Reports of Cases

JUDGMENT OF THE GENERAL COURT (Second Chamber)

5 February 2018 *

(Access to documents — Regulation (EC) No 1049/2001 — Documents held by the EMA and submitted in the context of the application for marketing authorisation for the veterinary medicinal product Bravecto — Decision to grant a third party access to the documents — Exception relating to the protection of commercial interests — No general presumption of confidentiality)

In Case T-729/15,

MSD Animal Health Innovation GmbH, established in Schwabenheim (Germany),

Intervet international BV, established in Boxmeer (Netherlands),

represented initially by P. Bogaert, lawyer, B. Kelly and H. Billson, Solicitors, J. Stratford QC, and C. Thomas, Barrister, and subsequently by P. Bogaert, B. Kelly, J. Stratford, and C. Thomas

applicants,

v

European Medicines Agency (EMA), represented by T. Jabłoński, A. Spina, S. Marino, A. Rusanov and N. Rampal Olmedo, acting as Agents,

defendant,

ACTION under Article 263 TFEU for the annulment of Decision EMA/785809/2015 of the EMA of 25 November 2015, granting to a third party, pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), access to documents containing information submitted in the context of an application for marketing authorisation for the veterinary medicinal product Bravecto,

THE GENERAL COURT (Second Chamber),

composed of M. Prek (Rapporteur), President, E. Buttigieg and B. Berke, Judges,

Registrar: S. Spyropoulos, Administrator,

having regard to the written part of the procedure and further to the hearing on 16 May 2017,

gives the following

* Language of the case: English.

Judgment

Background to the dispute

1 The applicants, MSD Animal Health Innovation GmbH ('MSD') and Intervet international BV ('Intervet'), are both part of the Merck group of companies, which is a global healthcare leader.

2 In November 2012, Intervet submitted an application for a marketing authorisation (MA) for Bravecto, a veterinary medicinal product used to treat tick and flea infestations in dogs. MSD is the sponsor of five toxicology tests which were submitted to the European Medicines Agency (EMA) in the form of detailed non-clinical trial reports as part of the process of securing an MA for Bravecto.

3 On 11 February 2014, the Commission granted the MA for Bravecto chewable tablets in different strengths for dogs of different weights. Bravecto was thus authorised for the treatment of tick and flea infestations in dogs.

4 By email of 24 August 2015, the EMA notified the applicants that it had received a request from a third party seeking access, on the basis of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), to the five toxicology test reports contained in the Bravecto file. Since it planned to disclose the content of three of those five reports, the EMA invited the applicants to send it their proposed redactions with a view to disclosure of these three reports, grouped under the heading 'the batch 1 study reports', namely the Study C45151 (a dermal toxicity study in rats); Study C88913 (a dermal toxicity study in rats); and Study C45162 (an oral toxicity study in rats) (together, 'the batch 1 study reports').

5 By letter of 8 September 2015, the applicants indicated that they had identified the information in the batch 1 study reports which they regarded as confidential, attaching copies of the reports on which they had marked the parts they claimed to be confidential.

6 By decision EMA/671379/2015 of 9 October 2015 ('the decision of 9 October 2015'), the EMA informed the applicants that it accepted some of the proposed redactions — namely details on the concentration range of the active substance and on the internal reference standard used for the analytical tests, as well as references to future development plans — but rejected others.

7 By email of 19 October 2015, the applicants observed that, by the decision of 9 October 2015, the EMA was in fact rejecting their proposed redactions in respect of the majority of the information they regarded as confidential. They stated that each batch 1 study report fell under a presumption of confidentiality.

8 On 28 October 2015, the EMA and the applicants held a conference call. During the call the applicants set out the reasons why they considered that the information they had identified ought to remain confidential. The EMA, for its part, reiterated the position it had adopted in the decision of 9 October 2015.

9 By letter of 3 November 2015, the applicants observed that the batch 1 study reports were subject to a presumption of confidentiality and that they had proposed, strictly in the alternative, specific redactions to the study reports with accompanying justifications.

10 By letter of 25 November 2015 ('the contested decision'), the EMA indicated that the decision contained in that letter superseded that of 9 October 2015. It also stated that it maintained the position which had been set out in the previous decision and confirmed its decision to disclose the

documents which, in its view, were not confidential. Attached to the contested decision were justification tables setting out the updated reasons put forward by the applicants and the EMA's updated responses.

Procedure and forms of order sought

11 The applicants brought the present action on 17 December 2015. By a separate document of the same date, they brought an application for interim measures pursuant to Article 278 TFEU, for the suspension of operation of the contested decision.

12 By order of 20 July 2016, *MSD Animal Health Innovation and Intervet international* v *EMA* (T-729/15 R, not published, EU:T:2016:435), the President of the General Court suspended the operation of the contested decision.

13 The applicants claim that the Court should:

– annul the contested decision;

– order the EMA to pay the costs.

14 The EMA contends that the Court should:

– dismiss the action:

– order the applicants to pay the costs.

Law

15 In the contested decision, the EMA first of all noted that the reports concerned by the request for access to documents and which were the subject of the contested decision were the batch 1 study reports.

16 After stating that the contested decision annulled and superseded the decision of 9 October 2015, the EMA drew attention to the fact that it had granted an extension of the deadline to enable MSD to submit further arguments in order to show the confidential nature of the documents in respect of which the EMA considered that disclosure would not seriously undermine any ongoing or future decision-making process of the EMA, or the applicants' competitive position and economic interest. The EMA states that it examined the additional arguments submitted to it on 3 November 2015 and agreed to the proposed redactions of the details on the concentration range of the active substance and on the internal reference standard used for analytical tests as well as a request to establish residue limits. However, it refused to redact other data and referred in that regard to three tables each compiled from the studies and consisting of 64, 72 and 48 pages, respectively. The tables annexed to the contested decision thus contain the detailed reasons for its refusal.

17 In support of their action, the applicants put forward five pleas, alleging that (i) the batch 1 study reports are protected by Article 4(2) or (3) of Regulation No 1049/2001 pursuant to a general presumption of confidentiality, (ii) the batch 1 study reports constitute commercially confidential information protected by Article 4(2) of Regulation No 1049/2001, (iii) those study reports are protected by Article 4(3) of Regulation No 1049/2001 on the ground that their disclosure would undermine the EMA's decision-making process, (iv) no balancing exercise has been carried out in respect of the relevant interests and, (v) no proper balancing exercise has been carried out in respect of the competing interests.

First plea in law: The batch 1 study reports are protected by Article 4(2) or (3) of Regulation No 1049/2001 pursuant to a general presumption of confidentiality

18 In the first plea, the applicants submit in essence that there is a general presumption of confidentiality in respect of documents produced in the context of the MA procedure for a medicinal product and put forward in that regard the following arguments:

– in the sectoral legislation relating to medicinal products, the legislature provided for a specific disclosure regime which prevails over the access regime to documents laid down by Regulation No 1049/2001. That specific regime provides that documents submitted in the context of the MA procedure for a medicinal product are protected by a general presumption of confidentiality for the purposes of Article 4(2) of Regulation No 1049/2001;

– furthermore, it is the very essence of the MA regime that all documents submitted as part of an MA file, and in particular non-clinical and clinical studies, are protected by a general presumption of confidentiality for the purposes of Article 4(2) of Regulation No 1049/2001;

– the existence of that presumption is reinforced by the interpretation of Regulation No 1049/2001 and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), in the light of the requirements of the agreement on Trade-Related Intellectual Property Rights (TRIPS) of 15 April 1994 (OJ 1994 L 336, p. 214) ('the TRIPS agreement'), in particular Article 39(3) thereof;

– the general presumption of confidentiality must apply throughout the period of marketing data exclusivity and beyond, rather than expiring once the MA decision has been made. Any other interpretation would not be in accordance with the *effet utile* of Regulation No 726/2004;

– in any event, the reports should be presumed to be confidential at least until the anticipated decision-making processes have been completed;

– in accordance with the case-law, the batch 1 study reports all belong to the same category of documents and should fall under a general presumption of confidentiality, in order to guarantee that the objectives of the MA procedure are not jeopardised and ensure the integrity of the conduct of the bilateral procedure by limiting intervention by third parties. Moreover, the batch 1 study reports should be entitled to greater protection than the reports of the Committee for Medicinal Products, since they are documents generated by the applicants rather than by the Committee for Medicinal Products for Veterinary Use ('the CVMP');

– the EMA has failed to provide a sufficient statement of reasons as to why disclosure of parts of the batch 1 study reports was justified as an exception to the general presumption of confidentiality. On the contrary, without giving any reasons, the EMA applied an irrebuttable presumption that all information relating to the MA in question is disclosable, calling in question the non-disclosure policy that it had applied until 2010.

19 The EMA disputes those arguments.

20 In the context of that plea, the applicants submit in essence that the general presumptions of confidentiality justifying refusal of access applying to certain categories of documents also apply to the batch 1 study reports presented in the context of the MA procedure for Bravecto, provided for in Regulations Nos 141/2000 and 726/2004, and accordingly, that the disclosure of those documents

would in principle undermine commercial interests. Thus, the general presumption of confidentiality on which the applicants rely is based on the exception relating to the protection of their commercial interests, which is referred to in the first indent of Article 4(2) of Regulation No 1049/2001.

21 Under Article 2(3) of Regulation No 1049/2001, the provisions on public access to EMA documents apply to all documents held by that agency, that is to say, all documents drawn up or received by it and in its possession in all its areas of activity. Moreover, although that regulation is intended to give the fullest possible effect to the right of public access to documents of the institutions, that right is nonetheless subject to certain limitations based on grounds of public or private interest (judgment of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraph 85).

22 It must also be noted that the Court of Justice has recognised that it is open to the institutions and agencies concerned to base their decisions in that regard on general presumptions which apply to certain categories of documents, as considerations of a generally similar kind are likely to apply to requests for disclosure relating to documents of the same nature (judgment of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50). The existence of such a presumption does not exclude the right of the person concerned to demonstrate that a document whose disclosure has been requested is not covered by that presumption (judgment of 21 September 2010, *Sweden and Others* v *API and Commission*, C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 103).

23 However, it must be pointed out that the existence of a general presumption of confidentiality of certain categories of documents constitutes an exception to the obligation, laid down in Regulation No 1049/2001 on the institution concerned, to make a specific and individual examination of each document which is the subject of an application for access in order to determine whether it falls within the scope of one of the exceptions provided for in Article 4(2) of that regulation. In the same way that the case-law requires that the exceptions to disclosure referred to in the abovementioned provision be interpreted and applied strictly – inasmuch as they derogate from the principle of the widest possible public access to documents held by EU institutions (see, to that effect, judgments of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 75, and of 3 July 2014, *Council* v *in't Veld*, C-350/12 P, EU:C:2014:2039, paragraph 48) –, the recognition and application of a general presumption of confidentiality must be considered strictly (see, to that effect, judgment of 16 July 2015, *ClientEarth* v *Commission*, C-612/13 P, EU:C:2015:486, paragraph 81).

24 The Courts of the European Union have therefore identified, in several judgments, certain criteria for recognising such a presumption depending on the type of case.

25 First, it is apparent from a number of judgments of the Court of Justice that, in order for a general presumption to be validly relied upon against a person requesting access to documents on the basis of Regulation No 1049/2001, it is necessary that the documents requested belong to the same category of documents or be documents of the same nature (see, to that effect, judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50, and of 17 October 2013, *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:671, paragraph 72).

26 Moreover, the application of general presumptions may be dictated by the overriding need to ensure that the procedures at issue operate correctly and to guarantee that their objectives are not jeopardised. Accordingly, a general presumption may be recognised on the basis that access to the documents involved in certain procedures is incompatible with the proper conduct of such procedures and the risk that those procedures could be undermined, on the understanding that general presumptions ensure that the integrity of the conduct of the procedure can be preserved by limiting intervention by third parties (see, to that effect, Opinion of Advocate General Wathelet, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:528, points 66, 68, 74 and 76).

27 To that effect, for example, the Court has held that, so long as, during the pre-litigation stage of an inquiry carried out as part of an EU Pilot procedure, there is a risk of affecting the nature of the infringement procedure, altering its progress or undermining the objectives of that procedure, the application of the general presumption of confidentiality of the documents exchanged between the Commission and the Member State concerned is justified (see, to that effect, judgment of 25 September 2014, *Spirlea* v *Commission*, T-306/12, EU:T:2014:816, paragraphs 57 to 63).

28 Moreover, in all the cases which gave rise to the judgments establishing such presumptions, the refusal of access in question related to a set of documents which were clearly defined by the fact that they all belonged to a file relating to ongoing administrative or judicial proceedings (see, to that effect, judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 128; of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 49 and 50, and of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraphs 69 and 70).

29 Lastly, the Courts of the European Union consider that the application of specific rules provided for by a legal measure relating to a procedure conducted before an EU institution for the purposes of which the documents requested were produced is also one of the criteria for recognising a general presumption (see, to that effect, judgment of 11 June 2015, *McCullough* v *Cedefop*, T-496/13, not published, EU:T:2015:374, paragraph 91, and Opinion of Advocate General Cruz Villalón in *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:325, point 75). The exceptions to the right of access to documents contained in Article 4 of Regulation No 1049/2001 cannot be interpreted without taking account of the specific rules governing access to those documents, which are laid down in the relevant regulations.

30 Accordingly, the Court of Justice has pointed out that, under a procedure for the application of Article 101 TFEU, certain provisions of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 TFEU and 102 TFEU] (OJ 2003 L 1, p. 1) and Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles [101 TFEU and 102 TFEU] (OJ 2004 L 123, p. 18) lay down restrictive rules for the use of documents in the file relating to that procedure, since they provide that the parties to a proceeding under Article 101 TFEU do not enjoy an unlimited right of access to the documents in the Commission's file and that third parties, with the exception of complainants, do not, under such proceedings, have the right of access to the documents in the Commission's file. The Court of Justice has held that allowing generalised access, on the basis of Regulation No 1049/2001, to the documents in a file relating to a proceeding under Article 101 TFEU would jeopardise the balance which the EU legislature sought to ensure in Regulations Nos 1/2003 and 773/2004 between the obligation on the undertakings concerned to submit to the Commission possibly sensitive commercial information to enable it to ascertain whether a concerted practice was in existence and to determine whether that practice was compatible with Article 101 TFEU, on the one hand, and the guarantee of increased protection, by virtue of the requirement of professional secrecy and business secrecy, for the information so provided to the Commission, on the other. The Court of Justice concluded from this that the Commission, for the purpose of applying the exceptions provided for in the first and third indents of Article 4(2) of Regulation No 1049/2001, is entitled to presume, without carrying out a specific, individual examination of each of the documents in a file relating to a proceeding under Article 101 TFEU, that disclosure of those documents would, in principle, undermine the protection of the commercial interests of the undertakings involved in such proceedings (see, to that effect, judgment of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraphs 86, 87, 90 and 93).

31 It is also on the basis of that criterion that the General Court, on the contrary, found that no general presumption of confidentiality is to be inferred from the provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals

Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006, L 396, p. 1), since that regulation does not restrict the use of the documents in the file relating to an authorisation procedure for the use of a chemical substance, unlike the situations in which the Court of Justice and the General Court have accepted that the general presumptions justifying refusal of access to documents apply (see, to that effect, judgment of 13 January 2017, *Deza* v *ECHA*, T-189/14, EU:T:2017:4, paragraph 39).

32 In the present case, the documents at issue do not relate to ongoing administrative or judicial proceedings, since MA for Bravecto was issued on 11 February 2014 and the request for access to the documents at issue was made only on 24 August 2015. Thus, even if the case-law cited in paragraphs 26 and 27 above, according to which the application of a general presumption may be justified by the overriding need to ensure that the procedure concerned operates correctly, applies in the context of an MA procedure, disclosure of the documents at issue cannot alter that procedure, since the procedure was closed before the request for access to the documents at issue by a third party had been made.

33 Similarly, unlike the situations in which the Court of Justice and the General Court have accepted that the general presumptions of confidentiality justifying refusal of access to documents apply, Regulation No 726/2004 does not restrict the use of documents in the file relating to an MA procedure for a medicinal product. That regulation does not provide that access to the file is limited to the 'parties concerned' or to 'complainants'.

34 Regulation No 726/2004 provides expressly in Article 73 thereof that Regulation No 1049/2001 is to apply to documents held by the EMA and that the EMA's Management Board is to adopt the arrangements for implementing Regulation No 1049/2001. No other provision of Regulation No 726/2004 can be interpreted as evidence of the intention of the EU legislature to set up a system of restricted access to documents by means of a general presumption of confidentiality of documents.

35 Regulation No 726/2004 requires the EMA, in Article 11, Article 13(3), Article 36, Article 38(3) and Article 57(1) and (2) thereof, to publish three documents, namely the European Public Assessment Report ('the EPAR'), a summary of the characteristics of the medicinal products concerned and the user package leaflet, after deletion of all information of a commercially confidential nature. Those provisions mention the minimum information, by means of the three abovementioned documents, that the EMA is required to make publicly available in a proactive manner. The objective of the EU legislature is, first, that the characteristics of the medicinal product concerned and the manner in which it should be prescribed to patients should be indicated as intelligibly as possible to health-care professionals and, second, that the non-professional public should be informed in understandable language of the optimal method of using the medicinal product and of that product's effects. That proactive scheme of publishing a minimum amount of information does not therefore constitute a specific regulatory scheme on access to documents which should be interpreted as meaning that all data and information not contained in the three abovementioned documents is presumed to be confidential.

36 Articles 11, 12, 36 and 37(3) of Regulation No 726/2004 also reflect the legislature's intention that the MA procedure should be transparent, even where that procedure does not result in a decision or leads to a decision refusing MA. Those provisions provide that both information relating to an MA application that an applicant has withdrawn before an opinion has been given by the EMA and information concerning an MA application which has been refused must be made publicly accessible.

37 It follows that the prevailing principle in Regulations Nos 726/2004 and 1049/2001 is that of public access to information and that the exceptions to that principle are those referred to in Article 4(2) of Regulation No 1049/2001, including the exceptions relating to commercially confidential information. In view of the requirement of a strict interpretation recalled in paragraph 23 above, it must be held

that the EU legislature did not make any provision for a specific regulatory scheme on access to documents and, to that effect, did not establish a general presumption of confidentiality in respect of the batch 1 study reports.

38 In view of all the foregoing, it must be held that there is no general presumption of confidentiality of the documents and reports of an MA file for a medicinal product arising from the application of the combined provisions of Regulations Nos 1049/2001 and 726/2004. Thus, once the MA procedure for a medicinal product has ended, the documents in the administrative case file, including the safety study reports, cannot be considered to enjoy a general presumption of confidentiality on the implicit ground that they are, as a matter of principle and in their entirety, clearly covered by the exception relating to the protection of the commercial interests of MA applicants. It is thus for the EMA to satisfy itself, by means of a concrete, individual examination of each document in the administrative case file, whether the document is covered in particular by commercial secrecy for the purposes of the first indent of Article 4(2) of Regulation No 1049/2001.

39 Moreover, it should be added that, pursuant to Article 73 of Regulation No 726/2004, the EMA adopted the arrangements for implementing Regulation No 1049/2001. Similarly, in order to strengthen its policy on access to documents, the EMA adopted, on 30 November 2010, document EMA/110196/2006, entitled '[EMA] policy on access to documents (related to medicinal products for human and veterinary use)'. It is stated in that document that, whilst providing adequate protection of commercially confidential information, personal data and other specific interests, access to a requested document is to be denied only if one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 is considered to be applicable.

40 It should also be observed that, in applying its policy on access to documents, the EMA drew up document EMA/127362/2006, in which the output of its policy on access to documents related to medicinal products for human and veterinary use is set out. That document contains a table of output which was added to as the EMA gained more experience in the field of requests for access to documents. That table was supplemented by, first, document EMA/484118/2010 on the recommendations of the Heads of Medicines Agencies on transparency and, second, the joint guidance document of the EMA and the Heads of Medicines Agencies on the identification of commercially confidential information and personal data within the structure of the MA procedure, which could be published once a decision had been adopted. It is apparent from that table that, as regards the files of applicants for authorisation, the EMA takes the view that, once the MA procedure for a medicinal product has been finalised, and after the holder of those documents has been consulted, those documents are in principle accessible.

41 It follows that the plea alleging the existence of a general presumption of confidentiality in respect of the information at issue must, in any event, be rejected.

42 None of the arguments put forward by the applicants can call that finding into question.

43 First, the fact that the batch 1 study reports were drawn up by the applicants and that they are not derived from a CVMP assessment report based on information provided by the MA applicant is not in itself a reason justifying greater protection for those reports. The question whether or not the information concerned is confidential is the decisive factor, and it is irrelevant whether the information was inserted by the CVMP in its assessment report or whether it comes directly from the MA holder. In that context, it must be observed that the mere fact that the data in the batch 1 study reports allegedly all belong to the same category of documents is not a sufficient basis on which to conclude that those reports enjoy the general presumption of confidentiality.

44 Second, the applicants assert unsuccessfully that it is of the very essence of the MA regime that all documents submitted as part of an MA application dossier, and in particular non-clinical and clinical studies, are protected by a general presumption of confidentiality for the purposes of Article 4(2) of

Regulation No 1049/2001 and that the case-law of the court hearing the application for interim measures and the case-law deriving from the judgment of 23 January 1997, *Biogen* (C-181/95, EU:C:1997:32), provides support for that approach. First of all, that assertion is in no way substantiated. Next, it is not clear that non-clinical and clinical studies are in themselves confidential. Those non-clinical and clinical studies may be limited to satisfying a regulatory scheme prescribed by the EMA and contain no new material. Moreover, it should be pointed out that the transparency of the process followed by the EMA and the possibility to obtain access to the documents used by that agency's experts to prepare their scientific assessment contribute to such an authority acquiring greater legitimacy in the eyes of the persons to whom that measure is addressed and increasing their confidence in that authority and to ensuring that the authority is more accountable to citizens in a democratic system (see, by analogy, judgment of 16 July 2015, *ClientEarth and PAN Europe* v *EFSA*, C-615/13 P, EU:C:2015:489, paragraph 56). Lastly, it cannot be inferred from the judgment of 23 January 1997, *Biogen* (C-181/95, EU:C:1997:32), and from the orders of 25 April 2013, *AbbVie* v *EMA* (T-44/13 R, not published, EU:T:2013:221), and of 1 September 2015, *Pari Pharma* v *EMA* (T-235/15 R, EU:T:2015:587), which are relied on by the applicants, that there is any recognition of the existence of a general presumption of confidentiality in respect of the batch 1 study reports. As the EMA correctly points out, such a conclusion cannot be inferred from the orders of the court hearing the application for interim measures. As regards the judgment of 23 January 1997, *Biogen* (C-181/95, EU:C:1997:32), apart from the fact that it was delivered before Regulation No 1049/2001 was adopted, it is not apparent from that judgment that the Court of Justice confirmed that all the information in an MA is confidential.

45 Third, the argument that the general presumption of confidentiality of the batch 1 study reports is essential in order to guarantee that the objectives of the MA procedure are not jeopardised and ensure the integrity of the conduct of the bilateral procedure is ineffective. In the present case, it must be stated, first of all, that the batch 1 study reports were submitted and assessed in the context of the MA application for Bravecto, subsequently, that the EMA granted the applicants MA for that medicinal product in respect of a specific therapeutic indication and, lastly, that the procedure for granting MA to Bravecto was closed at the time that the request for access to those reports was submitted by a third party.

46 In that context, the applicants claim that, to ensure the useful effect of Regulation No 726/2004, the general presumption of confidentiality must apply throughout the period of marketing data exclusivity and beyond, rather than expiring once the MA decision has been made. They submit that other data could be reused in connection with new MA applications. Those arguments must be rejected. The possibility that data could be reused does not, in itself, constitute a ground to consider that that information is confidential or that it might undermine the decision-making process within the meaning of Article 4(3) of Regulation No 1049/2001. It is apparent from the contested decision that only the elements in the batch 1 study reports that do not relate to the already authorised indication, which reveal details that are specific to the ongoing application or future development plans and which do not appear in a publicly-accessible document (such as the EPAR) may be considered commercially confidential information. The EMA cannot therefore refuse access to the elements contained in the batch 1 study reports which do not relate the three types of abovementioned data. To that effect, it should be pointed out that the contested decision stated that the references in the batch 1 study reports to any future development plans of the applicants were redacted and that that information 'does not reveal any details on the currently pending application for the addition of a new pharmaceutical form'. Those findings were not moreover called into question by the applicants.

47 Fourth, it is necessary to examine the argument that the interpretation of Regulations Nos 1049/2001 and 726/2004, in light of the requirements of the TRIPS Agreement, and in particular Article 39(2) and (3), should have led the EMA to conclude that the batch 1 study reports enjoyed a general presumption of confidentiality.

48 It should be pointed out that, although Article 39(2) and (3) of the TRIPS Agreement, to which the applicants refer, cannot as such be relied upon to challenge the validity of the contested decision, Regulations Nos 1049/2001 and 726/2004 must nonetheless be interpreted in such a way as to ensure that they comply with the content of that provision. The provisions of the TRIPS Agreement, which is part of the WTO Agreement, signed by the European Community and subsequently approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), constitute an integral part of the European Union legal order. Where there are EU rules in a sphere concerned by the TRIPS Agreement, EU law will apply, which will mean that it is necessary, as far as possible, to adopt an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to the provision of that agreement at issue (see judgment of 11 September 2007, *Merck Genéricos — Produtos Farmacêuticos*, C-431/05, EU:C:2007:496, paragraph 35 and the case-law cited).

49 It should be borne in mind that Article 39(2) of the TRIPS Agreement provides that commercially valuable information is protected against use and disclosure by third parties if it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question. Paragraph 3 of that article obliges the Member States to protect undisclosed test or other data against unfair commercial use when requiring, as a condition of approving the marketing of pharmaceutical products which utilise new chemical entities, the submission of that data, the origination of which involves a considerable effort.

50 Article 39(2) and (3) of the TRIPS Agreement cannot mean, however, that protection granted to intellectual property rights must be given absolute precedence over the presumption in favour of disclosure of the information submitted in the context of an application for derogation from the market exclusivity of an orphan medicinal product. To that effect, the approach advocated by the applicants of considering that the entirety of the information that they submitted is confidential amounts to disregarding the balance established by the abovementioned regulations and to not applying the mechanism which provides, in essence, for the disclosure of information relating to medicinal products which are the subject of an authorisation procedure with the exception of information of a confidential nature. Such an approach must be rejected, since, in reality, it challenges the legality of the mechanisms of Regulations No 1049/2001 and 726/2004 in the light of Article 39(2) and (3) of the TRIPS Agreement.

51 Moreover, the applicants' line of argument suggests that there is no mechanism for protecting intellectual property. However, first, holders of data enjoy a period of protection of those data under Article 39(10) of Regulation No 726/2004. Furthermore, they enjoy, pursuant to the exceptions provided for in Article 4 of Regulation No 1049/2001, protection of commercially confidential information contained in an MA application dossier, including information about the manufacturing of the product and other technical and industrial specifications of the quality processes adopted to manufacture the substance.

52 Fifth, the applicants complain that the EMA failed to provide a sufficient statement of reasons for taking the view that the batch 1 study reports do not enjoy a general presumption of confidentiality and dispute the grounds on which that finding was based. Inasmuch as the applicants' arguments must in reality be understood as a complaint alleging infringement of the obligation to state reasons, they must be rejected. Indeed, the contested decision contains full and detailed reasoning which makes it possible to understand fully the reasons for the EMA's finding that there is no general presumption of confidentiality in respect of the information at issue. In particular, the EMA observes that the general presumption of confidentiality is contrary to the provisions of the FEU Treaty and of Regulation No 1049/2001 on transparency. It recalls in that regard the content of Article 2(3) and (4) and of Article 4(6) of Regulation No 1049/2001. As regards the assertion made by the applicants of the existence of a risk of unfair use of the data in order to justify the general presumption of

confidentiality, the EMA observes that data submitted in the context of an MA application are protected by a period of data exclusivity provided for in Articles 13 and 13a of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1). In that regard, the EMA observes that the release of information in accordance with Regulation No 1049/2001 cannot undermine the protection put in place by Article 39 of the TRIPS Agreement and Articles 13 and 13a of Directive 2001/82. The contested decision states, moreover, that, in accordance with Article 16 of Regulation No 1049/2001, the EMA's decision to grant access to documents is without prejudice to intellectual property rights which may exist over documents or their content and cannot be interpreted as an explicit or implicit permission or licence for the requestor to use, reproduce, publish, disclose or otherwise exploit the documents or their content. The EMA further states that the risk of documents being used to circumvent data exclusivity in breach of Directive 2001/82 and Regulation No 1049/2001 cannot constitute a ground for refusing access to documents, since otherwise in practice almost full paralysis of the EMA's relating to access to documents would ensue. Such an approach would be contrary to the transparency provisions in the FEU Treaty and in Regulation No 1049/2001. The EMA observes lastly that the risk of unlawful use of documents released in accordance with Regulation No 1049/2001 is always present and other EU and national legislation provide related remedies. Accordingly, the reasons set out in the contested decision for rejecting the existence of a general presumption of confidentiality in respect of the batch 1 study reports fulfil the requirement to state reasons laid down in Article 296 TFEU.

53 Inasmuch as the applicants' objection relates to the actual grounds of that finding, it cannot succeed. First of all, as is apparent from the analysis carried out in paragraphs 19 to 40 above, it is not possible to infer from the provisions of Regulation No 726/2004 the existence of any general presumption of confidentiality in respect of the batch 1 study reports.

54 Next, the requirement set out in the TRIPS Agreement to protect documents submitted to the EMA against their unfair commercial use is fulfilled for the reasons noted in paragraphs 47 to 51 above. In that regard, the applicants are wrong to assert that the EMA's approach necessarily presupposes that all their competitors will behave lawfully at all times and that they will not be able to obtain a commercial advantage by using the batch 1 study reports in a lawful manner. First, the data protection provided for in Regulation No 726/2004 is aimed specifically at preventing competitors from using studies contained in an MA dossier. Second, the confidentiality of certain data guaranteed by Article 4 of Regulation No 1049/2001 constitutes a bulwark against unfair use of commercially sensitive data.

55 The applicants claim that the EMA provided for proactive conditions of use of documents and thus recognises the potential for unfair use to be made of those documents. They state that the EMA accepts no responsibility for interested parties' compliance with those conditions, and that that amounts to an acknowledgement that those conditions are inadequate to prevent competitors taking unfair advantage. Those arguments must be rejected on the ground that they presuppose that data which may be used unfairly must be considered confidential. It is not possible to guarantee with absolute certainty that data will not be used unfairly. It is therefore reasonable for the EMA not to accept responsibility in that regard. Moreover, that consideration does not support the conclusion that all the data must enjoy a presumption of confidentiality.

56 In addition, the applicants submit that there are numerous ways in which their competitors might use knowledge gained from sight of the batch 1 study reports to obtain a competitive advantage at the applicants' expense. However, that in no way shows that all the information merits protection by a general presumption of confidentiality.

57 Lastly, the applicants assert unsuccessfully that, in view of the disclosure of data, MA applicants would have an interest in submitting the minimum information necessary to satisfy the conditions required to submit the MA dossier and obtain MA for their medicinal product. That argument presupposes that

the EMA would be satisfied with minimum information to issue an opinion in favour of issuing an MA for a medicinal product, which, given the standard of the requirements laid down by EU legislation, is unlikely.

58 In view of all the foregoing, the first plea must be rejected as unfounded.

Second plea in law: The batch 1 study reports constitute commercially confidential information protected by Article 4(2) of Regulation No 1049/2001

59 In the second plea, the applicants claim that the batch 1 study reports as a whole are of a commercially confidential nature for the purposes of Article 4(2) of Regulation No 1049/2001, since in particular, they disclose regulatory know-how, clinical assessment abilities and MSD's innovative strategic approach to running its safety studies. Scientific data in the public domain and scientific data covered by secrecy have been configured and assembled using an inventive strategy and have become an inseparable whole with economic value. They thus provide a benchmark which could assist competitors and provide a 'road-map' for obtaining an MA for any medicinal product containing the same active substance. They reveal planned product developments and can be used in their entirety to supplement competitors' MA application files. In that regard, the applicants submit that they have invested significant resources in producing the batch 1 study reports and that the use of those reports for benchmarking purposes could thus provide an advantage to a potential competitor. The period of data exclusivity granted to MA holders does not provide complete protection from unfair competition.

60 The EMA disputes the applicants' arguments.

61 As a preliminary point, it should be recalled that Article 15(3) TFEU provides that any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the European Union's institutions, bodies, offices and agencies subject to the principles and the conditions defined in accordance with the ordinary legislative procedure. The purpose of Regulation No 1049/2001, as indicated in recital 4 and Article 1 thereof, is to give the public a right of access to documents of the institutions that is as wide as possible (judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 111, and of 28 June 2012, *Commission* v *Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 53; see also, to that effect, judgment of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 40).

62 Moreover, it must be pointed out that the MA application procedure for medicinal products is governed by Regulation No 726/2004, which lays down a procedure in EU law in that regard. Article 73 of Regulation No 726/2004 provides that Regulation No 1049/2001 applies to documents held by the EMA. It follows that the principle that the public should have the widest possible access to the documents must in principle be respected with regard to the documents held by the EMA.

63 The principle that the public should have the widest possible access to the documents is nonetheless subject to certain limits based on reasons of public or private interest. Regulation No 1049/2001, in particular in recital 11 and Article 4 thereof, provides for a system of exceptions requiring institutions and bodies not to disclose documents in the event that disclosure would undermine one of these interests (see, to that effect, judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 111; of 28 June 2012, *Commission* v *Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 53, and of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 40).

64 Since the exceptions provided for in Article 4 of Regulation No 1049/2001 derogate from the principle that the public should have the widest possible access to the documents, they must be interpreted and applied strictly (see, to that effect, judgments of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 75, and of 3 July 2014, *Council* v *in't Veld*, C-350/12 P, EU:C:2014:2039, paragraph 48).

65 It must also be noted that the system of exceptions laid down in Article 4 of Regulation No 1049/2001, particularly in Article 4(2), is based on a weighing of the opposing interests in a given situation, that is to say, on the one hand, the interests which would be favoured by the disclosure of the documents in question and, on the other, those which would be jeopardised by such disclosure. The decision taken on a request for access to documents depends on which interest must prevail in the particular case (judgments of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 42, and of 23 September 2015, *ClientEarth and International Chemical Secretariat* v *ECHA*, T-245/11, EU:T:2015:675, paragraph 168).

66 The Court points out that, in order to justify refusal of access to a document, it is not sufficient, in principle, for that document to fall within an activity or an interest mentioned in Article 4 of Regulation No 1049/2001. The institution concerned or, where applicable, the person who has provided the information in the documents at issue must also explain how access to that document could specifically and actually undermine the interest protected by an exception laid down in that article (see, to that effect, judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 116; of 28 June 2012, *Commission* v *Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 57, and of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraph 64) and that the risk of that interest being undermined is reasonably foreseeable and not purely hypothetical (judgments of 13 April 2005, *Verein für Konsumenteninformation* v *Commission*, T-2/03, EU:T:2005:125, paragraph 69, and of 22 May 2012, *Sviluppo Globale* v *Commission*, T-6/10, not published, EU:T:2012:245, paragraph 64).

67 As regards the concept of commercial interests, it is apparent from the case-law that it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001 without frustrating the application of the general principle of giving the public the widest possible access to documents held by the institutions (judgments of 15 December 2011, *CDC Hydrogene Peroxide* v *Commission*, T-437/08, EU:T:2011:752, paragraph 44, and of 9 September 2014, *MasterCard and Others* v *Commission*, T-516/11, not published, EU:T:2014:759, paragraph 81). It should also be pointed out that the joint guidance document of the EMA and the Heads of Medicines Agencies on the identification of commercially confidential information and personal data within the structure of the MA procedure defines 'commercial confidential information' as any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information.

68 Consequently, in order to apply the exception provided for by the first indent of Article 4(2) of Regulation No 1049/2001, it must be shown that the documents at issue contain elements which may, if disclosed, seriously undermine the commercial interests of a legal person. That is the case, in particular, where the requested documents contain commercially sensitive information relating, in particular, to the business strategies of the undertakings concerned or to their commercial relations or where those documents contain information particular to that undertaking which reveal its expertise (see, to that effect, judgment of 9 September 2014, *MasterCard and Others* v *Commission*, T-516/11, not published, EU:T:2014:759, paragraphs 82 to 84).

69 It is in the light of the considerations set out in paragraphs 61 to 68 above that the applicants' arguments that the EMA infringed the first indent of Article 4(2) of Regulation No 1049/2001 by adopting the contested decision, authorising disclosure of the information at issue, must be analysed.

70 As a preliminary point, it should be recalled that the analysis of the first plea revealed that there is no general presumption of confidentiality protecting the batch 1 study reports in their entirety from disclosure. It follows that, in order for it be found that the batch 1 study reports are commercially confidential in their entirety for the purposes of Article 4(2) of Regulation No 1049/2001, it is necessary that all the data in those reports constitute commercially confidential information.

71 In the first place, the applicants submit that the batch 1 study reports disclose regulatory know-how, clinical assessment abilities and MSD's innovative strategic approach to running its safety studies.

72 However, the EMA correctly notes that all safety tests included in MA applications for veterinary medicinal products must have satisfied the requirements set out in Annex I to Directive 2001/82/EC. Similarly, it is necessary to take account of the fact that the EMA published guidelines on toxicity studies following agreement on a harmonised approach between the EU, Japan and the United States of America, and that those public guidelines, built up gradually over many years, now constitute an extensive body of guidelines which seek to guide the pharmaceutical industry in conducting the studies required for approval of a veterinary medicinal product.

73 In the present case, in the contested decision, the EMA recalls that the studies were designed in accordance with internationally accepted guidelines and recommendations. The EMA refers in particular to the 'OECD Guidelines for Testing of Chemicals, Section 4, Health Effects, No. 410, Repeated Dose Dermal Toxicity: 21/28-day Study, adopted 12 May 1981', 'ICH Topic S3A Toxicokinetics: A Guidance for Assessing Systemic Exposure in Toxicology Studies (CPMP/ICH/384/95)', 'VICH Guideline 31 Studies to evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90 Days) Toxicity Testing, October 2002', and 'Guidance for Industry. Bioanalytical Method Validation. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM), May 2001'.

74 It should be noted that the applicants have not disputed that they followed the protocol provided for in the abovementioned guidelines and recommendations. Thus, they have not called in question the fact that the batch 1 study reports follow the applicable guidelines and are based on known principles which are widely available in the scientific community. That thus tends to confirm the EMA's conclusion that those reports fail to show any novelty.

75 Moreover, the applicants' assertion that the batch 1 study reports provide an innovative strategy for planning a toxicology programme is in no way substantiated. The applicants have not put forward any specific evidence to show that the reports contain any elements that are unique and important for informing their overall strategy and development programme.

76 Similarly, the applicants submit that, even though the study design for safety studies is partly standardised, the guidelines are no substitute for data know-how in relation to the active substance. However, as the EMA observes, the claim regarding know-how allegedly contained in the documents is vague and does not make it possible to ascertain what the innovative approach followed consists in. For the same reasons, the applicants claim unsuccessfully that is a considerable difference between guidance documents suggesting what information should and should not be provided in an application and the actual documents making up the file submitted in support of that application.

77 The applicants also rely on details relating to the standards for running a toxicology study developed in-house by MSD, but do not identify or, a fortiori, adduce specific evidence making it possible to understand how those standards would reflect 'secret know how that was developed through significant effort and expense'. It should moreover be noted that the EMA agreed that the details on the internal reference standard used for the analytical tests would not be disclosed.

78 In the second place, the applicants essentially complain that the EMA did not put forward any reasons contradicting the argument that the information is confidential because it provides a 'road-map' for obtaining an MA for any medicinal product containing the same active substance.

79 First, to the extent that that consideration must be understood as a complaint alleging a failure to state reasons, it must be rejected. The contested decision contains precise reasons regarding the applicants' arguments in that respect, as is apparent from the replies to both the general and specific considerations relating to the information at issue which, according to the EMA, is not of a confidential nature (see pages 331 and 339 of the annex to the letter of 25 November 2015).

80 Second, if the applicants' arguments must be interpreted as a complaint intended to show that the batch 1 study reports are confidential in their entirety and to seek a finding that the EMA has failed to adduce proof to the contrary, it must be rejected. First of all, the consideration that all the information at issue is confidential on the ground that it would provide a 'road-map' for obtaining an MA is more akin to pleading the existence of a general presumption of confidentiality which would be for the EMA to rebut. However, the examination of the first plea has revealed that such a presumption does not exist in the context of MA procedures for veterinary medicinal products. Next, the arguments in support of that complaint are vague and unsubstantiated. The mere assertion that the information at issue would provide a 'road-map' for obtaining an MA does not make it possible to determine that that information is confidential. It cannot reasonably be claimed that the EMA should have provided reasons capable of demonstrating the contrary. Lastly, it should be noted that, in the contested decision, the EMA decided to redact a number of items of information. The EMA states, without being contradicted in that respect by the applicants, that the documents do not contain any information on the composition or manufacturing of Bravecto, since the following information in the batch 1 study reports was redacted: details on the concentration range of the active substance, details on the internal reference standard used for analytical tests, and references to future development plans.

81 In the third place, the applicants' argument that, in accordance with the case-law resulting from the orders of 25 July 2014, *Deza* v *ECHA* (T-189/14 R, not published, EU:T:2014:686), and of 1 September 2015, *Pari Pharma* v *EMA* (T-235/15 R, EU:T:2015:587), the batch 1 study reports form an 'inseparable whole with economic value' meriting confidential treatment in their entirety cannot succeed. First, it is not disputed that those reports contain a number of items of information that were published. The EPAR relating to Bravecto is publicly accessible and contains data emanating directly from the batch 1 study reports, which necessarily implies that at least some of the data in those reports is publicly accessible. Consequently, in order to be able to claim confidential treatment in respect of the entire reports, it is for the applicants to show that the assembly of the publicly-accessible data together with the data which is not publicly accessible constitutes a commercially sensitive item of data whose disclosure would undermine their commercial interests. The applicants' claim that the EPAR is less detailed and does not contain any explanations on how the results relating to Bravecto are generated is irrelevant in that regard. The applicants have provided only vague and generic explanations showing that that assembly of the information at issue could produce the alleged consequent harm to their know-how and their commercial secrets. It was all the more necessary to adduce precise and proper explanations since, as has been pointed out in paragraph 64 above, the exceptions provided for in Article 4 of Regulation No 1049/2001 derogate from the principle that the public should have the widest possible access to the documents and must therefore be interpreted and applied strictly.

82 Moreover, the infringement of the protection of the commercial interests of a person as referred to in Article 4(2) of Regulation No 1049/2001 is not necessarily determined by reference to the financial value of the information subject to disclosure.

83 In that context, it is also necessary to reject the argument alleging that, unlike reports drafted by the Committee for Medicinal Products for Human Use which contain data submitted by an MA applicant, the batch 1 study reports originate from the applicants themselves, which reinforces their confidential nature. As was indicated in paragraph 81 above, the applicants have not demonstrated specifically that disclosure of the information at issue would undermine their commercial interests.

84 In the fourth place, the applicants' assertion that competitors will be able to use the studies to help design their own toxicology studies and to benchmark their own MA applications against what was submitted by MSD must be qualified on two grounds. First, competitors have to run their own studies in accordance with the applicable scientific guidelines and provide all the data required for a complete dossier. It is not therefore apparent that disclosure of the batch 1 study reports would allow competitors to accelerate the process of obtaining MA for their medicinal product and gain swifter approval for clinical trials. No specific argument has been submitted in that regard. Moreover, as the EMA notes in the contested decision, Regulation No 726/2004 and Directive 2001/82 grant protection, by means of data exclusivity, to regulatory documents submitted for the purposes of obtaining an MA. A competitor will not therefore be able merely to use the applicants' safety studies, but will have to submit the studies that it has performed itself.

85 In the fifth place, the applicants claim unsuccessfully that the period of data exclusivity granted to MA holders does not provide complete protection from unfair competition and that there are numerous commercial disadvantages to which MA holders are exposed if their clinical and non-clinical data are released *erga omnes*. It is apparent from the preceding paragraphs that the applicants have not demonstrated the actual existence of the commercial disadvantages alleged in their pleadings.

86 In that context, the applicants submit that the active substance and the reference standard are both needed to perform the analyses leading to the anticipated results, and that their competitors are unable to produce those results without infringing the applicants' exclusivity rights over the active substance. It must, however, be recalled that the EMA found that the concentration range of the active substance and details on the internal reference standard used for the analytical tests should be redacted. The applicants have failed to adduce any evidence to explain why those redactions are insufficient, or therefore, how competitors would infringe their exclusivity rights over the active substance.

87 In the sixth place, the applicants refer to a risk of immediate loss of the benefit of the period of data exclusivity in the event of disclosure of the batch 1 study reports on the ground that those reports could be used by competitors in third countries that permit such use. However, apart from the fact that that argument of the applicants is vague and imprecise, there is nothing to permit the conclusion that access to the information at issue – which is not confidential from the point of view of the applicants' commercial interests – would on its own make it easier for a competing pharmaceutical undertaking to obtain an MA in a third country. That is all the clearer because the data, such as those relating to the concentration range of the active substance, to the details on the internal reference standard used for analytical tests and to a request to establish residue limits, remain confidential. The applicants have not put forward any specific argument to show that the alleged danger in certain third countries is real. Moreover, the non-disclosure of all studies in order to prevent the authorities of a third country granting access to its market to a manufacturer without that manufacturer being required to submit its own studies would amount to depriving the public of the right – granted by EU law – to have access to documents containing information relating to authorised medicinal products.

88 In the seventh place, on the assumption that the batch 1 study reports could be used as part of an MA dossier filed by competitors when applying for an MA for a generic competitor to Bravecto, the fact remains that it does not appear possible that such a generic medicinal could be marketed before a

period of ten years has elapsed (see the second subparagraph of Article 13(1) of Directive 2001/82. Thus, it is difficult to see how the use of information almost ten years after the placing on the market of the medicinal product Bravecto could undermine the applicants' commercial interests.

89 In the eighth place, the applicants also claim unsuccessfully that they have invested significant resources in producing the reports and that that clearly demonstrates their potential commercial value. First of all, as was noted in paragraph 81 above, the infringement of the protection of the commercial interests of a person as referred to in Article 4(2) of Regulation No 1049/2001 is not necessarily determined by reference to the financial value of the information subject to disclosure. In other words, the fact that implementation of safety studies involves financial investments for pharmaceutical undertakings does not per se mean that those studies are confidential. Next, as was pointed out in paragraph 2 above, all safety tests included in MA applications for veterinary medicinal products must have satisfied the requirements of Directive 2001/82 and the EMA's guidelines on toxicity studies. Lastly, the data in the batch 1 study reports are protected by exclusivity (see paragraph 4 above). In the light of those factors, it must be stated that all pharmaceutical undertakings must perform their own safety studies, since they cannot merely refer to the safety studies of competitors. They must therefore make financial investments in that context in the same way as the applicants. It is not therefore apparent that disclosure of such information with alleged commercial value could for that reason alone undermine the applicants' commercial interests and that that information is automatically commercially confidential.

90 In the ninth place, the argument that competitors may be able to undermine MSD's future plans for Bravecto, inside and outside the European Union, cannot succeed. It is apparent from the contested decision that the EMA agreed to redact the references in the batch 1 study reports to any future development plans of the applicants. In the light of that factor and as the EMA notes, it is unclear how the release of the documents could possibly affect future plans for the development of other indications for Bravecto.

91 In the tenth place, the assertion that competitors could harm the applicants by releasing portions of the batch 1 study reports out of context in order to undermine Bravecto's reputation is irrelevant. The possibility of harming the reputation of the holder of documents is not a criterion capable of identifying whether or not an item of information is confidential.

92 In the eleventh place, the assertion that the non-clinical information in the batch 1 study reports would enable MSD's competitors to obtain an MA more easily must be rejected. The applicants have not identified any information from those reports or substantiated their comments with any specific arguments to suggest that the non-clinical information is of a confidential nature.

93 In the last place, the applicants state that the EMA's approach of requiring them to show that an MA for a competing product is based on the unfair use of their documents is not consistent with the case-law, which merely requires that it be shown that unfair use of their data is reasonably foreseeable as opposed to purely hypothetical. Such an argument is irrelevant, since the applicants have failed to demonstrate a hypothetical risk of unfair use of their data, as the EMA observed. It was pointed out in paragraph 4 above that competitors have to run their own studies in accordance with the applicable scientific guidelines and provide all the data required for a complete dossier. Accordingly, it does not appear to be reasonably foreseeable that a comparative assessment with the applicants' dossier could allow competitors to accelerate their own regulatory approval process and gain swifter approval to conduct clinical trials.

94 It follows from all the foregoing that the second plea must be rejected.

Third plea in law: The batch 1 study reports are protected by Article 4(3) of Regulation No 1049/2001 on the ground that their disclosure would undermine the EMA's decision-making process

95 In support of the third plea, the applicants submit, first of all, that disclosure of the batch 1 study reports would in any event be premature. They state that the EMA takes the view that it can only redact information which relates to the applicants' later applications and not the information in the MA application for which the reports were submitted. However, the applicants take the view that, if release of the information has the potential to affect a future MA application, it falls within the scope of Article 4(3) (as well as Article 4(2) of Regulation No 1409/2001) and should be treated as confidential. The applicants then claim that disclosure of the data would encourage MA applicants to provide only the minimum information necessary in support of their applications. They submit lastly that they are directly and individually concerned by the effect that disclosure of the batch 1 study reports might have on the EMA's decision-making process in relation to Bravecto and that they are therefore entitled to make submissions under Article 4(3) of Regulation No 1049/2001.

96 The EMA disputes that disclosure of the batch 1 study reports could affect the MA procedure for Bravecto.

97 In the third plea, the applicants claim that disclosure of the batch 1 study reports undermines the decision-making process and is therefore contrary to Article 4(3) of Regulation No 1049/2001.

98 As a preliminary point, it should be recalled that, according to settled case-law, in order to apply the exception provided for in Article 4(3) of Regulation No 1049/2001, it must be shown that access to the documents requested was likely specifically and actually to undermine the Commission's decision-making process and that that risk was reasonably foreseeable and not purely hypothetical (see judgment of 18 December 2008, *Muñiz* v *Commission*, T-144/05, not published, EU:T:2008:596, paragraph 74 and the case-law cited).

99 It should also be noted that Article 4(3) of Regulation No 1049/2001 makes a clear distinction according to whether or not the procedure has been terminated. Thus, first, according to the first subparagraph of Article 4(3) of that regulation, any document drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution falls within the scope of the exception for protecting the decision-making process. Secondly, the second subparagraph of Article 4(3) of that regulation provides that, after the decision has been taken, the exception at issue covers only documents containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned (judgment of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 78).

100 It is thus only for part of the documents for internal use, namely those containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned, that the second subparagraph of Article 4(3) of Regulation No 1049/2001 allows access to be refused even after the decision has been taken, where their disclosure would seriously undermine the decision-making process of that institution (judgment of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 79).

101 It follows that the EU legislature took the view that, once the decision is adopted, the requirements for protecting the decision-making process are less acute, so that disclosure of any document other than those mentioned in the second subparagraph of Article 4(3) of Regulation No 1049/2001 can never undermine that process and that refusal of access to such a document cannot be permitted, even if its disclosure would have seriously undermined that process if it had taken place before the adoption of the decision in question (judgment of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 80).

102 In the present case, it must be stated, first of all, that the batch 1 study reports were submitted and assessed in the context of the MA application for Bravecto, subsequently, that the EMA granted the applicants MA for that medicinal product in respect of a specific therapeutic indication and, lastly, that the procedure for granting MA to Bravecto was closed at the time that the request for access to those reports was submitted by a third party. The second subparagraph of Article 4(3) of Regulation No 1049/2001 is thus the provision to which the applicants essentially refer.

103 It is in the light of those considerations that the applicants' arguments should be analysed.

104 At the outset, it is necessary to respond to the EMA's argument by which it takes the view that the applicants' third plea should be rejected on the ground that they do not have a legitimate interest in raising the plea. The EMA's reasoning is based on the fact that Article 4(4) of Regulation No 1049/2001 provides that, in the case of third-party documents, the institution is to consult the third party concerned with a view to assessing whether an exception under Article 4(1) or (2) of that regulation is applicable, unless it is clear that the document should or should not be disclosed. Given that the wording of that provision indicates that the exception relied on by the holder of the documents to justify their non-disclosure can be based only on Article 4(1) and (2) of Regulation No 1049/2001, the applicants allegedly have no interest in pleading possible infringement of Article 4(3) of that regulation before the General Court.

105 That amounts in essence to taking the view that the limit according to which the third party from whom the data originate must be consulted only 'with a view to assessing whether an exception in [Article 4(1) or (2) of Regulation No 1049/2001] is applicable' and not in Article 4(3) of that regulation also applies during the proceedings before the General Court.

106 It must, however, be stated that there is no legal obstacle preventing the applicants from pleading infringement of Article 4(3) of Regulation No 1049/2001 in the context of an action for annulment before the General Court. The requirement, laid down in Article 4(4) of that regulation, that the applicants must confine themselves during the consultation to the exceptions provided for in Article 4(1) and (2) of that regulation cannot constitute *ipso jure* an obstacle to pleading infringement of Article 4(3) of that regulation before the General Court. That is all the more true given that, as the applicants point out, they are directly concerned by both the EMA's decision to disclose the documents that they consider to be confidential and the effects of that disclosure on the EMA's decision-making process as regards Bravecto.

107 Accordingly, the plea cannot be rejected on the alleged ground that the applicants have no interest in raising it.

108 On the substance, in the first place, the applicants claim that the batch 1 study reports are going to be used for new applications for authorisation, since they intend to rely on those reports for their future applications. They thus take the view that the information at issue falls within the scope of Article 4(3) of Regulation No 1049/2001 and that its disclosure will therefore seriously undermine the EMA's decision-making process in the context of the pending administrative procedure and of future administrative procedures.

109 However, those arguments cannot succeed. First, as the EMA correctly observes, MA holders – who, to obtain MAs, have submitted safety study data – enjoy protection of their data in various respects after the MA procedure has been completed. Data holders enjoy a period of protection of those data under Article 39(10) of Regulation No 726/2004. Furthermore, they enjoy protection of commercially confidential information contained in an MA application dossier, including information about the manufacturing of the product and other technical and industrial specifications of the quality processes adopted to manufacture the substance. In the light of those guarantees, it does not appear, a priori, that, once MA has been granted, access to the batch 1 study reports could undermine the applicants' interests.

110 Second, the fact that other data could be reused in connection with new MA applications does not, in itself, constitute a ground for considering that that information is confidential, or that it might undermine the decision-making process within the meaning of Article 4(3) of Regulation No 1049/2001. As was noted in paragraph 46 above, the EMA ensured, in the contested decision, that the data not relating to the already authorised indication and the data relating to future development projects would remain confidential.

111 Third, and in any event, it must be stated that the applicants have not submitted any evidence from which it might be concluded that the alleged undermining of the decision-making process was serious. However, as is apparent from the case-law cited in paragraphs 988 and 99 above and in light of the finding in paragraph 102 above, it was for the applicants to show that access to the batch 1 study reports was likely specifically and actually to undermine the Commission's decision-making process and that that risk was reasonably foreseeable and not purely hypothetical (see, to that effect, judgment of 18 December 2008, *Muñiz* v *Commission*, T-144/05, not published, EU:T:2008:596, paragraph 74 and the case-law cited). It was all the more necessary for the applicants to demonstrate the above given that the requirements for protecting the decision-making process were less acute.

112 In the second place, the applicants argue unsuccessfully that disclosure of data such as the batch 1 study reports would encourage MA applicants to entrust the EMA with minimum sensitive information and would in essence have a counter-productive effect.

113 Pharmaceutical undertakings seeking MA for their medicinal products have no interest in providing the EMA with the minimum information possible, since such an approach significantly reduces their chances of success in that regard.

114 Moreover, to acknowledge the possible unwillingness of a pharmaceutical undertaking to entrust, in the context of its MA application for a medicinal product, information to the EMA on the ground that that information could be disclosed under Regulation No 1049/2001 cannot constitute evidence that the decision-making process would be seriously undermined for the purposes of the second subparagraph of Article 4(3) of Regulation No 1049/2001 (see, to that effect and by analogy, judgment of 24 May 2011, *Batchelor* v *Commission*, T-250/08, EU:T:2011:236, paragraph 80).

115 It follows from all the foregoing that the third plea must be rejected.

Fourth plea in law: No balancing exercise has been carried out in respect of the relevant interests

116 The applicants note that the EMA observed in passing on several occasions, in the contested decision, that the information could be disclosed in any event if there was an overriding public interest in its disclosure. They observe, however, that the EMA does not identify either the public interest in question or the reasons why it takes precedence over the applicants' interests. In the applicants' submission, the effect of Article 4(3) of Regulation No 1049/2001, interpreted in the light of Article 39(3) of the TRIPS agreement, is that where there is a risk of unfair commercial use of data, the circumstances in which there is an overriding public interest in disclosure are limited to cases where there is a need to protect the public; however, no such need arises in the present case. The applicants add that, in the light of their fundamental rights to privacy, to the protection of their professional data and to property (including intellectual property), the EMA ought to have ascertained whether disclosure was proportionate to the harm to the applicants' interests and whether there might be alternatives (such as disclosure limited to independent academic researchers). They submit that the public health concerns identified by the EMA are not capable of amounting to an overriding public interest because they are in fact based on general, unsubstantiated claims. To that effect, the EMA cannot rely on its public health mandate or the transparency obligation laid down by

Regulation No 104912001 as a basis for disclosing the batch 1 study reports, since Regulation No 726/2004 already sets out a detailed disclosure regime under which commercially confidential data cannot be disclosed.

117 The EMA rejects all of those arguments.

118 At the outset, it is necessary to determine the precise scope of the applicants' fourth plea. It appears from paragraph 111 of the application that the criticism that the EMA failed to carry out a balancing exercise of the relevant interests applies '[o]nce it has been concluded that the Batch 1 Study Reports are (in whole or in part) confidential'. The plea does not therefore concern the point in time – earlier in chronological terms – when the EMA raises the question of whether or not a certain piece of information is confidential. The applicants' reasoning in paragraph 114 et seq. of the application is, however, ambivalent and suggests that they might also be complaining that the EMA failed to carry out a balancing exercise of the relevant interests at the first stage of its reasoning, namely when assessing whether or not a certain item of information is confidential.

119 That having been specified, it is necessary to examine the plea, primarily, inasmuch as it relates to the lack of a balancing exercise of the relevant interests, even though the information at issue is confidential and, in the alternative, inasmuch as the plea concerns the actual existence of one of the exceptions provided for in Article 4(2) of Regulation No 1049/2001.

120 In the first place, it must be recalled that the final phrase of Article 4(2) of Regulation No 1049/2001 provides that EU institutions must not refuse access to a document where its disclosure is justified by an overriding public interest, even if it could undermine the protection of a particular natural or legal person's commercial interests or the protection of the purpose of inspections, investigations and audits of the institutions of the European Union (judgment of 7 October 2014, *Schenker* v *Commission*, T-534/11, EU:T:2014:854, paragraph 74). In that respect, it is necessary to weigh, on the one hand, the particular interest to be protected by non-disclosure of the document concerned against, on the other hand, inter alia, the public interest in the document being made accessible, having regard to the advantages of increased openness, as described in recital 2 of Regulation No 1049/2001, in so far as it enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system (judgment of 21 October 2010, *Agapiou Joséphidès* v *Commission and EACEA*, T-439/08, not published, EU:T:2010:442, paragraph 136).

121 Although an overriding public interest capable of justifying the disclosure of a document must not necessarily be distinct from the principles which underlie Regulation No 1049/2001 (judgment of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 92), it is nonetheless apparent from the case-law that general considerations alone cannot provide an appropriate basis for establishing that the principle of transparency is of particularly pressing concern and capable of prevailing over the reasons justifying the refusal to disclose the documents in question, and that it is the task of the party requesting information to make specific reference to circumstances showing that there is an overriding public interest to justify the disclosure of the documents concerned (see, to that effect, judgments of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 93 and 94, and of 23 September 2015, *ClientEarth and International Chemical Secretariat* v *ECHA*, T-245/11, EU:T:2015:675, paragraph 193).

122 As the EMA points out, the latter did not conclude that the information at issue should be protected by an exception referred to in Article 4(2) or (3) of Regulation No 1049/2001. As a result, it was under no obligation to determine or assess the public interest in the disclosure of the information or to weigh it against the applicants' interest in keeping that information confidential.

123 Moreover, it should be noted that the applicants' assertion that the EMA observed in passing on several occasions, in the contested decision, that the information could be disclosed in any event if there was an overriding public interest in its disclosure is imprecise and unsubstantiated. The applicants do not identify the points of the contested decision in which the EMA referred to the overriding public interest and do not therefore make it possible to take account of the context in which those observations were allegedly made.

124 In the second place, on the assumption that the applicants are criticising the EMA for having failed to carry out a balancing exercise of the relevant interests when examining whether or not each item of information was confidential, the arguments put forward cannot succeed.

125 First, the applicants' reasoning is based on the incorrect premiss that there is a general presumption of confidentiality. The analysis of the first plea has revealed that there was no such presumption in respect of the safety study reports concerned by the request for access to documents.

126 Second, the applicants submit in essence that, in the light of the specific rules in Regulation No 726/2004, the EMA should have taken a precautionary approach when it analysed the question of whether the batch 1 study reports should be disclosed pursuant to Regulation No 1049/2001 and that it ought thus to have included the question of the overriding public interest in its assessment.

127 However, Article 73 of Regulation No 726/2004 expressly provides that Regulation No 1049/2001 applies to documents held by the EMA. The latter is therefore required, in the name of the principle of transparency enshrined in Article 15 TFEU and in Regulation No 1049/2001, to grant access to the documents that it holds, namely, inter alia, study reports provided to it in the context of MA applications. It is only if those documents fall within the scope of one the exceptions referred to in Article 4 of Regulation No 1049/2001 that access to them must be refused. Thus, and contrary to the applicants' assertion, Regulation No 726/2004 does not provide for a specific access regime which derogates from the general principle of transparency laid down in Regulation No 1049/2001.

128 The EMA did not therefore err in law by not including the criterion of the overriding public interest in its assessment of whether or not the data in the batch 1 study reports were confidential.

129 Third, the applicants claim in essence that Article 4(3) of Regulation No 1049/2001 should have been interpreted and applied in light of Article 39(3) of the TRIPS Agreement. They submit that, since there was a risk of unfair use of the data, the batch 1 study reports could be disclosed only if there was an overriding public interest in that disclosure, and that that interest could exist only if it was necessary to protect the public. However, no such interest existed in the present case.

130 Those arguments must be rejected. It should be pointed out that 'regulatory data' covered by Article 39(3) of the TRIPS Agreement are protected by both Article 39(10) of Regulation No 726/2004 and Article 4 of Regulation No 1049/2001. Those two provisions prescribe measures aimed at ensuring that data are protected against unfair commercial use. Such measures are consistent with what is required by Article 39(3) in fine of the TRIPS Agreement. It was thus for the applicants to show how the protection envisaged by the abovementioned provisions was insufficient and that it was therefore necessary to demonstrate an overriding public interest.

131 Fourth, the applicants submit that, in the light of the applicants' fundamental rights to privacy, to the protection of their professional data and to property (including intellectual property), the EMA ought to have ascertained whether disclosure was proportionate to the harm to the applicants' interests and whether there might be alternatives (such as disclosure limited to independent academic researchers). However, those arguments cannot succeed. This question must be examined in the context of the provisions of Regulation No 1049/2001. As the EMA correctly observes, it is apparent from the combined application of Regulations Nos 1049/2001 and 726/2004 that any citizen has a right to have access to documents of the EMA, including those submitted by pharmaceutical companies for the

purposes of obtaining an MA, subject to the exceptions laid down by Regulation No 1049/2001. In the present case, the EMA has merely applied those provisions. In view of the absence of any general presumption of confidentiality of the batch 1 study reports, the EMA was thus entitled to refuse access to the entirety of those reports only if all the information in them had been considered commercially confidential information whose disclosure could undermine the applicants' commercial interests; the applicants have not demonstrated this. Accordingly, the EMA could not infringe the applicants' fundamental rights by applying the provisions of Regulation No 1049/2001.

132 In that regard, with respect to the specific criticism levelled at the EMA that it failed to ascertain whether disclosure was proportionate to the harm to the applicants' interests, it should be noted that Article 4(6) of Regulation No 1049/2001 provides that, if only parts of the requested document are covered by any of the exceptions, the remaining parts of the document are to be released and that examination of partial access to a document of the EMA must be carried out in the light of the principle of proportionality (see, to that effect, judgment of 6 December 2001, *Council* v *Hautala*, C-353/99 P, EU:C:2001:661, paragraphs 27 and 28).

133 The case-law states that it is clear from the very wording of Article 4(6) of Regulation No 1049/2001 that an institution or body is required to consider whether it is appropriate to grant partial access to requested documents and to limit any refusal to information covered by the relevant exceptions referred to. The institution or body must grant such partial access if the aim pursued by that institution or body, in refusing access to a document, may be achieved by merely redacting the passages which might harm the public interest to be protected (see, to that effect, judgments of 6 December 2001, *Council* v *Hautala*, C-353/99 P, EU:C:2001:661, paragraph 29, and of 12 September 2013, *Besselink* v *Council*, T-331/11, not published, EU:T:2013:419, paragraph 84).

134 The detailed analysis of the various documents in the contested decision reveals that the EMA examined the request for access to the documents in strict compliance with the principle of proportionality the application of which in the field of access to documents was described by the case-law mentioned in paragraphs 1322 and 1333 above.

135 Fifth, the public health concerns identified by the EMA are not capable, in the applicants' submission, of amounting to an overriding public interest because they are in fact based only on general, unsubstantiated claims which are not specifically linked to the batch 1 study reports. That argument must be rejected, since the applicants have not identified any point in the contested decision in which the EMA mentioned public health considerations. Moreover, it does not appear that the EMA based its decision to disclose the batch 1 study reports on public health concerns. The only grounds which determined the content of the contested decision relate to whether the documents concerned fell within the scope of one of the exceptions referred to in Article 4 of Regulation No 1049/2001.

136 Sixth, the applicants' criticism of the EMA for referring to the safety of Bravecto in relation to disclosure of the documents is irrelevant for reasons similar to those set out in paragraph 135 above. The applicants did not mention any point in the contested decision which would indicate that the EMA relied on Bravetco's safety when deciding to disclose the batch 1 study reports. As the EMA correctly observes, the general rule is that documents held by EU institutions are public. It was therefore necessary to determine whether the batch 1 study reports as a whole or a part of those reports fell within the scope of one of the exceptions referred to in Article 4 of Regulation No 1049/2001. Since the EMA took the view that those exceptions did not apply in the present case, it was not required to weigh up the relevant interests, or, *a fortiori*, to identify and show the overriding public interest allowing disclosure, as is apparent from paragraph 128 above.

137 In addition, it should be pointed out that, by their arguments, the applicants create confusion by giving the impression that any decision by the EMA to disclose a document is taken in the context of its mandate for the protection of public health and is made on grounds of public health which the EMA regards as falling within the scope of the overriding public interest. However, the fact that the impact

that the documents concerned may have on public health is one of the reasons why the EU legislature strengthened transparency and set up the right of access to documents held inter alia by the EMA does not mean that disclosure of documents such as the batch 1 study reports should be carried out automatically on grounds of the overriding public interest of public health and should automatically imply the need to weigh up the relevant interests. As was pointed out in paragraphs 135 and 1366 above, it was first of all necessary to determine whether the batch 1 study reports as a whole or a part of those reports fell within the scope of one of the exceptions referred to in Article 4 of Regulation No 1049/2001.

138 In the light of all those considerations, the fourth plea must, on any view, be rejected as unfounded.

Fifth plea in law: No proper balancing exercise has been carried out in respect of the competing interests

139 In their fifth plea, the applicants maintain that, in any event, had the EMA conducted a proper balancing exercise taking account of the disclosure regime established by Regulation No 726/2004, the TRIPS agreement, the fundamental rights of the applicants and the principle of proportionality, the outcome would evidently have been in their favour. They emphasise that the EPAR had already made adequate information available to the public and that any desire to share the data contained in the batch 1 study reports for public health reasons could have been given effect in a manner less detrimental to the rights of the MA holder (for example by means of restricted access subject to conditions). Moreover, no concerns have been raised about the safety of Bravecto justifying a special examination.

140 The EMA notes that it has emphasised that the documents do not qualify as confidential business information and that, accordingly, it could not have balanced any overriding public interest in disclosure against the non-disclosure of the documents.

141 The fifth plea raised by the applicants is based once again on the premiss that the batch 1 study reports or a part thereof are confidential. However, it is apparent from the examination of the preceding pleas that the EMA did not err in finding the absence of confidential information for the purposes of Article 4(2) and (3) of Regulation No 1049/2001 and that it was not therefore required to weigh the specific interest in confidentiality against the overriding public interest justifying disclosure.

142 The analysis of the first four pleas also revealed that that approach of the EMA is consistent with the TRIPS Agreement, the applicants' fundamental rights to privacy and to protection of their professional data and of the right to property, as well as the principle of proportionality.

143 It follows that the EMA cannot be criticised for not having carried out a proper balancing exercise in respect of the competing interests.

144 Accordingly, the fifth plea must, on any view, be rejected as unfounded.

145 It follows from all of the foregoing that the action must be dismissed.

Costs

146 Under Article 134(1) of the Rules of Procedure of the General Court, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In the present case, since the applicants have been unsuccessful in the main proceedings, they must be ordered to pay the EMA's costs, in accordance with the form of order sought by the latter, including those relating to the application for interim measures.

On those grounds,

THE GENERAL COURT (Second Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders MSD Animal Health Innovation GmbH and Intervet international BV to bear their own costs and to pay those incurred by the European Medicines Agency (EMA), including those relating to the application for interim measures.**

Prek Buttigieg Berke

Delivered in open court in Luxembourg on 5 February 2018.

E. Coulon
Registrar

M. Prek
President

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