EUROPEAN COMMISSION

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PUBLIC VERSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

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Subject: **Case M.10680 – PERMIRA / SESTANT / KEDRION / BPL**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 8 July 2022, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 of the Merger Regulation by which Permira Holdings Limited ("**Permira**",

1 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

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Guernsey) and Sestant Internazionale S.p.A ("**Sestant**", Italy) intend to acquire within the meaning of Article 3(1)(b) of the Merger Regulation joint control of Kedrion S.p.A. ("**Kedrion**", Italy) and Bio Products Laboratory Holdings Limited ("**BPL**", United Kingdom) (together, the "**Targets**") (the "**Transaction**").[3] Permira and Sestant are referred to as the "**Notifying Parties**" and, together with the Targets, the "**Parties**".

1. THE PARTIES

(2) **Permira** is a private equity firm that makes private equity investments in companies active in a wide variety of sectors.

(3) **Sestant** is a financial holding company primarily committed to overseeing the international assets of the Marcucci family.

(4) **Kedrion** is part of a global biopharmaceutical group specializing in the collection of human plasma and the development, production and sale of therapeutic plasma-derived products. Kedrion is currently solely controlled by Sestant.

(5) **BPL** operates plasma collection centres across the US and produces a range of plasma-derived products for the treatment of immune deficiencies, bleeding disorders and infectious diseases, as well as for critical care. BPL is currently solely controlled by Tiancheng International Investment Limited (China).

2. THE CONCENTRATION

(6) The Transaction will take place pursuant to the following agreements, simultaneously signed on 20 January 2022:

(a) A sale and purchase agreement in relation to Kedrion between, on the one side, a special purpose vehicle Kevlar S.p.A., which is wholly-owned by Kevlar 2 S.p.A. ("**TopCo**") and currently (*i.e.* prior to closing) ultimately wholly-owned by Permira; and on the other side, the sellers, the current shareholders of Kedrion[4] (the "**Kedrion SPA**");

(b) A sale and purchase agreement in relation to Naga UK Topco Limited (the parent company of BPL) between Kevlar S.p.A., the buyer, and the seller, Tiancheng International Investment Limited (the current owner of BPL) (the ("**BPL SPA**"); and

(c) A binding term sheet relating to the re-investment[5] of Sestant in TopCo between Permira and Sestant (the "**Sestant Term Sheet**").

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3 Publication in the Official Journal of the European Union No C 277, 19.7.2022, p. 10.

4 Kedrion is owned by the following shareholders: Sestant (50.27%), CDP Equity S.p.A. ("**CDPE**"), through its subsidiary FSI Investimenti S.p.A., (25.06%), FSI SGR S.p.A. ("**FSI**") (24.11%), Refin S.R.L. (0.31%), and Pips S.R.L. (0.25%) and is solely controlled by Sestant.

5 Re-investment meaning that Sestant, as the majority shareholder in Kedrion pre-Transaction will reinvest certain agreed amount it receives as a result of the Kedrion SPA into the TopCo as per Sestant Term Sheet.

(7) Post-Transaction, as a result of Kedrion SPA, BPL SPA and Sestant Term Sheet, Kedrion and BPL will be wholly owned by TopCo, which, in turn, will be ultimately owned by Permira, Sestant and other minority non-controlling shareholders.[6]

(8) While it involves the acquisition of joint control by Permira and Sestant over two separate undertakings, i.e., Kedrion and BPL, the Proposed Transaction constitutes a single concentration within the meaning of the Merger Regulation and the Consolidated Jurisdictional Notice. The two transactions of which the overall Transaction is composed are interdependent in that they are linked by mutual conditionality (the Kedrion SPA and the BPL SPA refer to a shared transaction letter, which provides that the Parties shall not be obliged to complete the sale and purchase of either of the Targets unless the sale and purchase of both of them are simultaneously completed) and result in joint control over the TopCo (which will control BPL and Kedrion) being acquired by the same two undertakings, *i.e.*, Permira and Sestant.

(9) Each of Permira and Sestant will acquire decisive influence over Kedrion and BPL, via TopCo, for the purposes of the Merger Regulation because:

(a) An entity solely controlled, but not solely owned, by Permira will be the majority shareholder in TopCo with [Permira shareholding in TopCo and Permira's governance rights in TopCo][7].

(b) Sestant, a minority shareholder in TopCo with […]%, will have joint control by virtue of certain rights. Sestant will [control rights].

(10) For the above reasons, the Proposed Transaction constitutes a concentration within the meaning of Article 3(1)(b) EUMR. Because the Transaction constitutes a single concentration, and since the acquisition of joint control over BPL falls within the scope of paragraph 91 of the Consolidated Jurisdictional Notice, it is not necessary to assess full-functionality of Kedrion under Article 3(4) EUMR. In any event and for completeness, Kedrion fulfils the criteria to be considered full functional within the meaning of Article 3(4) EUMR, as it is an established business and performs all the functions of an autonomous economic entity.

3. UNION DIMENSION

(11) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million[8] (Permira: EUR […] million; Sestant, including Kedrion: EUR […] million; BPL: EUR […] million). At least two of them have a Union-wide turnover in excess of EUR 250 million (Permira: EUR […] million, Sestant: EUR […] million), but not each of them achieve more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The notified operation therefore has a Union dimension.

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6 [Other non-controlling minority shareholders].

7 The shares in TopCo will be owned by an entity controlled by Permira ([…]%), Sestant ([…]%) and […] non-controlling minority shareholders, […].

8 Turnover calculated in accordance with Article 5 of the Merger Regulation.

4. RELEVANT MARKETS

(12) The Targets are both active in the development, production and supply of plasma-derived pharmaceutical products, as well as the collection / procurement of blood plasma needed to manufacture these products. Plasma-derived pharmaceutical products are pharmaceuticals derived from human plasma, which is a component of blood, through a series of technical processes including fractionation and purification.

(13) While Kedrion is active in several countries within the EEA, BPL's activities in the EEA are very limited (it is primarily active in the US and the UK). The Transaction therefore only gives rise to a limited number of horizontal overlaps and vertical relationships.

(14) The Transaction does not give rise to horizontally affected markets. When applying a national geographic market definition to marketed pharmaceutical products, as is the Commission's decisional practice (see Section 4.1.1.2), the only EEA countries where BPL and Kedrion are both active in the supply of plasma-derived pharmaceuticals are France, Germany and Malta.[9] However, they do not sell the same pharmaceutical products in those countries (their products address different indications). Therefore, the Transaction does not give rise to horizontal overlaps between marketed products in the EEA under any plausible market definition. The Transaction also does not give rise to meaningful potential horizontal overlaps under any geographic market definition.[10]

(15) In addition, the Transaction gives rise to only a limited number of vertical relationships, which are set out in the Table 1 below.

Table 1: Vertical relationships because of the Transaction

Upstream activity	Downstream activity
Collection/procurement of blood plasma by Kedrion and BPL	Supply of plasma-derived pharmaceutical products by Kedrion and BPL
Supply of paste[11] by Kedrion	Supply of plasma-derived pharmaceutical products by BPL
Supply of certain chemicals by Permira portfolio company CABB	Supply of plasma-derived pharmaceutical products by Kedrion and BPL
Supply of CDMO, CRO and laboratory services by Permira portfolio companies[12]	Supply of plasma-derived pharmaceutical products by Kedrion and BPL

Source: Form CO, paragraph 182

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9 BPL has sold Factor VIII in Poland in the past [business strategy].

10 There are two potential horizontal overlaps: (i) pipeline to marketed Polyvalent Immunoglobulin (IG) products, and (ii) [development plans]. (i) Polyvalent IG is a sterile solution made from human plasma and it is possible that the market is not segmented by the concentration of the product; as such a potential overlap arises because Kedrion is developing KIG10 (10% IG product) (phase III) and BPL had some spot sales of Subgam (16% IG product) in [EEA country] and [EEA country]. However, going forward BPL will not have authorisation to carry out any spot sales in [EEA country] and [EEA country] because of regulatory change (in the past it relied on the [non-EEA country] authorisation to do so). (ii) [development plans].

11 Paste is an intermediate product resulting from the fractioning of plasma.

12 By certain Permira's portfolio companies: Cambrex, Quotient and, to a very minor extent, Neuraxpharm.

(16) Vertically affected markets arise due to market shares by the Targets in the downstream markets exceeding 30%; these market shares are listed in Table 2. The market shares in the upstream markets are included in the relevant parts of the competitive assessment below.

4.1. Downstream markets

4.1.1. Plasma-derived pharmaceutical products

(17) Plasma-derived pharmaceutical products are pharmaceuticals that are derived from human plasma, which is one of the components of whole blood. Plasma is obtained from whole blood by centrifugation. It can also be collected directly from donors (plasmapheresis). Plasma-derived medicinal products are obtained from plasma by means of a series of technical processes, which include fractionation and purification.

4.1.1.1. Product market definition

(18) For pharmaceutical products, the Commission has traditionally adopted the Anatomical Therapeutic Classification ("**ATC**") taxonomy devised by the European Pharmaceutical Marketing Research Association ("**EphMRA**").

(19) With regard to plasma-derived pharmaceutical products specifically, the Commission previously found that they differ from other pharmaceutical products because they come from a natural body fluid for the collection of which manufacturers depend on the willingness of donors. The Commission found separate product markets for human albumin, intravenous immunoglobulin ("**IG**"), Factor VIII and Factor IX.[13] The Notifying Party agrees with the Commission's decisional practice.

(20) For the purposes of this Decision, it is not necessary to conclude on the product market definition, because the Parties do not overlap horizontally in any of these products and the focus of the competitive assessment is potential customer foreclosure and the Targets' share of demand is not significant taking into that they are overall small purchasers of the upstream products/services. The Transaction does not give rise to any competitive concerns under any plausible market definition.

4.1.1.2. Geographic market definition

(21) According to the decisional practice of the Commission, the relevant geographic market for the sale of pharmaceutical products is national due to regulatory barriers resulting from, among others, the national reimbursement systems of EEA countries. The Notifying Parties agree with this decisional practice. For the purposes of this Decision, the Commission does not find any reasons to depart from this definition.

[13] See Case M.495 – *Behringwerke AG / Amour Pharmaceutical Co.*, paragraph 16 and M.821 – *Baxter / Immuno*, paragraph 7.

4.2. Upstream markets

4.2.1. Collection and supply of plasma

(22) The production and supply of certain therapeutic products derived from blood plasma involves collecting blood from donors and using it to manufacture therapeutic products via a process called fractionation. Most entities that manufacture plasma-derived pharmaceutical products are vertically integrated, operating their own collection centres and therefore sales to third parties that manufacture plasma-derived pharmaceuticals appear most commonly on an ad hoc basis.

(23) The Commission previously found that a market for the collection of blood plasma through collection centres may exist, but did not conclude on the exact market definition of the market for collection of plasma.[14]

(24) The Notifying Parties consider that there may be separate markets for the collection of normal plasma and specialty plasma, and consider that these markets (either combined or separate) should include collection through collection centres as well as the limited volumes of blood plasma procured otherwise.[15] Normal plasma differs from speciality plasma both on the supply-side (since the latter is collected from donors who have specific antibodies in their plasma) and on the demand-side (since they are used to manufacture different therapeutical products).

4.2.1.1. Product market definition

(25) For the purposes of this Decision, it is not necessary to conclude on the exact product market definition for the collection and supply of blood plasma, as regardless of the market definition considered, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement.

4.2.1.2. Geographic market definition

(26) The majority of blood plasma is collected in the US, but is distributed globally. There are no limitations on the distances that both blood plasma and the resulting finished plasma-derived products can be transported. In practice, most manufacturers of plasma-derived products also source some quantities of blood plasma outside of the US.[16]

(27) For the purposes of this Decision, it is not necessary to conclude on the exact geographic market definition. Both Targets exclusively operate collection centres in the US, and therefore a vertical relationship with the supply of plasma-derived pharmaceutical products only exists when considering a global market definition for the collection of blood plasma.

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14 See Case M.495 – *Behringwerke AG / Amour Pharmaceutical Co.*, paragraph 45.

15 Form CO, paragraph 131.

16 Form CO, paragraph 134.

4.2.2. Supply of paste

(28) Paste is an intermediate product resulting from the fractioning of plasma. Similar to blood plasma collection and supply, plasma-derived pharmaceutical producers are in most instances vertically integrated for paste and only occasionally sell limited volumes to third parties that manufacture plasma-derived pharmaceuticals (for example, in case of surplus). There are different types of paste, the main ones include: (i) CRYO paste, from which Factor VIII is obtained; (ii) prothrombin complex concentrate, from which Factor IX is obtained; (iii) Fraction II and Fraction II+III, from which IGs are obtained, and (iv) Fraction V, from which albumin is obtained.

4.2.2.1. Product market definition

(29) It is likely that the product market definition for paste could be considered along similar lines as the product definition for the collection and supply of blood plasma. In the present case, the Notifying Parties did not express a view on the appropriate product market definition for paste. However, for the purposes of this Decision, it is not necessary to conclude on the exact product market, as regardless of the product market definition considered, the Transaction does not raise competition concerns under any plausible market definition.

4.2.2.2. Geographic market definition

(30) It is likely that the geographic market definition for paste is global as similar considerations as for blood plasma supply apply. In the present case, the Notifying Parties did not express a view on the appropriate geographic market definition for paste. However, for the purposes of this Decision, it is not necessary to conclude on the exact geographic market, as regardless of the geographic market definition considered, the Transaction does not raise competition concerns under any plausible market definition.

4.2.3. CDMO services

(31) Contract development and manufacturing organisation ("**CDMO**") services are an arrangement under which a manufacturer provides upstream manufacturing services of finished dose pharmaceuticals ("**FDP**"s) and active pharmaceutical ingredients ("**API**"s) under contract on behalf of third party pharmaceutical companies.

4.2.3.1. Product market definition

(32) In previous decisions, the Commission identified separate markets for CDMO services for FDPs and active pharmaceutical ingredients APIs.[17] In the present case, the Notifying Parties did not express a view on the appropriate market definition of CDMO services. For the purpose of this Decision, there is no need to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition.

[17] See cases M.9995 – *Permira / Neuraxpharm*, paragraph 13 et seq. and M.9315 – *CHR. Hansen / Lonza / JV*, paragraph 17.

4.2.3.2. Geographic market definition

(33) In the past, the Commission has considered the market for CDMO services to be at least EEA-wide in scope.[18] In the present case, the Notifying Parties did not express a view on the appropriate market definition of CDMO services. For the purpose of this Decision, there is no need to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition.

4.2.4. CRO services

(34) Contract research organisation ("**CRO**") services consist in assisting pharmaceutical or biotech companies in conducting and evaluating clinical trials. This mainly involves organising the interaction between patients and doctors at clinical trial sites.

4.2.4.1. Product market definition

(35) In previous decisions, the Commission found a separate market for CRO services without further segmentation.[19] In the present case, the Notifying Parties did not express a view on the appropriate market definition of CRO services. For the purpose of this Decision, there is no need to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition.

4.2.4.2. Geographic market definition

(36) In the past, the Commission has considered the market for CRO services to be at least EEA-wide in scope.[20] In the present case, the Notifying Parties did not express a view on the appropriate market definition of CRO services. For the purpose of this Decision, there is no need to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition.

4.2.5. Laboratory services

4.2.5.1. Product market definition

(37) In a previous decision, the Commission identified separate markets for laboratory services for clinical development (for which the customers are e.g. pharmaceutical and biotechnology companies, CROs and CDMOs) and laboratory services for diagnostic purposes (for which customers are hospitals / clinics and physicians), and left the possibility of further segmentation open.[21] In the current case, the Notifying Parties did not express a view on the appropriate market definition of laboratory services. For the purpose of this Decision, it is not

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18 See cases M.9995 – *Permira / Neuraxpharm*, paragraph 17 et seq. and M.5953- *Reckitt Benckiser / SSL*, paragraphs 64-66.

19 See cases M.10304 – *Thermo Fisher / PPD*, paragraph 21 and M.8061 – *IMS Health / Quintiles*, paragraph 39 et seq.

20 See cases M.10304 – *Thermo Fisher / PPD*, paragraph 25 and M.8061 – *IMS Health / Quintiles*, paragraph 39 et seq.

21 See case M.10304 – *Thermo Fisher / PPD*, paragraph 33 and 34.

necessary to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition. In this case, only the market for laboratory services for clinical development is relevant, as it forms part of an affected vertical relationship.

4.2.5.2. Geographic market definition

(38) In the past, the Commission has considered the market for laboratory services for clinical development to be at least EEA-wide in scope.[22] In the present case, the Notifying Parties did not express a view on the appropriate market definition of laboratory services. For the purpose of this Decision, there is no need to depart from the Commission's decisional practice, as the Transaction does not raise competition concerns under any plausible market definition.

4.2.6. Chemicals

(39) The relevant chemicals that give rise to a vertical relationship because they could potentially be purchased by the Targets include: (i) acetic acid, (ii) hydrochloric acid, (iii) sodium hypochlorite; (iv) sodium hydroxide; (v) sodium acetate anhydrous and (vi) sodium acetate trihydrate.[23]

4.2.6.1. Product market definition

(40) In previous decisions, the Commission considered that different chemicals fall into separate product markets depending on their characteristics and potential use, as well as lack of supply side substitution.[24] The Notifying Parties do not express a view on the market definition for these products. For the purposes of this Decision, it is not necessary to conclude on the exact product market definition for these chemicals, as regardless of the product market definition considered, the Transaction does not raise competition concerns under any plausible market definition.

4.2.6.2. Geographic market definition

(41) In previous decisions, the Commission considered that, for certain chemicals, markets could be either national or EEA-wide.[25] As the outcome of the competitive assessment of the Transaction remains the same under all alternative geographic market definitions, it is not necessary for the Commission to conclude on the exact geographic market definition.

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22 See cases M.10304 – *Thermo Fisher / PPD*, paragraph 36.

23 The only two products for which there may be an affected market upstream by virtue of [Permira portfolio company's market share] could be [chemical product] and [chemical product], but these two products are not used in the production processes of the Targets.

24 More generally on the approach to product market for chemical products see M.8674 – *BASF/Solvay's Polyamide Business*.

25 More generally on the approach to geographic market for chemical products see M.8674 – *BASF/Solvay's Polyamide Business*.

5. COMPETITIVE ASSESSMENT

5.1. Analytical framework

(42) Article 2 of the Merger Regulation requires the Commission to examine whether notified concentrations are compatible with the internal market, by assessing whether they would significantly impede effective competition in the internal market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position.[26]

(43) In the assessment of non-horizontal mergers, the Commission distinguishes between two broad types of such mergers: vertical mergers and conglomerate mergers.

(44) Vertical mergers involve companies operating at different levels of the supply chain. For example, when a manufacturer of a certain product (the "upstream firm") merges with one of its distributors (the "downstream firm"), this is called a vertical merger.[27]

(45) In assessing potential vertical effects of a merger, the Commission analyses whether a merger results in foreclosure so that actual or potential rivals' access to supplies or markets is hampered or eliminated as a result of the merger, thereby reducing these companies' ability and/or incentive to compete. Such foreclosure may discourage entry or expansion of rivals or encourage their exit. Foreclosure thus can be found even if the foreclosed rivals are not forced to exit the market: it is sufficient that the rivals are disadvantaged and consequently led to compete less effectively. Such foreclosure is regarded as anti-competitive where the merging companies — and, possibly, some of its competitors as well — are as a result able to profitably increase the price charged to consumers.[28]

(46) Two forms of foreclosure can be distinguished. The first is where the merger is likely to raise the costs of downstream rivals by restricting their access to an important input (input foreclosure). The second is where the merger is likely to foreclose upstream rivals by restricting their access to a sufficient customer base (customer foreclosure).[29]

(47) In assessing both types of foreclosure, the Commission assesses whether (i) the merged entity would have the ability to engage in foreclosure, (ii) it would have the incentive to do so, and (iii) what would be the overall impact on effective competition in the affected markets.[30]

5.2. Affected markets

(48) The Transaction does not give rise to affected horizontal overlaps. The Transaction gives rise to the following affected vertical relationships, primarily

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26 Regarding rules relating to the functioning of the EEA Agreement, see Annex XIV to the EEA Agreement.

27 OJ C 265, 18.10.2008, p. 6-25 (the 'Non-horizontal Merger Guidelines'), paragraph 4.

28 Non-horizontal Merger Guidelines, paragraph 29.

29 Non-horizontal Merger Guidelines, paragraph 30.

30 Non-horizontal Merger Guidelines, paragraphs 32 and 59.

because of the Targets' position of certain plasma-derived pharmaceutical products at the downstream level in certain EEA countries:

(a) Collection/supply of blood plasma by the Targets (upstream) and supply of plasma-derived products by the Targets (downstream),

(b) Supply of paste by Kedrion (upstream) and supply of plasma-derived products by the Targets (downstream),

(c) Supply of CDMO services by certain Permira portfolio companies, i.e. Cambrex, Quotient and, to a very minor extent, Neuraxpharm (upstream) and supply of plasma-derived pharmaceutical products by the Targets (downstream),

(d) Supply of CRO services by Permira portfolio company Quotient (upstream) and supply of plasma-derived pharmaceutical products by the Targets (downstream),

(e) Supply of laboratory services for clinical development by Permira portfolio company Cambrex (upstream) and supply of plasma-derived pharmaceutical products by the Targets (downstream), and

(f) Supply of certain chemicals by Permira portfolio company CABB (upstream) and supply of plasma-derived pharmaceutical products by the Targets (downstream).

(49) In each case, the vertical relationship is affected by virtue of the Targets' (primarily Kedrion's) market share in the downstream markets for specific plasma-derived pharmaceutical products in some EEA countries. The Targets' market shares for the plasma-derived pharmaceutical products for which they are active in the EEA are shown below in Table 2.

Table 2: The Targets' market shares for plasma-derived pharmaceutical products in EEA countries leading to affected vertical relationships (>30%)

Country	Target	Product	Market share (%)	Market size (EUR million)
Austria	Kedrion	Anti-Hepatitis B Immune Globulin	[40-50]%	[…]
Belgium	Kedrion	Rh0(D) Immune Globulin	[90-100]%	[…]
Cyprus[31]	BPL	Albumin	*Not available*	*Not available*
		Anti-Hepatitis B immune globulin	*Not available*	*Not available*
		Polyvalent immune globulin	*Not available*	*Not available*
		Varicella-Zoster Immunoglobulin	*Not available*	*Not available*

[31] The Notifying Parties are not able to estimate the Targets' market shares in Cyprus, Ireland, Malta and market shares for Factor X in France. However, even if for some of these markets would be 100%, the same competitive assessment as set out below would apply.

Country	Target	Product	Market share (%)	Market size (EUR million)
France	Kedrion	Plasminogen	[90-100]%	[…]
	BPL	Factor X	[90-100]%	*Not available*[32]
Germany	BPL	Factor X	[90-100]%	[…]
Hungary	Kedrion	Rh0(D) Immune Globulin	[40-50]%	[…]
		Anti-Tetanus Immune Globulin	[90-100]%	[…]
		Anti-Hepatitis B Immune Globulin	[40-50]%	[…]
		Factor IX	[90-100]%	[…]
Ireland[33]	BPL	Factor X	*Not available*	*Not available*
Italy	Kedrion	Rh0(D) Immune Globulin	[60-70]%	[…]
		Anti-Tetanus Immune Globulin	[30-40]%	[…]
		Anti-Hepatitis B Immune Globulin	[40-50]%	[…]
		Antithrombin III	[70-80]%	[…]
		Plasminogen	[90-100]%	[…]
Malta[34]	Kedrion	Anti-Tetanus Immune Globulin	*Not available*	*Not available*
	BPL	Albumin	*Not available*	*Not available*
		Anti-Rabies Immune Globulin	*Not available*	*Not available*
		Polyvalent Immune Globulin	*Not available*	*Not available*
		Factor IX	*Not available*	*Not available*
Netherlands	Kedrion	Anti-Tetanus Immune Globulin	[90-100]%	[…]
		Anti-Hepatitis B Immune Globulin	[70-80]%	[…]
Poland	Kedrion	Anti-Hepatitis B Immune Globulin	[70-80]%	[…]

32 See footnote 31.
33 See footnote 31.
34 See footnote 31.

Country	Target	Product	Market share (%)	Market size (EUR million)
Portugal	Kedrion	Anti-Hepatitis B Immune Globulin	[80-90]%	[…]
Romania	Kedrion	Polyvalent Immune Globulin	[80-90]%	[…]
Sweden	Kedrion	Anti-Hepatitis B Immune Globulin	[90-100]%	[…]

Source: Annex 7.1-I to the Form CO

(50) The Parties' market position in each upstream market for which the Transaction gives rise to an affected vertical relationship will be covered in the sections dedicated to each vertical relationship below.

(51) As in each case, the vertical relationship is affected by virtue of the Parties' downstream market share, the Commission's competitive assessment will focus on the scenario of customer foreclosure.

5.3. Vertical relationship – Collection and supply of plasma (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

5.3.1. The Notifying Parties' view

(52) The Notifying Parties argue that majority of plasma is collected by vertically integrated producers of plasma-derived pharmaceutical products. Sales of plasma from one vertically integrated manufacturer of plasma-derived products to another only represent a marginal portion of the overall procurement of blood plasma by such manufacturers and typically occur on an ad hoc basis. This usually takes place when such manufacturer has plasma in excess of its requirements for the production of its own finished plasma-derived products or, for specialty plasma, if so requested by a manufacturer of plasma-derived pharmaceuticals.

(53) The Notifying Parties explain that this means that most plasma-derived products' manufacturers are not dependent on any other vertically integrated supplier of blood plasma therapies for their plasma supply requirements for the production of its finished plasma-derived products. This in itself suffice to exclude that the Proposed Transaction may give rise to any anti-competitive foreclosure effects.

5.3.2. The Commission's assessment

(54) Kedrion and BPL each collect and/or source from third parties (if such supply is to be taken into account) only a small portion of the global share of blood plasma collection, their combined share representing below 5% of the global supply.

(55) In light of the limited market position of the Targets at the upstream level and the sporadic nature of their sales at the upstream level, the Commission considers that the Transaction will not give rise to input foreclosure concerns and therefore focusses in its competitive assessment on the possibility of customer foreclosure.

(56) At the downstream level, the Targets produce different plasma-derived pharmaceuticals, some of which are marketed in the EEA. It is the market shares in some Member States of some of these products that give rise to a vertically affected market (if the overall market of plasma supply is considered). The Commission therefore only considered the likelihood of customer foreclosure.

(57) An affected vertical relationship only exists with respect to one specialty type of plasma that BPL supplies to third-party customers and that Kedrion uses in its plasma-derived products. BPL supplies [a type of specialty plasma], which kedrion self-sources and uses for its [an hyperimmune globulin product]. BPL sells its own hyperimmune globulin products almost exclusively outside of the EEA, with minor sales only in Cyprus and Malta. The Commission assessed whether, as a result of the Transaction, the Targets would have an ability to engage in customer foreclosure with respect to their purchases of [a type of specialty plasma].

(58) The Commission found that the Targets would be unlikely to have the ability to engage in customer foreclosure with respect to the purchase of [a type of specialty plasma] from third parties and the vertical link is hypothetical. *First*, the Targets are vertically integrated and rely on self-supply for their respective plasma requirements. BPL does not purchase any plasma from third parties and the small amounts of normal plasma that Kedrion purchased from third parties was from suppliers that do not manufacture plasma-derived products. *Second*, the incentives to engage in a foreclosure strategy would not be changed as a result of the Transaction because going forward, BPL would not be able to sell its [a type of specialty plasma] product in the EEA. BPL does not hold any marketing authorization for any of its hyperimmune globulin products for any EEA country, and it is no longer able to obtain special import exemptions it relied upon in the past due to regulatory changes.

(59) It follows, based on the fact that the industry is organised in such a manner that third party purchases of plasma (normal and specialty) are rare and because BPL will not be able to sell its hyperimmune globulin products in the EEA, customer foreclosure as a result of the Transaction is highly unlikely. The Targets will have neither the ability, nor the incentive to engage in a successful customer foreclosure strategy post-Transaction.

5.3.3. Conclusion

(60) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for the collection and supply of plasma.

5.4. Vertical relationship – Supply of paste (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

5.4.1. The Notifying Parties' view

(61) The Notifying Parties explain that the supply of paste is an intermediate product which results from the fractionation of plasma. Manufacturers of plasma-derived products are typically vertically integrated and typically use the paste they obtain from their in-house plasma fractionation. Plasma-derived pharmaceutical producers only occasionally sell limited volumes of paste to each other, for

example in case of a surplus.[35] The Parties are not aware of any available data or sources of information on the supply of paste to third parties, based on which one could estimate each Target's market share.

5.4.2. The Commission's assessment

(62) Kedrion currently only sells limited quantities of [a type of specialty paste] – which it would otherwise dispose of as it does not use it in the production process of its current [plasma dervised product] product.[36] BPL does not sell paste to any other manufacturers of plasma-derived products.[37]

(63) In light of the limited sales by the Targets of paste at the upstream level and the sporadic nature of their sales at the upstream level, the Commission considers that the Transaction will not give rise to input foreclosure concerns and therefore focusses in its competitive assessment on the possibility of customer foreclosure.

(64) As regards customer foreclosure, BPL to date has not purchased any paste from third parties, and Kedrion only purchased a very small amount of paste over two years ago for its [plasma derived products]; the Parties are therefore not meaningful customers of paste.[38] Therefore, it is unlikely that the Targets would have an ability to engage in customer foreclosure with respect to plasma paste suppliers.

(65) In addition, the Commission considers that the Targets would not have an incentive to engage in a customer foreclosure strategy as a result of the Transaction because the product which BPL sells in the EEA is [a type of specialty plasma], not a product sold by Kedrion for which it purchases paste. Competitive concerns due to customer foreclosure can therefore be excluded.

5.4.3. Conclusion

(66) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for the supply of paste.

5.5. Vertical relationship – CDMO services (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

(67) The combined market share of Permira's portfolio companies in CDMO services is well under 5% under any plausible market definition.[39] Therefore, the vertical relationship with plasma-derived pharmaceutical products is affected by virtue of the Targets' market shares in the downstream market, and the Commission's assessment will focus on customer foreclosure.

35 Form CO, paragraph 222.
36 Form CO, paragraph 224.
37 Form CO, paragraph 225.
38 Form CO, paragraph 224.
39 Form CO, paragraph 208.

5.5.1. The Notifying Parties' view

(68) The Notifying Parties submit that customer foreclosure (as well as input foreclosure) can be excluded, and that the vertical link between Permira portfolio companies' CDMO services and the Targets' plasma-derived pharmaceutical products is at most theoretical. The Notifying Parties argue that:[40]

(a) neither of the Targets procures CDMO services from third parties to any meaningful extent (BPL did not have any CDMO spend in 2021, and Kedrion only procured [previous year's spend for cdmo services and future business strategies].

(b) Neuraxpharm, Quotient and Cambrex are each unable to provide CDMO services for plasma derived products as each of them does not have the necessary licenses, equipment, experience and know-how.

5.5.2. The Commission's assessment

(69) The Commission considers that in this case, customer foreclosure can be excluded as the Notifying Parties are highly unlikely to have the ability to engage in such a strategy.

(70) The Targets have a minimal share of overall demand for CDMO services (less than 1% under all plausible market definitions), considering they essentially do not procure such services. Furthermore, the overall demand for such services is represented by the entire life sciences sector, of which the sub-sector represented by manufacturers of plasma-derived products such as the Targets represents a very minor portion (and the Targets themselves an even smaller portion). In addition, Permira's portfolio companies currently do not serve plasma-derived pharmaceutical companies and are unable to do so, therefore the Targets cannot divert their CDMO purchases to Permira's portfolio companies post-Transaction.

(71) In light of the clear absence of ability to engage in customer foreclosure, the merged entity will likely have no incentive to foreclose, and any such strategy would be unlikely to have any impact on competition.

5.5.3. Conclusion

(72) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for CDMO services.

5.6. Vertical relationship – CRO services (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

(73) Quotient's market share for CRO services is less than 1% under any plausible market definition.[41] Therefore, the vertical relationship with plasma-derived pharmaceutical products is affected by virtue of the Targets' market shares in the downstream market, and the Commission's assessment will focus on customer foreclosure.

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40 Form CO, paragraphs 187-211.

41 Form CO, paragraph 211.

5.6.1. The Notifying Parties' view

(74) The Notifying Parties submit that customer foreclosure (as well as input foreclosure) can be excluded. The Notifying Parties argue that the Targets are not meaningful customers for CRO services (the Targets together represent less than 1% of total demand under any plausible market definition).[42]

5.6.2. The Commission's assessment

(75) The Commission considers that in this case, customer foreclosure can be excluded as the Notifying Parties are highly unlikely to have either the ability or incentive to engage in such a strategy.

(76) The Targets have a minimal share of overall demand for CRO services (less than 1% under all plausible market definitions). The overall demand for such services is represented by the entire life sciences sector, and contains large customers such as global pharmaceutical companies. Of this sector, the sub-sector represented by manufacturers of plasma-derived products such as the Targets represents a very minor portion (and the Targets themselves an even smaller portion).

(77) In light of the clear absence of ability to engage in customer foreclosure, the merged entity will likely have no incentive to foreclose, and any such a strategy would be unlikely to have any impact on competition

5.6.3. Conclusion

(78) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for CRO services.

5.7. Vertical relationship – Laboratory services for clinical development (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

(79) Cambrex's market share for laboratory services for clinical development is less than 5% under any plausible market definition.[43] Therefore, the vertical relationship with plasma-derived pharmaceutical products is affected by virtue of the Targets' market shares in the downstream market, and the Commission's assessment will focus on customer foreclosure.

5.7.1. The Notifying Parties' view

(80) The Notifying Parties submit that customer foreclosure (as well as input foreclosure) can be excluded. The Notifying Parties argue that the Targets are not meaningful customers for laboratory services for clinical development (the Targets together represent less than 1% of total demand under any plausible market definition).[44] Furthermore, the Notifying Parties indicate that Cambrex has

42 Form CO, paragraph 210.
43 Form CO, paragraph 211.
44 Form CO, paragraph 210.

only […]. Therefore, any supplier-customer relationship between Cambrex and the Targets in the future is highly unlikely and would not reflect market reality.[45]

5.7.2. The Commission's assessment

(81) The Commission considers that in this case, customer foreclosure can be excluded as the Notifying Parties are highly unlikely to have either the ability or incentive to engage in such a strategy.

(82) The Targets have a minimal share of overall demand for laboratory services for clinical development (less than 1% under all plausible market definitions). The overall demand for such services consists of the entire life sciences sector, and contains large customers such as global pharmaceutical companies. Of this sector, the sub-sector represented by manufacturers of plasma-derived products such as the Targets represents a very minor portion (and the Targets themselves an even smaller portion).

(83) In light of the clear absence of ability to engage in customer foreclosure, the merged entity will likely have no incentive to foreclose, and any such strategy would be unlikely to have any impact on competition.

5.7.3. Conclusion

(84) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for laboratory services for clinical development.

5.8. Vertical relationship – Supply of specific chemicals (upstream) and supply of plasma-derived pharmaceutical products (downstream) – customer foreclosure

5.8.1. The Notifying Parties' view

(85) The market share of CABB's activities as a global chemicals producer is below 30% under all plausible market definitions for all of the chemicals that could be hypothetically purchased by the Targets.[46] The Commission's assessment therefore focuses on customer foreclosure by virtue of Targets' market shares downstream.

(86) The Notifying Parties provide a number of reasons to support their view that both input and customer is highly unlikely with respect to CABB's activities as a global chemicals producer. *First*, CABB focuses its activities on the agro-chemicals industry, only a small proportion of CABB's products are actually sold to pharmaceutical companies, none of which are active in the supply of plasma-derived products. It is therefore only a hypothetical scenario that the Targets would purchase their chemical supplies for their plasma-derived pharmaceuticals from CABB to the detriment of other third-party suppliers of chemicals. *Second*, the chemicals produced by CABB and sourced by the Targets from third parties, for example acetic acid and hydrochloric acid, are considered commodity

45 Form CO, paragraph 209.
46 Form CO, paragraph 213.

chemicals, which are produced and supplied by a large number of market players around the globe for customers from different industries.

5.8.2. The Commission's assessment

(87) The Commission considers that in this case, customer foreclosure can be excluded as the Notifying Parties are highly unlikely to have either the ability or incentive to engage in such a strategy. The chemicals that the Targets could potentially purchase from CABB are commodity chemicals and used in many industries. The Targets therefore would represent only a very small proportion of demand. Due to the fact that the Targets represent only a small portion of total demand for the chemicals that are supplied by CABB, it is unlikely that the Targets would have an ability to engage in anti-competitive customer foreclosure.

5.8.3. Conclusion

(88) For the reasons set out above, the Transaction does not give rise to serious doubts as to its compatibility with the internal market or a substantial part thereof in relation to vertical effects for the supply of chemicals.

6. CONCLUSION

(89) For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President