



EUROPEAN COMMISSION
DG Competition

*Case M.9547 –
JOHNSON & JOHNSON
/ TACHOSIL*

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERCER PROCEDURE**

Article 22
Date: 26.09.2019



EUROPEAN COMMISSION

Brussels, 26.09.2019
C(2019) 7082 final

PUBLIC VERSION

<p>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 Where possible the information omitted has been replaced by ranges of figures or a general description.</p>
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To the Bundeskartellamt

Subject: Case M.9547 - Johnson & Johnson/Tachosil
Request for referral by Germany to the Commission pursuant to Article 22(1) of Council Regulation (EC) No. 139/2004¹ and Article 57 of the Agreement on the European Economic Area²

Ref.: Letter of the Bundeskartellamt of 21 August 2019

Dear Sir or Madam,

1. INTRODUCTION

- (1) With the above-mentioned letter, the Bundeskartellamt (the “German Competition Authority”) formally requested the Commission to examine, in application of Article 22(3) of the Merger Regulation, the concentration whereby Johnson & Johnson (“J&J”, USA) acquires, from Takeda Pharmaceuticals International AG (“Takeda”, Switzerland), sole control over Tachosil, a haemostatic patch product (“Tachosil” or the “Target”), through the acquisition of Topaz Investment AS (“Topaz”, Norway) and additional assets related to Tachosil (the “Transaction”). J&J and the Target are hereafter referred to as the “Parties”.

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”).

- (2) Pursuant to Article 22(1) of the Merger Regulation, one or more Member States may request the Commission to examine any concentration as defined in Article 3 of the Merger Regulation that does not have a Union dimension within the meaning of Article 1 of the Merger Regulation but affects trade between Member States and threatens to significantly affect competition within the territory of the Member State or States making the request. Such a request must be made within 15 working days of the date of the notification of the concentration, or if notification is not required, otherwise made known to the Member State. Pursuant to Article 22(2) of the Merger Regulation, any other Member State may join the initial request within a period of 15 working days of being informed by the Commission of the initial request. Pursuant to Article 6(3) of Protocol 24 to the EEA Agreement, any EFTA State may join the request within a period of 15 working days from the day on which the Commission informed the EFTA Surveillance Authority of the initial request.
- (3) In the present case, J&J notified the Transaction to the German Competition Authority on 1 August 2019.³
- (4) The Commission received the referral request made by Germany pursuant to Article 22(1) of the Merger Regulation on 21 August 2019.
- (5) On 22 August 2019, in accordance with Article 22(2) of the Merger Regulation, the Commission informed the competent authorities of the other Member States and the EFTA Surveillance Authority of the above request. On 3 September 2019, the Commission also shared with them additional information received from the German Competition Authority relating to the Parties' market shares in the EEA.
- (6) Austria (23 August 2019), Spain (3 September 2019), France (6 September 2019), Finland (9 September 2019), and Norway (12 September 2019) joined the initial referral request made by Germany within a period of 15 working days of being informed by the Commission of the referral request (on 22 August 2019), thus within the time limit of Article 22(2), second indent, of the Merger Regulation.

2. THE PARTIES AND THE OPERATION

- (7) J&J is the ultimate parent company of a global group of companies active in three business sectors: (i) consumer, (ii) pharmaceuticals, and (iii) medical devices.
- (8) The Target consists of (i) Topaz, which holds the majority of the rights assets and obligations connected to Tachosil (and its predecessor products), as well as (ii) additional assets related to these products.
- (9) The Transaction notified to the German Competition Authority consists in the acquisition of sole control by J&J over the Target. Therefore, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

³ On the same day, J&J notified the Transaction to the Austrian Competition Authority. Besides Germany and Austria, in the EEA, the Transaction is also subject to merger control in Spain but has not been notified in this country yet.

- (10) The Transactions would not constitute a concentration with a Union dimension within the meaning of Article 1 of the Merger Regulation, according to the information provided by the competent authorities.

3. ASSESSMENT OF THE REFERRAL REQUEST

- (11) In order for a referral to be made by a Member State, one procedural and two substantive conditions must be fulfilled pursuant to Article 22(1) of the Merger Regulation. As to the procedural precondition *the referral shall be made at most within 15 working days of the date on which the concentration was notified, or if no notification is required, otherwise made known to the Member State concerned*. As to the substantial conditions, the concentration must: (i) *affect trade between Member States*; and (ii) *threaten to significantly affect competition* within the territory of the Member State(s) making the request.⁴

- (12) If the above legal requirements are met, the Commission may exercise discretion with regard to whether or not it is appropriate that the concentration is examined by the Commission. The Commission has, in the Referral Notice, set out in a general manner its understanding regarding the appropriateness of particular cases or categories of cases for referral.

3.1. Procedural criterion

- (13) As to the procedural condition, J&J formally notified the Transaction to the German Competition Authority on 1 August 2019. The Commission received the referral request made by Germany on 21 August 2019.

- (14) Therefore, the referral request was made within the deadline of Article 22(1) second indent of the Merger Regulation.

3.2. Substantive criteria

- (15) The Parties' activities overlap in the field of haemostatic and tissue sealing products. These products are developed to stop bleeding during surgery and are typically used when traditional techniques (such as suture, ligation or cauterisation) are either ineffective or impractical. Haemostatic and tissue sealing products are available in different forms and with various product properties.

- (16) Tachosil is a wound patch made of human fibrinogen and human thrombin, which has both a haemostatic and tissue sealing effect. J&J offers several haemostatic and tissue sealing products in the EEA, including Evicel (fibrin sealant liquid), Surgiflo (flowable gelatine-based foam), Tabotamp/Surgicel (cellulose-based absorbable haemostat) and Spongostan (haemostatic gelatine sponge). J&J's product portfolio also includes Evarrest, a surgical patch with dual haemostatic [...]*, similar to Tachosil, which is currently marketed outside of the EEA. Evarrest was sold in the EEA between 2013 and late 2017 until J&J filed an application to have its marketing authorisation revoked for commercial reasons.

* Should read: "effect".

⁴ See also Commission Notice on Case Referral in respect of concentrations (the "Referral Notice"), paragraphs 42-44 (OJ C 56, 05.03.2005, p. 2).

Effect on trade between Member States

- (17) Regarding the first substantive criterion, paragraph 43 of the Referral Notice provides that a concentration fulfils this requirement to the extent that it is liable to have some discernible influence on the pattern of trade between Member States.
- (18) The German Competition Authority argues that the acquisition of Tachosil by J&J affects trade between Member States since the Parties have sales of haemostatic and tissue sealing products in almost all Member States. Moreover, Tachosil is manufactured in one of Takeda's production sites in Austria, from which it is distributed in the EEA and globally. Similarly, J&J's haemostatic and tissue sealing products are each manufactured in [locations] (Evicel and Evarrest are manufactured in [the Middle East], Surgiflo and Spongostan in [Europe] and Tabotamp in [Europe] and [Latin America]), from which they are distributed in the EEA and globally.
- (19) Based on the above, the Commission considers that the Transaction is capable of having an appreciable impact on cross-border economic activity involving several Member States. Indeed, the Transaction gives rise to overlaps involving products sold in several Member States and, therefore, is by its very nature capable of affecting trade between Member States.⁵ In view of the foregoing, the Commission concludes that the first substantive legal requirement for an Article 22 referral request is met.

Threat to significantly affect competition within the territory of the Member State making the request

- (20) Regarding the second criterion, paragraph 44 of the Referral Notice provides that a referring Member State should demonstrate that, based on a preliminary analysis, there is a real risk that the transaction may have a significant adverse effect on competition within the territory of the Member State making the request and thus deserves close scrutiny, without prejudice to the outcome of a full investigation.
- (21) The German Competition Authority argues that the Transaction could significantly affect competition at least within Germany in the field of haemostatic and tissue sealing products, under all plausible market definitions.
- (22) In the absence of precedents in this sector, and based on its preliminary assessment of the Transaction, the German Competition Authority considered the following plausible product market definitions: (i) the overall market for haemostatic and tissue sealing products, as well as two potential narrower market segments, i.e. (ii) a market based on the European Pharmaceutical Marketing Research Association's (EphMRA) ATC 3 classification (Group B2F "Tissue Sealing Preparation") and (iii) a market limited to haemostatic patches with dual effect. As regards the geographic market, the German Competition Authority considers that the market is likely to be national in scope but that it can be left open as competition concerns would arise under all plausible geographic market definitions (national and EEA).

⁵ See by analogy Commission Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, paragraph 61.

- (23) On the overall market for haemostatic and tissue sealing products, the Parties have a combined market share in Germany of between 50-70% in 2018 (Tachosil: 30-40% and J&J's Evicel, Surgiflo, Tabotamp/Surgicel and Spongostan: 20-30%). The third largest player on this market is Baxter, with a market share of 20-30%.
- (24) On the market based on the EphMRA ATC 3 classification (Group B2F "Tissue Sealing Preparation"), the Parties also have high combined market shares in Germany: [60-70]% in volume (with an increment of [0-5]%) and [60-70]% in value (with an increment of [0-5]%) based on the IMS Health's data for the first quarter of 2018. The third largest player on this market is again Baxter, with a market share of [30-40]% in volume and [30-40]% in value. The other players active on this market have a marginal position.
- (25) On the narrower market limited to haemostatic patches with dual effect, currently J&J has no marketed products in the EEA, while Tachosil is the market leader in Germany with a market share of 80-90% in 2018. However, based on the information available at this stage, it appears that Tachosil and Evarrest are the only two haemostatic patches with dual effect based on human fibrinogen and thrombin and are classified as pharmaceuticals. Competing haemostatic patches with dual effect, sold by Baxter and Medtronic in the EEA, support the haemostatic process through synthetic ingredients and are classified as medical devices. The German Competition Authority also submits that it can be assumed that J&J could launch Evarrest in the EEA without any substantial effort since this product had already been authorised and distributed in the EEA, between 2013 and 2017, until the withdrawal of the European marketing authorisation at J&J's request (reportedly for economic reasons). In view of the fact that Evarrest has already been authorised and distributed in the EEA and that such authorisation was only removed pursuant to J&J's own request, the acquisition of Tachosil and the likely negative impact that this could have on J&J's incentives to recommence distribution of Evarrest in the EEA could result in the elimination of Tachosil's closest potential competitor.
- (26) Based on the above, the Commission considers that the second substantive legal requirement for an Article 22 referral request is met.
- (27) On the basis of the *prima facie* analysis submitted by Germany, the Commission considers, without prejudice to the outcome of its investigation that the concentration threatens to significantly affect competition within the territory of Germany. In view of the foregoing, the Commission concludes that the second substantive legal requirement for an Article 22 referral is met.

3.3. Appropriateness of the referral

- (28) Pursuant to paragraph 45 of the Referral Notice, referrals of concentrations already notified should normally be limited to those cases which appear to present a real risk of negative effects on competition and trade between Member States and where it appears that these would be best addressed at the Community level.
- (29) One of the categories of cases normally most appropriate for referral under Article 22 of the Merger Regulation are cases giving rise to serious competition concerns in a series of national or narrower than national markets located in a number of EEA countries, in circumstances where coherent treatment of the case

(regarding possible remedies, but also, in appropriate cases, the investigative efforts as such) is considered desirable, and where the main economic impact of the concentration is connected to such markets.⁶

- (30) In the present case, at this stage of the procedure, it appears that the Transaction could threaten to significantly affect competition in a series of national markets in EEA countries which have requested a referral to the European Commission, namely in Germany, Austria, Spain, France, Finland and Norway. In this respect, it should be noted that the main economic impact of the Transaction is connected to these EEA countries, which account for more than [...] % of the Target’s turnover in the EEA.
- (31) Without prejudice to the outcome of a full investigation, and based on the information available at this stage, the Commission notes that the Parties’ combined market shares in the above-mentioned EEA countries appear to be very high (under one possible market definition for which market shares are available at this stage):

Table 1 - Market shares of the Parties in the EEA countries which have requested a referral to the Commission, based on the EphMRA ATC 3 classification, Group B2F “Tissue Sealing Preparation”

EEA country	Market shares in volume (Q1 2018)			Market shares in value (Q1 2018)		
	J&J	Tachosil	Combined	J&J	Tachosil	Combined
Germany	[50-60]%	[0-5]%	[60-70]%	[60-70]%	[0-5]%	[60-70]%
Austria	[5-10]%	[60-70]%	[70-80]%	[10-20]%	[60-70]%	[70-80]%
Spain	[0-5]%	[50-60]%	[50-60]%	[0-5]%	[50-60]%	[50-60]%
Finland	[20-30]%	[40-50]%	[60-70]%	[10-20]%	[50-60]%	[60-70]%
France	[20-30]%	[30-40]%	[60-70]%	[10-20]%	[30-40]%	[50-60]%
Norway	[5-10]%	[70-80]%	[80-90]%	[5-10]%	[80-90]%	[80-90]%

Source: IMS – Q1 2018. Market shares in 2017 do not vary significantly.

- (32) A coherent treatment of the case in terms of investigative efforts appears desirable for the several reasons.
- (33) First, the Transaction is notifiable in three Member States (namely Germany, Austria, and Spain). These multiple notifications of the same Transaction increase legal uncertainty and may lead to conflicting assessments. In particular, in the absence of precedents from the Commission or national competition authorities in this sector, it is important to adopt a consistent product market definition across the EEA.
- (34) Second, the examination of the Transaction will have to address the competitive significance of J&J’s branded dual effect haemostatic patch Evarrest and thus to clarify why J&J decided to exit the whole of the EEA in 2017 and whether (and under what conditions) a (re)authorisation by the European Medicines Agency would be possible.

⁶ Referral Notice, paragraph 45.

- (35) Third, the Parties' competitors are active throughout the EEA (directly or through distributors) and it would be more efficient for the Commission to centralise contacts with competitors in one merger review procedure.
- (36) Finally, a coherent treatment of the case in terms of potential remedies is desirable, taking into account that the Parties' manufacturing facilities are located in few locations worldwide, serving several EEA countries.
- (37) Therefore, it is appropriate to refer the Transaction to the Commission pursuant to Article 22 of the Merger Regulation.

4. CONCLUSION

- (38) In view of the foregoing, the Commission has decided to examine the concentration by which J&J acquires sole control over Tachosil. This decision is based on Article 22(3) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Member of the Commission