portfolio Company 1] is active in originator drugs only and manufactures and sells* [finished dose pharmaceuticals ("FDPs")]. *It does not have generic drugs in its portfolio, nor does it license generic drugs for manufacture or resale. [Portfolio Company 1] markets its drugs in the EEA, including in the State.*"[14]

8. The Parties provided the following description of the business activities of [Portfolio Company 2]: "[[Portfolio Company 2]] *is a global contract research organisation ("CRO") and biopharmaceutical services company. The company provides a comprehensive suite of services to pharmaceutical companies from portfolio optimization and regulatory strategy, to Phase I-IV clinical trials, and market access planning.*"[15]

9. The Parties provided the following description of the business activities of [Portfolio Company 3]: "[[Portfolio Company 3]] *is a global CRO services company that provides (i) contract research and development services; (ii)* [redacted] *and (iii) custom manufacturing solutions of new chemical entities and manufacturing of active pharmaceutical ingredients and intermediaries. ... The company has a presence in the EEA (in the Netherlands), but not in Ireland.*"[16]

10. The Parties provided the following description of the business activities of [Portfolio Company 4][Portfolio Company 4]: "[[Portfolio Company 4]] *is a ... specialist software company that provides clinical trial support. [Portfolio Company 4]* [redacted][17] The Parties also state that [Portfolio Company 4] generated turnover in the State of less than EUR [redacted] in 2023.[18]

[13] [Portfolio Company 1] is incorporated in the Netherlands.
[14] Merger notification form, p. 14.
[15] Merger notification form, p. 15.
[16] Merger notification form, p. 15.
[17] Merger notification form, p. 15.
[18] Merger notification form, p. 15.

11. For the financial year ending 31 December 2021,[19] Goldman Sachs's total worldwide turnover was approximately [redacted], of which approximately [redacted] was generated in the State.[20]

The Target – Stamina TopCo (Synthon)

12. Stamina TopCo[21] is the ultimate holding company of Synthon[22], a dossier[23] developer focused on the development, contract manufacturing, packaging and out-licensing of complex generic finished dose pharmaceuticals ("FDPs").[24]

13. The Parties state in the notification that "*Synthon manufactures in-house at least [redacted]% of the Active Pharmaceutical Ingredients ("APIs", also referred to as "molecules") used in its FDPs and procures the rest from third party API manufacturers.*"[25] Synthon is not active in new drug or API discovery; it develops new formulations of existing APIs originally patented by "originators"[26].[27]

14. Synthon's product portfolio is centred around complex small-molecule generics[28] and hybrids[29] in the following therapeutic areas: allergy, anti-infective, cardiovascular, central nervous system, musculoskeletal systems, oncology and urology.

15. Synthon is active in the following business areas:

- **Drug Formulation Development**: Synthon develops generic formulations of existing APIs through an in-house research and development ("R&D") function. Synthon monitors originator pharmaceuticals for loss of exclusivity due to the

[19] The Parties informed the Commission that this is the most recent financial year for which a detailed breakdown of Goldman Sachs's revenues is available.
[20] Merger notification form, p. 12.
[21] Stamina TopCo B.V. is a Netherlands incorporated entity.
[22] Synthon B.V. is incorporated in the Netherlands.
[23] A dossier is an organized and comprehensive compilation of documents that are required in order to obtain market approval for a pharmaceutical product. Source: DDReg Pharma see: https://www.ddregpharma.com/what-is-a-dossier-submission.
[24] Merger notification form, p. 6. The Parties state the following in the merger notification form at p. 16: *"Synthon also prepares the so-called marketing authorisation dossiers which comprise the package of documents including all required information on the newly developed generics that is required by regulatory authorities in the EU and elsewhere for granting marketing authorisation approvals."*
[25] Merger notification form, p. 16.
[26] Originators are active in research, development, manufacturing, marketing, and the supply of innovative medicines. They typically compete 'for the market' by trying to be the first to discover, patent and bring to the market a new medicine, but originator drugs of different active ingredients may also compete against each other 'in the market' on price, quality and choice, source: Report from the Commission to the Council and the European Parliament, Update on competition enforcement in the Pharmaceutical Sector (2018-2022), p.13.
[27] Merger notification form, p. 16.
[28] Small-molecule generics are chemically synthesised generic medicines, source: Report from the Commission to the Council and the European Parliament, Update on competition enforcement in the Pharmaceutical Sector (2018-2022), pp.13-14.
[29] Hybrid medicines are generics where the medicinal product does not fall within the definition of a generic medicinal product (e.g. because it has a different strength, a different route of administration or a slightly different therapeutic indication compared to the reference medicine), source: Report from the Commission to the Council and the European Parliament, Update on competition enforcement in the Pharmaceutical Sector (2018-2022), p.13.

expiry of intellectual property protection and develops generic alternatives of those drugs that it considers to be commercially attractive.

- **Intellectual Property & Regulation**: Synthon obtains patent protection and marketing authorisations for its generic formulations. Synthon also prepares the marketing authorisation dossiers required by regulatory authorities in the European Union and elsewhere for granting marketing authorisation approvals.

- **Manufacturing**: Synthon manufactures FDPs and, as noted above, at least [redacted]% of the APIs used in its FDPs. Synthon also outsources some of its production to third-party contract manufacturing organisations.

- **Licensing**: Synthon licenses its intellectual property and marketing authorisation dossiers to customers that use its services and buy its products.

- **Marketing & Sales:** Synthon supplies generic drugs to pharmaceutical companies through long-term, non-exclusive supply agreements. The supply agreements are tied to the licensing of the relevant intellectual property and marketing authorisation dossiers from Synthon.[30]

16. Synthon has no physical presence in the State. However, it supplies its FDPs to pharmaceutical companies that manufacture generic pharmaceutical products in the State for resale. In addition, Synthon generates licensing revenue from generic pharmaceutical companies located in the State.

17. For the financial year ending 31 December 2023, the total worldwide turnover of Stamina TopCo (i.e. the ultimate holding company of Synthon) was approximately [redacted], of which approximately [redacted] was generated in the State.[31]

Rationale for the Proposed Transaction

18. In the merger notification form, the Parties state the following:

> *"The GS & Co Managed Funds are diversified investment funds aimed at providing their limited partners with favourable risk-adjusted returns from the*

[30] Merger notification form, pp. 16-17.
[31] Merger notification form, p. 14.

asset classes in which such funds invest. Private Equity at Goldman Sachs Alternatives[32] believes that Synthon represents an attractive investment opportunity. The Proposed Transaction is a purely financial investment. No industrial synergies are anticipated from the concentration as a result of the investment in Synthon."[33]

Contact with the undertakings involved

19. During its review of the Proposed Transaction, the Commission requested and received further information and clarifications from the Parties.

Third-Party Submissions

20. No third-party submissions were received.

Competitive Analysis

Horizontal overlap

21. There is no horizontal overlap between the Parties in the State.

Vertical relationships

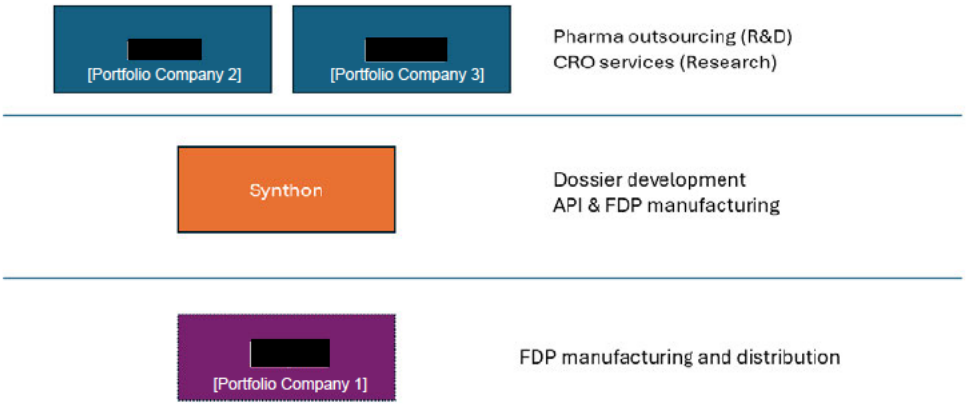
22. There is no existing vertical relationship between the Parties in the State. There are, however, four portfolio companies owned and controlled by Goldman Sachs which either operate upstream or downstream from Synthon in the State. Therefore, there are potential vertical relationships between the Parties in the State, which are described and analysed below.

23. The four Goldman Sachs portfolio companies referred to in the preceding paragraph are [Portfolio Company 1], [Portfolio Company 2], [Portfolio Company 3] and [Portfolio Company 4]. The Parties state the following in the merger notification form in relation to [Portfolio Company 4]: "*In light of this de minimis turnover* [less than EUR [redacted] in the State in 2023], *a SLC cannot arise in relation to any potential vertical overlap with [Portfolio Company 4], regardless of how the relevant markets are defined.*" Given [Portfolio Company 4]'s minimal turnover in the State

[32] The alternative investments platform is part of Goldman Sachs Asset Management, which delivers investment and advisory services across public and private markets for the world's leading institutions, financial advisors and individuals. See Merger notification form, p.6.
[33] Merger notification form, p. 10.

in 2023, the Commission does not consider it necessary to assess in detail the potential vertical relationship between Synthon and [Portfolio Company 4] in the State.

24. The figure below illustrates the potential vertical relationships between the Parties in the State:



Source: The Commission based on information provided by the Parties

Potential Vertical Relationship 1: Downstream – [Portfolio Company 1]

25. There is a potential vertical relationship in the State between the upstream dossier development and API and FDP manufacturing activities of Synthon and the downstream FDP manufacturing and distribution activities of [Portfolio Company 1] ("Potential Vertical Relationship 1").

26. As noted above at paragraph 7, the Parties provided the following description of the business activities of [Portfolio Company 1]: "*[[Portfolio Company 1]] develops, manufactures, and markets pharmaceutical goods mainly for the following therapeutic areas:* [redacted]. *[Portfolio Company 1] is active in originator drugs only and manufactures and sells FDPs. It does not have generic drugs in its portfolio, nor does it license generic drugs for manufacture or resale*." The potential vertical relationship arises from the fact that [Portfolio Company 1] could source APIs (i.e., molecules), which are an input into the manufacture of FDPs, from Synthon following completion of the Proposed Transaction.

Potential Vertical Relationship 2: Upstream – [Portfolio Company 2], [Portfolio Company 3]

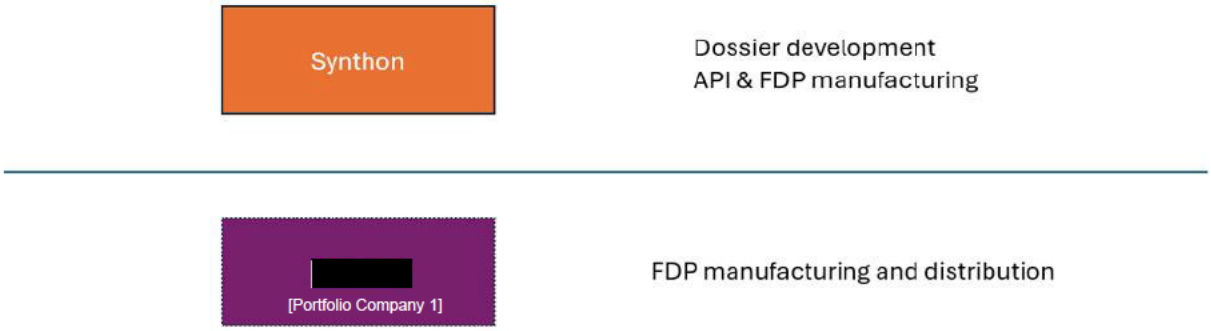
27. There is a potential vertical relationship in the State between the downstream dossier development, and API and FDP manufacturing activities of Synthon and the upstream pharmaceutical outsourcing services (in particular, CRO services) of [Portfolio Company 2] and [Portfolio Company 3] ("Potential Vertical Relationship 2"). The potential vertical relationship arises from the fact that Synthon could source CRO services, which are used in the development of FDPs, from [Portfolio Company 2] and [Portfolio Company 3] following completion of the Proposed Transaction.

Relevant Markets

Relevant Product Markets

Potential Vertical Relationship 1

28. The figure below illustrates potential vertical relationship 1 between the Parties in the State:



Source: The Commission based on information provided by the Parties

Upstream Market

Views of the Parties

29. In the merger notification form, the Parties state that the relevant upstream market for Potential Vertical Relationship 1 is either the market for the provision of Contract Development and

Manufacturing Organisation ("CDMO") services to pharmaceutical companies, or the out-licensing of pharmaceutical dossiers for each individual molecule.[34]

30. The Parties state the following in the merger notification: "*Synthon generates its turnover from the development of pharmaceutical dossiers for generics, which it licenses to other pharmaceutical companies. It then contract manufactures the outlicensed generic drugs for its licensees, which accounts for the bulk of Synthon's turnover. With the exception of a few instances where Synthon only out-licenses its drug and the licensee manufactures the drug inhouse (or procures manufacturing elsewhere), the out-licensing and contract manufacturing activities of Synthon cannot be neatly separated.*"[35]

Previous decisions of the European Commission

31. The European Commission ("EC") has previously considered the market for the supply of CDMO services to pharmaceutical companies for APIs in *M.9315 – Chr. Hansen/Lonza/JV*.[36] The EC noted that it had concluded in previous decisions[37] that the market for the supply of CDMO services to pharmaceutical companies for APIs is distinct from the market for the supply of contract manufacturing for FDPs.[38]

32. In *M.9315 – Chr. Hansen/Lonza/JV*, within the market for the supply of CDMO services at the API level, the EC noted that it previously considered a separate product market for biopharmaceutical CDMO services (as opposed to CDMO services in relation to chemically-synthesised drugs).[39]

33. In the same decision, within the market for the supply of CDMO services at the FDP level, the EC considered a separate market for the supply of contract manufacturing services ("CMO") but ultimately left open the question of whether this market should be further segmented according to: (i) the pharmaceutical form; (ii) the conditions of manufacture; (iii) the type of API used; (iv) the delivery mechanism used; and (v) between the supply of CDO and CMO services.[40]

[34] Merger notification form, p. 24.
[35] Merger notification form, p. 18.
[36] *M.9315 – Chr. Hansen/ Lonza/ JV*, available at: https://ec.europa.eu/competition/mergers/cases/decisions/m9315_365_3.pdf.
[37] See, for example, *M. 8362 – Lonza Group/Capsugel*, available at https://ec.europa.eu/competition/mergers/cases/decisions/m8362_333_3.pdf; and *M.8541 – Thermo Fisher Scientific/Patheon*, available at https://ec.europa.eu/competition/mergers/cases/decisions/m8541_147_3.pdf.
[38] M.9315 – Chr. Hansen / Lonza / JV, paragraph 17.
[39] M.9315 – Chr. Hansen / Lonza / JV, paragraph 18.
[40] M.9315 – Chr. Hansen / Lonza / JV, paragraphs 20-22.

34. In *Chr. Hansen /Lonza / JV*, the EC considered that the exact product market definition for the supply of CDMO services to pharmaceutical companies could be left open since that transaction did not raise serious doubts as to its compatibility with the internal market irrespective of whether the product market was defined as encompassing all CDMO services or was segmented by type of CDMO services.[41]

35. In *M.9517 - Mylan/Upjohn*, the EC noted that out-licensing in the pharmaceutical industry refers to a company (the licensor) licensing to another company (the licensee) the rights to use a dossier to obtain a marketing authorization for a pharmaceutical product in one or more countries and commercialise the licensed product in those countries.[42]

36. In *M.7746 – Teva/Allergan*, the EC noted that out-licensing agreements are generally accompanied by a supply agreement by which the licensor supplies the licensee with an FDP, which is produced either by the licensor or by a third party (the latter case is referred to as "contract manufacturing").[43]

37. In *M.9517 - Mylan/Upjohn*, the EC noted that in previous decisions[44] it considered out-licensing for each individual molecule to potentially constitute a distinct product market which is upstream of the market for the supply of FDPs.[45]

Views of the Commission

38. The Commission defines markets to the extent necessary depending on the particular circumstances of a given case. In this instance, it is not necessary for the Commission to define precise relevant product markets since doing so will not alter the Commission's assessment of the likely competitive impact of the Proposed Transaction. The Commission sees no reason to depart from the EC precedent discussed above.

39. Therefore, the potential upstream markets for Potential Vertical Relationship 1 are: (i) the provision of CDMO services to pharmaceutical companies for FDPs; and (ii) the out-licensing of pharmaceutical dossiers to pharmaceutical companies for each API.

[41] M.9315 – Chr. Hansen / Lonza / JV, paragraph 23.
[42] M.9517 - Mylan/Upjohn, paragraph 602, available at: https://ec.europa.eu/competition/mergers/cases1/202041/m9517_2719_3.pdf.
[43] M.7746 – Teva/Allergan, paragraph 595, available at: https://ec.europa.eu/competition/mergers/cases/decisions/m7746_4632_3.pdf.
[44] See, for example, *M.7746 – Teva/Allergan*, para. 596; *M.7480 – Actavis/Allergan*, para. 75, available at: https://ec.europa.eu/competition/mergers/cases/decisions/m7480_20150316_20310_4195749_EN.pdf; and *M.6613 – Watson/Actavis*, para. 120, available at: https://ec.europa.eu/competition/mergers/cases/decisions/m6613_1147_2.pdf.
[45] M.9517 - Mylan/Upjohn, paragraph 603.

Downstream Market

Views of the Parties

40. In the merger notification, the Parties state that the relevant downstream market for Potential Vertical Relationship 1 can be left open, but that [Portfolio Company 1] is active in the manufacturing and distribution of FDPs.[46]

Previous decisions of the European Commission

41. The EC has held that FDPs may be subdivided into therapeutic classes by reference to the Anatomical Therapeutic Classification ("ATC"), devised by the European Pharmaceutical Marketing Research Association who maintain it with IQVIA.[47]

42. The ATC system is a hierarchical and coded four-level system, which classifies medicinal products according to their indication, therapeutic use, composition, and mode of action. In the first and broadest level (ATC1), medicinal products are divided into the 16 anatomical main groups. The second level (ATC2) is either a pharmacological or a therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications. Finally, the fourth level (ATC4) is generally the most detailed and refers to the mode of action or any other subdivision of the relevant products. When defining relevant markets in past decisions dealing with FDPs, the EC has often referred to the third level (ATC3) as the starting point for defining the relevant product market.[48]

43. In merger decisions involving genericised FDP markets, the EC typically defines the relevant product market at the level of the relevant molecule (API) or group of molecules that are considered interchangeable.[49] This is relevant to the Proposed Transaction as Synthon and [Portfolio Company 1] are both active in FDP markets.

44. In previous merger decisions, the EC has concluded that, at molecule level, the originator (i.e., the first product that was launched on the market for a specific molecule) and generics generally form part of the same market. This is because generics are versions of originator medicines, and

[46] Merger notification form, p. 25.
[47] M.9517 - Mylan/Upjohn, paragraph 13.
[48] M.9517 - Mylan/Upjohn, paragraphs 14-15.
[49] For example, M.9517 - Mylan/Upjohn, paragraphs 16, 20, and 24.

are specifically designed to compete with originator medicines and normally represent their closest substitute.[50]

Views of the Commission

45. The Commission defines markets to the extent necessary depending on the particular circumstances of a given case. In this instance, it is not necessary for the Commission to define precise relevant product markets since doing so will not alter the Commission's assessment of the likely competitive impact of the Proposed Transaction. The Commission sees no reason to depart from the EC precedent discussed above.

46. As mentioned above, the EC has considered out-licensing of pharmaceutical dossiers to be upstream of the market for the supply of FDPs.[51] Synthon is involved in the out-licensing of pharmaceutical dossiers and [Portfolio Company 1] develops, manufactures and markets FDPs.

47. Therefore, the potential downstream market for Potential Vertical Relationship 1 is the supply of FDPs assessed for each API used in production.

Potential Vertical Relationship 2

48. The figure below illustrates Potential Vertical Relationship 2 between the Parties in the State:

Source: The Commission based on information provided by the Parties

Views of the Parties

49. In the merger notification form, the Parties state that the relevant product market for Potential Vertical Relationship 2 is the same as above with regards to Synthon, i.e., either the market for

[50] M.9517 - Mylan/Upjohn, paragraph 17.
[51] M.9517 - Mylan/Upjohn, paragraph 603.

the provision of CDMO services to pharmaceutical companies for FDPs or the out-licensing of pharmaceutical dossiers for each molecule.[52] Regarding [Portfolio Company 2] and [Portfolio Company 3], the Parties state in the merger notification form that the relevant product market is the market for CRO services.[53]

Previous decisions of the European Commission

50. CRO services refer to product development services used by healthcare companies to outsource the clinical development process from first-in-human clinical trials[54] to post-launch monitoring.[55] In *M.8061 – IMS Health/Quintiles*, the EC noted that CRO services range from drug discovery tasks (including organic synthesis, analytical chemistry, biochemistry, molecular modelling, and medicinal chemistry) to clinical research trials.[56]

Views of the Commission

51. [Portfolio Company 2] and [Portfolio Company 3] provide CRO services to pharmaceutical companies. According to EC precedent mentioned above, CRO services refer to the outsourcing of research related to the development of pharmaceutical products such as FDPs. The Commission considers the outsourcing of research related to FDP development to be upstream of the manufacturing of FDPs.

52. Therefore, the upstream market for Potential Vertical Relationship 2 is the provision of CRO services to pharmaceutical companies.

53. The downstream markets for Potential Vertical Relationship 2 are: the provision of CDMO services to pharmaceutical companies for FDPs; and the out-licensing of pharmaceutical dossiers for each API (as discussed above[57] under Potential Vertical Relationship 1).

<u>Commission conclusions on relevant product markets</u>

54. The Commission defines markets to the extent necessary depending on the particular circumstances of a given case. In this instance, it is not necessary for the Commission to define

[52] Merger notification form, p. 19.
[53] Merger notification form, p. 19.
[54] First-in-human trials are a key step in medicines development, where a medicine already tested in vitro, in animals or in other preclinical studies is administered to people for the first time, source: https://www.ema.europa.eu/en/news/revised-guideline-first-human-clinical-trials.
[55] Merger notification form, p. 19, M.8061 – IMS Health/Quintiles, paragraph 39.
[56] M.8061 – IMS Health/Quintiles, paragraph 39.
[57] Paragraph 39.

precise relevant product markets since doing so will not alter the Commission's assessment of the likely competitive impact of the Proposed Transaction. For the purposes of its competitive assessment of the potential vertical relationships, the Commission has assessed the Proposed Transaction by reference to the following potential product markets:

- The provision of CDMO services to pharmaceutical companies for FDPs (upstream market for Potential Vertical Relationship 1, downstream market for Potential Vertical Relationship 2);
- The out-licensing of pharmaceutical dossiers for each individual molecule (API) (upstream market for Potential Vertical Relationship 1, downstream market for Potential Vertical Relationship 2);
- The supply of FDPs assessed for each individual molecule (API) used in production (downstream market for Potential Vertical Relationship 1); and
- The provision of CRO services to pharmaceutical companies (upstream market for Potential Vertical Relationship 2).

Relevant Geographic Markets

Previous decisions of the European Commission

55. The EC has concluded that the geographic market for CDMO services to pharmaceutical companies, and its potential segments, is likely to be global in scope and, in any event, at least EEA-wide.[58]

56. The EC has considered the upstream out-licensing market(s) to be at least EEA-wide.[59] The EC has consistently defined the geographic markets for FDPs as being national in scope.[60] The EC has identified an EEA-wide market for CRO services.[61]

57. In this instance, it is not necessary for the Commission to define precise relevant geographic markets since doing so will not alter the Commission's assessment of the likely competitive

[58] M.9315 – Chr. Hansen / Lonza / JV, paragraph 26.
[59] M.9517 - Mylan/Upjohn, paragraphs 606 and 608.
[60] M.9517 - Mylan/Upjohn, paragraphs 25 and 28.
[61] M.8061 – IMS Health/Quintiles, paragraph 43.

impact of the Proposed Transaction. The Commission sees no reason to depart from previous decisions of the European Commission. For the purposes of its competitive assessment of the potential vertical relationships, the Commission has assessed the competitive impact of the Proposed Transaction on an EEA-wide basis for: the provision of CDMO services to pharmaceutical companies for FDPs; the out-licensing of pharmaceutical dossiers for each individual molecule (API); and the provision of CRO services to pharmaceutical companies. For the supply of FDPs assessed for each individual molecule (API) used in production, the Commission has assessed the competitive impact of the Proposed Transaction on a national basis.

Conclusion on Relevant Markets

58. The Commission has assessed the likely competitive impact of the Proposed Transaction by reference to the following potential markets:

- The provision of CDMO services to pharmaceutical companies for FDPs in the EEA;
- The out-licensing of pharmaceutical dossiers for each individual molecule (API) in the EEA;
- The supply of FDPs assessed for each individual molecule (API) used in production in the State; and,
- The provision of CRO services to pharmaceutical companies in the EEA.

Competitive Assessment

Horizontal Effects

59. As noted above, there is no horizontal overlap between the Parties in the State.

Non-Horizontal Effects

Potential Vertical Relationship 1

60. As noted above, there is a potential vertical relationship in the State between the upstream dossier development and API and FDP manufacturing activities of Synthon and the downstream FDP manufacturing and distribution activities of [Portfolio Company 1].

61. As noted above, the potential upstream markets for Potential Vertical Relationship 1 are (i) the provision of CDMO services to pharmaceutical companies; and (ii) the out-licensing of pharmaceutical dossiers to pharmaceutical companies. The potential downstream market is the supply of FDPs assessed for each API used in production.

Input foreclosure

The provision of CDMO services to pharmaceutical companies

62. The Parties state the following in the merger notification form: "*As a CDMO, Synthon is one of many medium-sized service providers that is competing with much larger providers. There is therefore no ability for the merged entity to engage in input foreclosure following the Proposed Transaction".*[62]

63. Synthon's estimated market share for the provision of CDMO services to pharmaceutical companies is less than 5% in the world, in the EEA and in the State.[63]

64. The Parties also expressed the view to the Commission that *"Synthon's business is in the development, sale and outlicensing of generic drugs that are no longer patented (i.e., the original patent protection on the drug/molecule combination has expired) such that any drug manufacturer can develop, manufacture and outlicence the drug/molecule (with no competitive constraints to do so) further reducing any conceivable foreclosure concern".*[64]

65. The Parties state that "*FDP manufacturers tend to be international, well-resourced and sophisticated pharmaceutical businesses (with associated buyer power) that can and do source supply inputs from a number of providers."*[65]

The out-licensing of pharmaceutical dossiers for each individual molecule (API)

[62] Merger notification document, p. 29.
[63] The Parties estimated market shares based on IQVIA data, see: Confidential Annex 14.
[64] Email correspondence with the Parties.
[65] Ibid.

66. There is no overlap, by molecule, between the generic FDPs in the product portfolio of Synthon (including Synthon's pipeline products) and the FDPs in [Portfolio Company 1]'s product portfolio (including [Portfolio Company 1]'s pipeline products).

67. Table 3 below lists the Synthon products with shares above 20% in the EEA and/or above 15% in the State for out-licensing of pharmaceutical dossiers for each individual molecule (API).

Table 3: Synthon products with shares above 20% in the EEA and/or above 15% in the State in out-licensing of pharmaceutical dossiers for each individual molecule (API)

Product	World	EEA	The State
ABIRATERONE ACETATE	[5-10]%	[25-30]%	[20-25]%
ANAGRELIDE	[15-20]%	[35-40]%	[0-5]%
ANASTROZOLE	[5-10]%	[20-25]%	[0-5]%
BENDAMUSTINE	[5-10]%	[20-25]%	[0-5]%
BICALUTAMIDE	[5-10]%	[15-20]%	[0-5]%
BORTEZOMIB	[5-10]%	[25-30]%	[0-5]%
CELECOXIB	[0-5]%	[10-15]%	[20-25]%
CLOFARABINE	[5-10]%	[55-60]%	[0-5]%
DASATINIB	[5-10]%	[35-40]%	[0-5]%
EVEROLIMUS	[5-10]%	[25-30]%	[0-5]%
FLUVOXAMINE	[0-5]%	[40-45]%	[0-5]%
GLATIRAMER ACETATE	[10-15]%	[15-20]%	[20-25]%
LEVOCETIRIZINE	[0-5]%	[10-15]%	[15-20]%
SEVELAMER	[15-20]%	[55-60]%	[20-25]%
TAMSULOSIN	[15-20]%	[35-40]%	[60-65]%
ZOPICLONE	[5-10]%	[10-15]%	[75-80]%

Source: The Parties, based on IQVIA data in 2023

68. In relation to the shares presented in Table 3 above, the Parties expressed the view to the Commission that *"although Synthon's market shares may be large for certain molecules, there are typically a multitude of competing molecules that can be used in the same therapeutic area i.e., to treat the same condition or illness. This means that Synthon's actual market position is significantly diminished in Ireland and elsewhere in the EEA (and Synthon cannot be said to be one of only a small number of providers of a drug that is needed to treat a particular condition or illness)".*[66]

[66] Email correspondence with the Parties.

69. Synthon's market shares do not exceed 20% in the EEA when looking at the ATC3 level of classification of the molecules, the highest being [10-15]% in the EEA ([redacted]).[67]

70. Table 4 below provides a list of alternative suppliers that FDP manufacturers could switch to in the event of Synthon deciding to no longer supply them with a molecule (abiraterone acetate, sevelamer, tamsulosin or zopiclone) following completion of the Proposed Transaction. The molecules abiraterone acetate, sevelamer, tamsulosin and zopiclone were chosen because they have large market shares in either the EEA or in the State. The molecules abiraterone acetate, sevelamer and tamsulosin were chosen because their market shares exceed 20% in both the EEA and in the State. Zopiclone was chosen because its market share exceeds 75% in the State and 10% in the EEA.

Table 4: list of suppliers or CDMOs to whom downstream FDP manufacturers could switch in the event of Synthon deciding to no longer supply them with a molecule (abiraterone acetate, sevelamer, tamsulosin, zopiclone)

ABIRATERONE ACETATE	SEVELAMER	TAMSULOSIN	ZOPICLONE
Johnson and Johnson (Originator)	Sanofi (Originator)	Astellas (originator)	Viatris
Pharos	Drehm Pharma	Zentiva	Sanofi
Zentiva	Zentiva	Sun Pharmaceuticals	Aurobindo
Teva		Sandoz	Chanelle
KRKA		Siegfried	Teva
MEDAC		Gedeon Richter	Stada
Bluepharma		Aurobindo	Zentiva
Chemo		Bluepharma	
Aristo Pharma		Teva	
Haupt Pharma		Famar	
Pluspharma		Adamed	
		Sanofi	
		Helm	
		Cipla	

Source: *The Parties*

71. As can be seen in Table 4 above, there are several alternative suppliers for each of the four molecules (abiraterone acetate, sevelamer, tamsulosin, zopiclone).

[67] Confidential Annex 15.

72. Based on the information set out above, the Commission considers that there are alternative suppliers that FDP manufacturers could switch to if Synthon were to no longer supply them with a particular API/molecule. Therefore, the Commission considers that no input foreclosure concerns are likely to arise following completion of the Proposed Transaction in the potential market for the supply of FDPs.

Customer foreclosure

73. In relation to the likelihood of customer foreclosure arising following implementation of the Proposed Transaction, the Parties expressed the following view to the Commission: *"On the relevant market on which [Portfolio Company 1] might procure CDMO services, [Portfolio Company 1]'s market share is marginal at best and, in any event, far below 20% in the EEA. As a source of demand for CDMO services, [Portfolio Company 1] is, both at the level of the EEA and Ireland, insignificant. Even if [Portfolio Company 1] switched all of its demand for CDMO services to Synthon post-completion, there would still be a huge number of other pharmaceutical companies available to Synthon competitors as customers".*[68]

74. On the basis that there are many other pharmaceutical companies available to competitors of Synthon as customers of CDMO services, the Commission considers that there is no prospect of the Proposed Transaction raising any customer foreclosure concerns in the potential markets for the provision of CDMO services to pharmaceutical companies; and (ii) the out-licensing of pharmaceutical dossiers to pharmaceutical companies.

Potential Vertical Relationship 2

75. As noted above, there is a potential vertical relationship in the State between the downstream dossier development and API and FDP manufacturing activities of Synthon and the upstream pharmaceutical outsourcing services (in particular, CRO services) of [Portfolio Company 2] and [Portfolio Company 3].

76. As noted above, the potential upstream market for Potential Vertical Relationship 2 is the provision of CRO services to pharmaceutical companies. The potential downstream markets are (i) the provision of CDMO services to pharmaceutical companies for FDPs; and (ii) the out-licensing of pharmaceutical dossiers to pharmaceutical companies for each API.

[68] Merger notification form, p. 29.

Input foreclosure

77. Table 4 below details estimated shares in the provision of CRO services to pharmaceutical companies worldwide in 2023.[69]

Table 4: The Provision of CRO Services, Worldwide, 2023

Company	Estimated Share (%)
IQVIA	[20-25]%
ICON[70]	[15-20]%
PPD[71]	[15-20]%
Syneos Health[72]	[5-10]%
[Portfolio Company 2]	[5-10]%
[Portfolio Company 3]	[0-5]%
Other	[30-35]%

Source: The Parties

78. The Parties estimate that [Portfolio Company 2]'s share in the provision of CRO services to pharmaceutical companies worldwide in 2023 was approximately [5-10]%.[73] The Parties informed the Commission that [Portfolio Company 2]'s estimated share in the provision of CRO services in the EEA is similar and, in any event, less than 10%.[74] The Parties estimate that

[69] The Parties only provided share data in the provision of CRO services on a worldwide basis as no EEA-wide share data is available.
[70] ICON public limited company.
[71] PPD, Inc.
[72] Syneos Health, Inc.
[73] Merger notification form, p. 29.
[74] Merger notification form, p. 29.

[Portfolio Company 3] had a negligible share (less than [0-5]%) in the provision of CRO services worldwide and in the EEA in 2023.[75]

79. The Commission considers that, as the shares of [Portfolio Company 2] and [Portfolio Company 3] are both small in the provision of CRO services in the EEA, and given that there are several bigger competitors active in this area (as detailed in Table 4 above), no input foreclosure concerns are likely to arise following completion of the Proposed Transaction in the potential downstream markets for (i) the provision of CDMO services to pharmaceutical companies for FDPs; and (ii) the out-licensing of pharmaceutical dossiers to pharmaceutical companies.

Customer foreclosure

80. In relation to the likelihood of customer foreclosure arising following implementation of the Proposed Transaction, the Parties expressed the following view to the Commission: "*Customer foreclosure should only be considered as a function of Synthon's position as a buyer of CRO services, which is an EEA-wide market. There are no product-specific CRO services (the European Commission has been clear in defining a single CRO services markets), so Synthon sources CRO services in competition with all other pharmaceutical companies. Synthon's share of the purchasing markets is negligible in this respect, therefore precluding the risk of the purchaser engaging in customer foreclosure following the Proposed Transaction".*[76]

81. The Commission has confirmed that Synthon's share of the purchasing markets for CRO services in the EEA does not exceed 5%.[77] Therefore, the Commission considers that no customer foreclosure concerns are likely to arise following completion of the Proposed Transaction in the potential market for the provision of CRO services to pharmaceutical companies.

Conclusion of Competitive Analysis

82. In light of the above, the Commission considers that the Proposed Transaction will not substantially lessen competition in any market for goods or services in the State.

Ancillary Restraints

83. No ancillary restraints were notified.

[75] Merger notification form, p. 29.
[76] Email correspondence with the Parties.
[77] Synthon's share of the CDMO market in the EEA does not exceed 5%, source: Confidential Annex 14.

Determination

84. The Competition and Consumer Protection Commission, in accordance with section 21(2)(a) of the Competition Act 2002, as amended, has determined that, in its opinion, the result of the proposed acquisition whereby Skio Bidco B.V. would acquire sole control of Stamina TopCo B.V., being the ultimate holding company of Synthon B.V., will not be to substantially lessen competition in any market for goods or services in the State, and, accordingly, that the acquisition may be put into effect.

For the Competition and Consumer Protection Commission.

Úna Butler

Member

Competition and Consumer Protection Commission