EUROPEAN COMMISSION

Hearing Officer for competition proceedings

Brussels, 30 April 2021

Final Report of the Hearing Officer[1]

Case M.8181 – Merck/Sigma-Aldrich (Article 14(1) Procedure)

I. INTRODUCTION

1. This report concerns a draft decision (the 'Draft Decision') pursuant to Article 14(1) of Council Regulation (EC) No 139/2004[2] (the 'Merger Regulation'). The Draft Decision finds that Sigma-Aldrich Corporation ('Sigma') intentionally or negligently provided incorrect and/or misleading information to the Commission during the review of the acquisition by Merck KGaA ('Merck') of sole control over Sigma in Case *M.7435 – Merck/Sigma Aldrich* (the 'Merger Review').[3] According to the Draft Decision, Sigma provided incorrect and/or misleading information in its response to two Commission requests for information made pursuant to Article 11(2) of the Merger Regulation and in the Final Form RM, submitted under Article 20(1a) of Council Regulation (EC) 802/2004[4] (the 'Implementing Regulation').

II. BACKGROUND

2. On 15 June 2015, following the Merger Review, the Commission declared the acquisition by Merck of Sigma compatible with the internal market, subject to certain remedies (the 'Merger Decision'). The remedies package approved by the Merger Decision included the divestiture of most of Sigma's solvents and inorganics business in the EEA (the 'Divestment Business'). The closing of the agreement between Merck and Sigma was conditional on the signing of an agreement for the sale of the Divestment Business with a suitable purchaser approved by the Commission.

3. On 19 and 20 October 2015, Merck and Sigma signed an agreement with Honeywell International Inc. ('Honeywell') for the sale of the Divestment Business. This agreement included a schedule that listed certain assets that were explicitly excluded from the scope of the business that Sigma would sell to Honeywell (the 'Excluded Assets Schedule'). The Excluded Assets Schedule included a reference to a patent application entitled '*closure for a container*,' which was in fact a reference to

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1 Pursuant to Articles 16 and 17 of Decision 2011/695/EU of the President of the European Commission of 13 October 2011 on the function and terms of reference of the hearing officer in certain competition proceedings, OJ L 275, 20.10.2011, p. 29 ('Decision 2011/695/EU').

2 Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (OJ L 24, 29.1.2004, p.1).

3 Sigma and Merck are referred to together in the present report as 'the Parties'.

4 Commission Regulation (EC) No 802/2004 of 21 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ L 133, 30.04.2004, p. 1-39).

Sigma's iCap project. ICap, a project jointly developed by Sigma and Metrohm AG, is an intelligent bottle cap that seals liquid chemical bottles and connects them to titration instruments.

4. On 10 November 2015, the Commission approved Honeywell as a suitable purchaser of the Divestment Business and on 18 November 2015, Merck completed the acquisition of Sigma. On 15 December 2015, Honeywell completed the acquisition of the Divestment Business.

5. On 10 February 2016, the monitoring trustee appointed in Case M.7435 ('Monitoring Trustee') informed the Directorate General for Competition ('DG Competition') of Honeywell's claim that iCap should have been part of the Divestment Business. According to Honeywell, iCap was of the utmost importance for the viability of the Divestment Business and had been inappropriately included in the Excluded Assets Schedule.

6. On 29 July 2016, the Commission informed Merck that proceedings were ongoing concerning the possible provision of incorrect and/or misleading information by Merck and Sigma with a view to the possible imposition of fines pursuant to Article 14(1) of the Merger Regulation.

III. LEGAL PROFESSIONAL PRIVILEGE CLAIMS

7. On 14 October 2016, the Commission adopted two decisions pursuant to Article 11(3) of the Merger Regulation requesting Merck and Sigma to provide the email data of certain Merck and Sigma individuals generated in 2015 ('the October Article 11(3) Decisions').[5] While Merck and Sigma did provide certain documents, their response was not considered by the Commission to be complete, in particular because of Merck and Sigma's legal professional privilege ('LPP') claims that were considered to be too broad. Consequently, on 1 December 2016, the Commission adopted two new decisions pursuant to Article 11(3) of the Merger Regulation requesting the information which had not been provided by Merck and Sigma in response the October Article 11(3) Decisions (the 'December Article 11(3) Decisions').[6] Merck and Sigma provided responses to the December Article 11(3) Decisions in December 2016 and January 2017 and submitted updated privilege logs in February 2017, March 2017, April 2017 and June 2017.

8. However, DG Competition and Merck continued to disagree on the scope of Merck's LPP claims and, as a result, on 30 August 2017, Merck requested that the Hearing Officer examine, under Article 4(2)(a) of Decision 2011/695/EU, Merck's claims that certain documents sought by the Commission in the context of proceedings under Article 14(1) of the Merger Regulation (the 'Contested Documents') are covered by LPP. Merck submitted the Contested Documents to the Hearing Officer in an acceptably secure format on 7 November 2017.[7]

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5 C(2016) 6772 (final) (Merck), C(2016) 6771 final (Sigma).

6 C(2016) 8202 (final) (Merck), C(2016) 8210 (final) (Sigma).

7 Merck initially requested the Hearing Officer to examine Merck's LPP claims over 9.635 documents but this was subsequently reduced to 7.980 documents following initial comments by the Hearing Officer on the scope of LPP under EU law.

9. The two Hearing Officers in function at the time decided that one of them, Mr Stragier, would act as Hearing Officer with respect to Merck's request under Article 4(2)(a) of Decision 2011/695/EU and that the other one, Mr Wils, would act as Hearing Officer for all other purposes in Case M.8181, and that the latter would not have access to the Contested Documents.

10. On 1 August 2018, pursuant to Article 4(2)(a) of Decision 2011/695/EU, the Hearing Officer sent his preliminary view regarding the privileged nature of certain Merck documents to the director responsible for this case, and to Merck. The preliminary view was, in essence, that Merck's general arguments were in large measure misconceived or exaggerated and that the inadequate manner in which its numerous specific claims were presented meant that they could not be further entertained on the basis of Merck's application of August 2017. On 8 September 2018, Merck replied to the preliminary view, contesting its findings, but encouraging the Hearing Officer to propose appropriate steps to promote a '*mutually acceptable solution*' to the matter pursuant to Article 4(2)(a) of Decision 2011/695/EU. On 16 October 2018, the Hearing Officer chaired a meeting between DG Competition and Merck in which solutions to the issue of the Contested Documents were discussed.

11. On 9 November 2018, Merck agreed to a protocol that would allow DG Competition to access the Contested Documents in a data room (the 'Protocol'). On 23 November 2018, DG Competition, following a review under the procedure described in the Protocol, identified certain documents that it wished to rely on in its investigation and invited Merck to waive its LPP claims regarding these documents. Merck agreed to waive its claims in relation to some of the documents but not in relation to others. On 2 May 2019, members of DG Competition's case team attended a meeting with Merck's legal counsel, during which the case team took notes on the documents over which Merck continued to claim LPP. These notes were added to the Commission's file in the present case for the sole purpose of a possible procedure rejecting the LPP claims on those specific documents.[8]

IV. STATEMENT OF OBJECTIONS AND FIRST ORAL HEARING

12. The Commission addressed a statement of objections ('SO') to Merck and Sigma on 7 July 2017, and provided access to the file on 10 July 2017. In the SO, the Commission preliminarily concluded that, during the Merger Review, both Merck and Sigma had infringed Article 14(1) of the Merger Regulation by intentionally (in the case of Sigma) or at least negligently (in the case of Merck) providing incorrect and/or misleading information to the Commission.

13. The Parties' initial deadline to provide comments of 31 August 2017 was extended on several occasions, primarily in order for the Commission to determine a possible range of fines that might be imposed on the Parties in the event that they would enter into a cooperative settlement. On 30 April 2018, the Parties informed DG

[8] Pursuant to the Protocol, the Commission could decide to launch proceedings to reject Merck's LPP claims over certain documents, in case Merck maintained its claims over documents that, in the Commission's view, would not be covered by LPP. Decision 2011/695/EU does not give the Hearing Officer decision-making powers in relation to LPP claims, but only the ability to formulate a reasoned recommendation to the competent member of the Commission, without revealing the potentially privileged content of the document. Given the agreement between DG Competition and Merck, there was no need for such a recommendation by the Hearing Officer.

Competition that they were not willing to enter into a cooperative settlement under the terms proposed by the Commission. The Parties provided their written comments to the SO ('SO response') on the same day and made a request for further access to the file.

14. Following the request for further access to the file, DG Competition provided a number of additional documents to the Parties on a rolling basis. The last outstanding documents were sent to the Parties on 5 October 2018.

15. In the SO response, the Parties requested the opportunity to develop their arguments at an oral hearing. The oral hearing ('first oral hearing') was held on 11 September 2018.

16. On 12 November 2018, the Parties provided a supplementary reply to the SO, in particular including their observations following the additional access to the file.

V. SUPPLEMENTARY STATEMENT OF OBJECTIONS AND SECOND ORAL HEARING

17. On 30 June 2020, the Commission adopted a supplementary statement of objections ('SSO') against Sigma. The SSO fully replaced the SO and did not maintain the allegations in the SO concerning Merck.

18. In the SSO, the Commission preliminarily concluded that, by not disclosing iCap to the Commission during the Merger Review, Sigma, intentionally or at least negligently, supplied incorrect and/or misleading information: (a) within the meaning of Article 14(1)(b) of the Merger Regulation in its replies to two requests of the Commission made pursuant to Article 11(2) of the Merger Regulation and (b) within the meaning of Article 14(1)(a) of the Merger Regulation in a submission of information and documents in the Form RM prescribed in Annex IV of the Implementing Regulation.

19. Sigma was granted access to the file on 7 July 2020 and provided its written comments to the SSO on 15 September 2020 (the 'SSO response'), within the (extended) deadline specified by DG Competition.

20. In the SSO response, Sigma requested the opportunity to develop its arguments at an oral hearing. This oral hearing ('second oral hearing') took place on 13 November 2020.[9]

VI. SIGMA'S CLAIMS REGARDING LACK OF IMPARTIALITY

VI.1. Sigma's arguments

21. In both the first oral hearing and the second oral hearing, as well as in the SO response[10] and SSO response,[11] Sigma (and Merck) argued that the setup of the

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9 Due to the ongoing coronavirus pandemic, the second oral hearing was held remotely by secure encrypted videoconference as well as via a password protected (web streamed) virtual listening room for persons that did not need to speak at the second oral hearing.

10 SO response, paragraphs 147, 148 and 322.

11 SSO response, paragraphs 284 – 294.

investigation in Case M.8181 was prone to bias and therefore infringed the principles of impartiality and good administration. According to Sigma, the issue of bias arises because of the particular circumstances of the case, which involves allegations of Sigma providing misleading information to the case team during the Merger Review, and the fact that these allegations are being investigated by the same case team that is the '*victim*' of the allegedly misleading behaviour.[12] In the SSO response, Sigma, referring to Court of Justice ('Court') and European Court of Human Rights ('ECtHR') case-law on impartiality,[13] argued that the investigation in the present proceedings was set up in such a way so as to give the '*strong impression that the investigation was not objectively impartial*.' Sigma also argued that certain aspects of the investigation suggest that the case team '*might not have been completely subjectively impartial*.' In support of its arguments, Sigma presented a number of factual arguments that it argued supported its view that the handling of the case by the Commission lacked impartiality, including the following:

a. The fact that the SO included a reference to an internal email from Sigma's in-house counsel about the case manager '*being obstinate*',[14] without this being clearly related to the substance of the case.[15,16]

b. The Commission's press release of 6 July 2017 announcing the adoption of an SO,[17] which included a statement that '*[iCap] was closely linked to the divested business and had the potential to substantially increase its sales. By not including it, the viability of the divested business was impaired.'* According to Sigma, the wording of the press release was inappropriate as it '*drew firm conclusions about iCap's role for the Divestment Business and refused to grant Sigma (and, at the time, Merck) the required benefit of doubt*.'[18]

c. In the SO, the case team showed an '*undue eagerness to rely on evidence supporting its conclusions at first sight*,' including by unduly relying on Honeywell's submissions.[19] In the same vein, in the SSO (according to Sigma)

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12 SSO response, paragraph 286.

13 In Section 5.1 of the SSO response and during the second oral hearing, Sigma referred to *Ziegler v Commission*, C-439/11 P, EU:C:2011:815 ('*Ziegler*'), paragraph 155; *Spain* v *Council of the European Union*, C-521/15, EU:C:2017:982 ('*Spain v Council*'), paragraph 91; *Padovani v Italy*, 13396/87, 26 February 1993 paragraph 25; *Grande Stevens and others v Italy*, 18640/10, 4 March 2014, paragraph 137 and *Toziczka v. Poland*, 29995/08, 24 July 2012, paragraph 36. During the second oral hearing, Sigma also referred to the recent judgment in *August Wolff and Remedia v Commission*, C-680/16 P, EU:C:2019:257 ('*August Wolff*'). In paragraph 282 of the SSO response and during the second oral hearing, Sigma also cited a number of judgments of courts of England and Wales or of the United Kingdom but did not explain why these were relevant for the interpretation of EU law.

14 SO, footnote 351.

15 SSO response, paragraph 290.

16 As the SSO response acknowledges, this reference was deleted in the SSO.

17 Commission's Press Release of 6 July 2017 titled '*Commission alleges Merck and Sigma-Aldrich, General Electric, and Canon breached EU merger procedural rules*,' IP/17/1924 ('the press release').

18 SSO response, paragraph 292(a).

19 For example, in paragraph 292(e) of the SSO response, Sigma states that '[i]*n the spring of 2016, the case team initially accepted Honeywell's idea that iCap was a key project, which clouded the case at the stage of the Statement of Objections of 6 July 2017 and continues to cloud it now. […]*.'

the case team also '*mischaracterised the documents and market test results in relation to the alleged importance of R&D*.'[20]

d. The case team, while (according to Sigma) at first recognising that the clear text of the Commitments and the Excluded Assets Schedule of the Sale and Purchase Agreement between Merck and Honeywell[21] did not leave much room for an investigation, still informed Honeywell that it '*will see what can be done*.'[22]

e. The SSO implies a '*dual standard as to the level of diligence that different players in the merger review process are expected to show*.'[23] Sigma argues that while, on the one hand, the SSO purports to hold Sigma quasi-criminally liable for not disclosing iCap, on the other hand, the SSO does not expect the case team (or the Monitoring Trustee) to have noticed a reference to iCap in the Excluded Assets Schedule.

22. Finally, Sigma argued that the current proceedings differ from those in *GE/LM Wind*[24] where the Hearing Officer, in his Final Report,[25] rejected General Electric's arguments that a similar investigation set up (*i.e.*, one where the case team was responsible for both the authorisation procedure and the misleading information investigation) created an appearance of bias.[26] In the *GE/LM Wind* Final Report, the Hearing Officer concluded that General Electric's allegations of objective bias were unconvincing, in particular because these overlooked '*(i) the fact that a final decision in these proceedings is not one of the Case Team but of the Commission as an institution, acting through the College, at the end of a procedure involving numerous actors other than the Case Team, and (ii) the associated internal checks and balances in proceedings for the application of Article 14 EUMR*.'[27] According to Sigma, the current proceedings differ from those in *GE/LM Wind* because (a) the evidence demonstrates that the setup of the investigation gave rise to an appearance of bias; (b) Sigma (contrary to General Electric) expressed its concerns regarding bias during the first oral hearing; and (c) the involvement of '*numerous actors*' in the proceedings does not alleviate the appearance of bias, as the investigation in Case M.8181 has been '*driven from the outset*' by the case team. In Sigma's view, the involvement of the Commission's hierarchy in the approval of the final decision might remedy manifest instances of bias, but is not a sufficient safeguard when the overall setup of the case is affected by objective bias. According to Sigma, none of the '*numerous actors*' involved in the proceedings carried out a detailed review of the facts and

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20 SSO response, paragraph 292(c).

21 The Excluded Assets Schedule listed a number of assets that were intended to be excluded from the scope of the business sold to Honeywell. The patent relating to iCap was listed in this Excluded Assets Schedule.

22 SSO response, paragraph 292(d).

23 SSO response, paragraph 293.

24 Case M.8436 - *General Electric Company / LM Wind Power Holding (Art. 14.1 procedure)*.

25 Final Report of the Hearing Officer - *General Electric Company/LM Wind Power Holding* (Art. 14), 2020/C 24/05, OJ C 24, 24.1.2020, p. 7–11 ('*GE/LM Wind* Final Report').

26 SSO response, paragraphs 295 – 302.

27 *GE/LM Wind* Final Report, paragraph 17.

documents to form an independent, informed opinion and they had to rely on the information presented to them by the case team.

VI.2. Consideration of Sigma's arguments

VI.2.1. General principles

23. It must be first recalled that the Court has consistently stated that the Commission is not a court or tribunal within the meaning of Article 6 of the European Convention of Human Rights and Article 47 of the Charter of Fundamental Rights of the Union ('the Charter').[28] The Court has also affirmed that the European Union system of review is compatible with Article 6 of the European Convention of Human Rights and Article 47 of the Charter.[29]

24. With this in mind, it is apparent that the ECtHR case law cited by Sigma (mentioned in footnote 13 above) is not directly relevant in this context, as it refers to the requirement of impartiality by *courts*. Sigma's reference to *Ziegler* is also not supportive of its position: in that case, the Court actually found that since Commission decisions are subject to review by the European Union judicature and European Union law lays down a system enabling the courts to review Commission decisions, the Commission could not be regarded as both the '*victim*' of an infringement and the '*judge*' responsible for imposing penalties for the infringement.[30]

25. This does not, of course, imply that the Commission (as an administrative body) is exempt from the requirement to act with impartiality. To the contrary, the right to good administration, as enshrined in Article 41 of the Charter, requires that every person has the right to have his/her affairs handled impartially. In that regard, it becomes relevant to consider whether the Commission has, in this case, acted in an impartial manner. As is apparent from the case-law of the Court, the requirement of impartiality encompasses both subjective and objective elements.[31]

VI.2.2. Considerations on subjective impartiality

26. Sigma's arguments concerning subjective impartiality are not particularly convincing and, for the reasons described below, any arguments of actual bias on behalf of the *case team* become less relevant when the Commission's decision-making process is fully considered.

27. Concerning the press release, even if part of the wording may be criticised (in that it may have given the impression that the Commission prejudged the assessment of certain facts), Sigma's complaint is ultimately not convincing, since the press release

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28 See *Musique Diffusion française and Others v Commission*, Joined Cases C-100/80 to 103/80, EU:C:1983:158 paragraph 7.

29 See *Otis* v *Commission*, C-199/11, EU:C:2012:684, paragraphs 56-64 and *Chalkor* v *Commission*, C-386/10 P, EU:C:2011:815, paragraph 67.

30 See *Ziegler*, paragraph 159.

31 See *Ziegler*, paragraph 155, *Gorostiaga Atxalandabaso v Parliament*, C-308/07 P, EU:C:2009:103, paragraph 46, Opinion of AG Kokott in *Spain v Council*, C-521/15, EU:C:2017:420, paragraphs 97-115.

made clear that the SO's conclusions were preliminary.[32] The preliminary nature of the Commission's position at the time of the press release and the existence of the '*benefit of doubt*' is in fact perfectly illustrated by the fact that Merck, while an addressee of the SO, is not an addressee of the Draft Decision.

28. As regards Sigma's argument that the Commission was unduly eager to use evidence supporting its conclusions at first sight, Sigma seems to merely be attacking the SO's and SSO's use of (in its view) incorrect evidence as proof of the case team's '*enthusiasm*' and bias. However, the essence of a statement of objections is to provide parties with the opportunity to comment on the Commission's case, including its use of evidence. The allegation that the Commission has used the evidence incorrectly cannot, as such, amount to evidence of bias. Even if Sigma would be correct in stating that the Commission had misinterpreted certain evidence, this does not, in itself, demonstrate partiality, but, at worst, might betray a poor understanding of a document.[33]

29. Sigma's argument in relation to '*dual standards*' as set out in paragraph 21(e) above is similarly unconvincing since the issue at stake in Case M.8181 is whether *Sigma* intentionally or negligently provided incorrect and/or misleading information to the Commission. Whether or not the case team could have identified the existence of iCap in the Excluded Assets Schedule is not relevant to the finding of an infringement and Sigma does not explain why it would lead to a bias in the investigation. In addition, Sigma fails to explain why the Commission's standard of care in discharging its duties in the present case should be aligned to Sigma's in the circumstances that gave rise to the present case, where information asymmetry between Sigma and the Commission was particularly pronounced.[34]

30. In any case, even if it were to be accepted that Sigma had demonstrated subjective bias on the part of one or more members of the case team, that would not suffice to show that the Commission, as an institution, was subjectively biased, as Sigma appears to suggest.[35]

VI.2.3. Considerations on objective impartiality

31. The Court has repeatedly stated that the fact that the Commission, as an administrative body, carries out the functions of investigating and imposing penalties does *not* constitute a breach of the requirement of impartiality, since its decisions are

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32 Specifically, the press release stated that '*The Commission has informed the German company Merck KGaA and Sigma-Aldrich of its* ***preliminary conclusion*** *that the companies have provided incorrect or misleading information in the context of Merck's acquisition of Sigma-Aldrich. …The Commission's* ***preliminary conclusion*** *is that Merck and Sigma-Aldrich failed to provide the Commission with important information about an innovation project with relevance for certain laboratory chemicals at the core of the Commission's analysis.*' (emphasis added).

33 See, by analogy, *JCB Service v Commission*, T-67/01, EU:T:2004:3, paragraph 55.

34 Sigma's argument that the Commission should have noticed the mention of iCap in the Excluded Assets Schedule is in any case unrelated to the facts that may give rise to an infringement under Article 14(1) of the Merger Regulation. Even if the Commission had noticed that iCap was mentioned in the Excluded Assets Schedule, this would not have had any bearing on whether Sigma had negligently or intentionally provided incorrect and/or misleading information during the Merger Review.

35 See, by analogy, *ABB Asea Brown Boveri v Commission*, T-31/99, EU:T:2002:77, paragraph 104.

amenable to review by the EU judicature.[36] The essence of this case is whether the facts of the current proceedings are somehow different to other competition law cases where the Commission acts both as investigator and as decision-maker or whether there are '*sufficient guarantees to exclude any legitimate doubt as to bias*.'[37]

32. At the outset, it should be recalled that while the case team undoubtedly has an important function in the investigative process, it does not decide on the outcome of the case: this duty is performed by the College of Commissioners.[38] Furthermore, an allegation of bias of this sort ignores the system of checks and balances built in the Commission's internal decision-making procedures. The adoption of any decision necessitates the involvement of a number of actors.[39] Sigma's argument that the numerous actors involved in the decision-making process were not a '*sufficient safeguard*' because they had '*not carried out a detailed review of the facts and documents to form an independent, informed opinion in the case*' is not credible in this case. The involvement of these actors was instrumental in reducing the scope of the Commission's case, since the SSO did not (contrary to the SO) address any objections to Merck and provided Sigma with an opportunity to present its arguments during the second oral hearing. Sigma itself acknowledged the efficacy of the oral hearing process during comments in the second oral hearing,[40] which would indicate that Sigma's view is that the oral hearing provides an effective forum for parties to present their case to a wider audience than the case team, which can lead to a case being narrowed in scope or even dropped entirely.

33. The judgments in *Spain v Council* and *August Wolff* (cited by Sigma during the second oral hearing and/or in the SSO response) do not support Sigma's arguments either. In *Spain v Council*, Spain challenged a Council decision by which the latter imposed a fine on Spain for the misrepresentation of deficit data, following an investigation and recommendation by the Commission. Spain argued that the Commission breached the requirement of objective impartiality by entrusting the conduct of the investigation in question to largely the same team that had taken part in prior routine visits and assessments to verify the quality of certain data (including deficit data) provided by Spain prior to the start of the relevant procedure. In rejecting Spain's arguments that objective impartiality was breached, the Court noted, first, that the investigation leading to the Commission's recommendation to impose a fine and the visits and assessments of the quality of deficit and other data fall within

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36 See *Bollore v Commission*, T-372/10, EU:T:2012:325, paragraph 66 and *Enso Española v Commission*, T-348/94, EU:T:1998:102, paragraphs 56 to 64.

37 See *Ziegler*, paragraph 155.

38 See, by analogy, *Chronopost SA v. Commission*, C-341/06, EU:C:2007:20, paragraph 54.

39 The relevant actors (other than the case team dealing with the case) include the Commissioner for Competition, assisted by the members of their *cabinet*; DG Competition's senior management, including the Director-General of DG Competition; DG Competition's relevant horizontal coordination unit; the Chief Economist's Team (where appropriate); the Legal Service; '*associated services*' in the Commission, the Hearing Officer and the Advisory Committee on concentrations. Furthermore, the system also foresees the possibility of a '*peer review*' exercise within the Commission, which did take place in the present proceedings.

40 Specifically, during the oral hearing, one of Sigma's legal representatives, stated that '*oral hearings **do** work'* (emphasis added) and that the current proceeding '*perfectly illustrates the value of such hearings*.'

separate legal frameworks and have different purposes.[41] Therefore, the prior visits and assessments of the quality of the data did not, in themselves, prejudge the view that might be taken by the Commission regarding the existence of misrepresentations relating to the same data.[42] Second, the Court noted that the relevant regulations did not entrust a given Commission department[43] with the power to decide to initiate the investigation procedure, the responsibility for conducting the investigation or the power to submit to the Council the recommendation necessary at the conclusion of the investigation. This power was given to the Commission, an institution acting as a collegiate body. As a consequence, the Court found that the role assigned to the Commission staff in the investigation procedure could not be regarded as '*decisive*' for either the conduct or the outcome of that procedure.[44]

34. In *August Wolff,* the Court, applying similar considerations as in *Spain v Council*, concluded that the requirement of objective impartiality was *not* met in relation to the procedure under appeal. *August Wolff* concerned the referral by the competent German authority (BfArM) to the Committee of Medicinal Products for Human Use ('Committee') of the refusal of the marketing authorisation of a certain medicinal product. The question of breach of objective impartiality arose because the Committee appointed a chief rapporteur from Germany to prepare its opinion, while this rapporteur was also an employee of the BfArM. At the time of the referral to the Committee, the BfArM was engaged in litigation with the appellants in relation to its refusal to renew the marketing authorisation of the medicinal product in question. The Court considered the following factors as relevant for its analysis on objective impartiality: that the procedure before the BfArM and the procedure before the Committee aimed at fulfilling the same substantive purpose[45] and were also regarded as being of the same nature; that the Committee rapporteur takes on an important role in preparing the opinion which the Committee is called upon to issue and has responsibilities of their own in that procedure; and that it was only in exceptional circumstances that the Commission would be justified in not following the Committee's opinion.[46] According to the Court, third party observers could legitimately consider that the BfArM, by referring the matter to the Committee, was continuing to pursue its own national level interests and that persons employed by the

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41 Specifically, the prior visits were based on Article 8(1) of Regulation 479/2009, of 25 May, on the application of the Protocol on the excessive deficit procedure annexed to the Treaty establishing the European Community (OJ 2009 L 145, p. 1), and had the purpose of enabling the relevant Commission department (Eurostat) to assess the quality of the debt and deficit data reported twice a year by Member States. In contrast, the investigation procedure was based on Article 8(3) of the same Regulation, and had the purpose of enabling the Commission to conduct all investigations necessary to establish the existence of misrepresentations of that data, made either intentionally or by serious negligence, where it finds that there are serious indications of the existence of facts liable to constitute such a misrepresentation. *Spain v Council*, paragraphs 96-98.

42 See *Spain v Council*, paragraph 100 - 101.

43 In that case, Eurostat.

44 See *Spain v Council*, paragraphs 102 – 104.

45 Namely to decide on the quality, safety and efficacy of medicinal products for the purposes of granting marketing authorisation.

46 See *August Wolff,* paragraphs 31 - 35.

BfArM who are involved in the procedure before the Committee may not act impartially.[47]

35. The analysis conducted by the Court in the above-mentioned cases does not point to a finding of a breach of objective impartiality in the current proceedings. In both *Spain v Council* and *August Wolff*, the Court found that the commonality of the purpose of the two procedures that gave rise to a claim of conflict of interest to be a key consideration in its assessment. In *August Wolff*, the German and European procedures were both aimed at granting a marketing authorisation for the medicinal product in question. As a consequence, the German rapporteur inevitably faced a conflict of interest in the European process, since she could not be seen to be impartial when her employer had not only already refused the marketing authorisation in question, but was also engaged in litigation with the appellants on the issue. In *Spain v Council* on the other hand, the Court noted that the Commission investigation regarding the misrepresentations made in connection with certain deficit data, and the prior routine assessment of the quality of the same data fulfilled different purposes and therefore found that the prior assessment work did not prejudge the view that might be taken by the Commission regarding the subsequent investigation on misrepresentations.

36. Applying the above considerations to the current proceedings, it appears that the object and nature of the investigation in Case M.7435 and that of the investigation in Case M.8181 are different. Indeed, the investigation in M.7435 was aimed at reaching a decision on the authorisation of a merger based on Articles 8(1) to 8(3) of the Merger Regulation. The investigation in M.8181, on the other hand, aims to determine whether Merck and/or Sigma (negligently or intentionally) provided incorrect and/or misleading information to the Commission within the context of the Merger Review on the basis of Article 14(1) of the Merger Regulation. It is not clear how the case team's review of M.7435 would prevent it from acting impartially in M.8181.

37. Furthermore, the Court in *August Wolff* pointed to the particular importance of the rapporteur in the decision-making process in that case, stating that they have '*an important role in preparing the opinion*' and '*responsibilities of their own*'. Similarly, in *Spain v Council* the Court considered whether the role of the individuals accused of lacking impartiality was '*decisive*' for the conduct or the outcome of the procedure. In the current proceedings, the case team, while holding an important position in relation to the investigation, does not have responsibility for the decision-making role. Contrary to Sigma's assertion that '*the investigation in M.8181 has been driven from the outset by the case team*,'[48] the fact is that actors other than the case team have had a decisive role in reshaping the case and in reducing the scope of the possible infringement when compared to that described in the SO. This is certainly not a situation where the position of the case team would only '*exceptionally*' not be followed by the Commission, as was the case in *August Wolff*.

38. In light of the above considerations, Sigma's arguments regarding lack of impartiality are unconvincing.

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47 See *August Wolff*, paragraphs 38 - 39.

48 SSO response, paragraph 300.

VII. CONCLUDING REMARKS

39. The Draft Decision pursuant to Article 16(1) of Decision 2011/695/EU only deals with objections in respect of which Sigma has been afforded the opportunity of making its views known.

40. Overall, it can be concluded that the effective exercise of procedural rights has been respected during the present proceedings.

Dorothe DALHEIMER
Hearing Officer

Wouter WILS
Hearing Officer