Reports of Cases

JUDGMENT OF THE GENERAL COURT (Second Chamber)

5 February 2018 *

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

In Case T-718/15,

PTC Therapeutics International Ltd, established in Dublin (Ireland), represented initially by C. Thomas, Barrister, G. Castle, B. Kelly, H. Billson, Solicitors, and M. Demetriou QC, and subsequently, by C. Thomas, M. Demetriou, G. Castle and B. Kelly,

applicant,

supported by

European Confederation of Pharmaceutical Entrepreneurs (Eucope), represented by D. Scannell, Barrister, and S. Cowlishaw, Solicitor,

intervener,

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/722323/2015 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 a document containing information submitted in the context of an application for marketing authorisation for the medicinal product Translarna,

THE GENERAL COURT (Second Chamber),

composed of M. Prek, President, F. Schalin (Rapporteur) and M. J. Costeira, Judges,

Registrar: P. Cullen, Administrator,

having regard to the written part of the procedure and further to the hearing on 14 July 2017,

* Language of the case: English.

gives the following

Judgment

Background to the dispute

1 The applicant, PTC Therapeutics International Ltd, is a pharmaceutical company with expertise in the development of small-molecule compounds designed to correct or compensate for genetic defects. It designed Ataluren, which is the active ingredient in a medicinal product used to treat a condition called 'Duchenne Muscular Dystrophy', a medicinal product which is sold by the applicant under the trade name Translarna.

2 In October 2012, the applicant submitted an application for marketing authorisation ('MA') ('the MA application') to the European Medicines Agency (EMA), under the centralised procedure, for the medicinal product Translarna, for the treatment of Duchenne Muscular Dystrophy, stating that the presence of a nonsense mutation in the dystrophin gene had to be determined by genetic testing. In January 2014, the Committee for Medicinal Products for Human Use (CHMP) decided against granting an MA, on the ground that the benefits of the medicinal product Translarna had not been shown to outweigh its risks. Following the applicant's request for re-examination, the CHMP recommended, in May 2014, the grant of a conditional MA for the medicinal product Translarna, as provided for in Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6), which meant, in particular, that the medicinal product Translarna addressed an unmet medical need for patients suffering from a life-threatening disease, but that comprehensive clinical data were not yet available. On 31 July 2014, the MA applied for was granted.

3 On 13 October 2015, the EMA informed the applicant that it had received, on 29 July 2015, from a pharmaceutical company, a request 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), seeking access to a clinical study report in the MA application dossier for the medicinal product Translarna ('the report at issue'). The report is a Phase 2B placebo-controlled efficacy and safety study of Ataluren in subjects with nonsense mutation Duchenne and Becker Muscular Dystrophy. The document was the main clinical study conducted prior to the granting of the conditional MA for the medicinal product Translarna.

4 After obtaining an extension of time to respond, the applicant requested the EMA, on 30 October 2015, to treat the report at issue as confidential in its entirety.

5 On 5 November 2015, the EMA rejected the applicant's request for the entire clinical study report to be treated as confidential.

6 In its response of 12 November 2015, the applicant maintained its stance that the entire report at issue should be regarded as confidential, which was why it refused to redact specific passages in the report.

7 On 25 November 2015, the EMA adopted decision EMA/722323/2015 granting a third party, under Regulation No 1049/2001, access to the entire report at issue, subject to certain redactions ('the contested decision').

8 In support of the contested decision, the EMA stated that it had decided to give the requesting third party access to the entire report at issue, subject to certain redactions made of its own initiative, such as references to discussions on protocol design with the U.S. Food and Drug Administration, batch

numbers, materials and equipment, exploratory assays, the quantitative and qualitative description of the method for drug concentration measurement, and the start and end dates of treatment and further dates that could lead to the identification of the patients.

9 The EMA also replied to the observations made by the applicant in the context of the consultation in accordance with Article 4(4) of Regulation No 1049/2001. In that regard, the EMA referred to Article 4(6) of Regulation No 1049/2001 according to which access to the whole of a document requested could be refused only if one or more exceptions provided for by its Article 4 applied to all of its content. However, the applicant did not provide any evidence to show that each of the elements of the content of the report at issue constituted commercially confidential information. In that context, the EMA also noted that part of the content of the report at issue was already in the public domain. Moreover, according to the EMA, disclosure of the report at issue is consistent with the conditions provided for in Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15 April 1994 (OJ 1994 L 336, p. 214; 'the TRIPS Agreement') that forms Annex 1 C to the Agreement establishing the World Trade Organisation (WTO) (OJ 1994 L 336, p. 3), inasmuch as the holder of an MA is granted a period of data exclusivity by Article 14(11) of 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 an EMA (OJ 2004 L 136, p. 1), and, therefore, protection against unfair commercial use.

10 As regards the applicant's criticism relating to the deadline granted to it to make its comments, the EMA recalled that Article 7 of Regulation No 1049/2001 requires the EMA to respond to requests for access within 15 days. In the EMA's view, that also means that the procedure for consulting third parties should be limited in time.

11 As regards the cases that gave rise to 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), which are relied on by the applicant, the EMA stated that those orders did not give rise to decisions on the substance and, in any event, should be distinguished from the request for access to the report at issue, since the reports that those cases concerned had a content different from that of the report at issue.

12 Moreover, according to the contested decision, disclosure of the clinical study reports is consistent with Regulation No 1049/2001, the EMA's transparency policy and the TRIPS Agreement.

13 Lastly, the EMA contended, in the contested decision, that the decision to grant a conditional MA had already been made, so that Article 4(3) of Regulation No 1049/2001 could not apply and that, in any event it had to be shown that the decision-making process had been seriously undermined so that the mere fact that there was an ongoing 'regulatory relationship' was not enough.

Procedure and forms of order sought

14 By application lodged at the Court Registry on 9 December 2015, the applicant brought the present action. By separate document lodged on the same date, it brought an application for interim measures in order to obtain suspension of operation of the contested decision.

15 By order of 20 July 2016, *PTC Therapeutics International* v *EMA* (T-718/15 R, not published, EU:T:2016:425), the President of the General Court ordered the suspension of operation of the contested decision. By order of 1 March 2017, *EMA* v *PTC Therapeutics International* (C-513/16 P(R), not published, EU:C:2017:148), the Vice-President of the Court of Justice dismissed the appeal brought by the EMA against the order of 20 July 2016, *PTC Therapeutics International* v *EMA* (T-718/15 R, not published, EU:T:2016:425).

16 On 17 March 2016, the EMA submitted the defence.

17 The reply was lodged at the Court Registry on 30 May 2016.

18 By document lodged at the Court Registry on 29 March 2016, the intervener, the European Confederation of Pharmaceutical Entrepreneurs (Eucope) applied for leave to intervene in the proceedings in support of the form of order sought by the applicant. By order of 17 June 2016, the President of the Fourth Chamber of the General Court granted leave to intervene.

19 Following a change in the composition of the Chambers of the Court, pursuant to Article 27(5) of the Rules of Procedure of the General Court, the Judge-Rapporteur was assigned to the Second Chamber, to which the present case was accordingly allocated.

20 The rejoinder was received at the Court Registry on 12 July 2016.

21 The statement in intervention was lodged at the Court Registry on 19 August 2016.

22 The parties presented oral argument and replied to the Court's oral questions at the hearing on 14 July 2017.

23 The applicant claims, in the final form of its pleadings, that the Court should:

– annul the contested decision;

– order the EMA to pay the applicant's costs and other expenses in relation to the present case.

24 The EMA contends that the Court should:

– dismiss the application;

– order the applicant to pay the costs.

25 The intervener contends that the Court should annul the contested decision.

Law

26 In support of the action, the applicant relies on five pleas in law: first, that the report at issue is protected by Article 4(2) or (3) of Regulation No 1049/2001 pursuant to a general presumption of confidentiality; second, that the report at issue is in its entirety confidential commercial information protected by the first indent of Article 4(2) of Regulation No 1049/2001; third, that disclosure of the report at issue would undermine the EMA's decision-making process; fourth, that the EMA did not conduct a balancing exercise as required by law; and fifth, that a proper balancing exercise as required by law would have resulted in a decision not to disclose any part of the report at issue.

First plea in law, alleging that the report at issue is protected by the first indent of Article 4(2) or the first subparagraph of Article 4(3) of Regulation No 1049/2001 pursuant to a general presumption of confidentiality

27 In the context of the first plea, the applicant requests the Court to recognise the existence of a general presumption of confidentiality under which the EMA may refuse access to clinical study reports in an MA application dossier.

28 In the applicant's submission, the EMA was wrong not to apply a general presumption of confidentiality to the report at issue, as required by the correct application of Article 4(2) or (3) of Regulation No 1049/2001, read in conjunction with Regulations Nos 726/2004 and 141/2000 on orphan medicinal products (OJ 2000 L 18, p. 1), No 507/2006 and the TRIPS Agreement.

29 The applicant takes the view that the regulations mentioned in paragraph 28 above provide a specific disclosure and transparency regime in the pharmaceutical products sector, under which the legislature has weighed up the public and private interests at stake in order to determine what level of disclosure usually strikes the right balance in the public health field and in particular in the unusually sensitive orphan medicinal products field.

30 In that context, the applicant, supported by the intervener, submits that:

– where access to documents held by the EMA is sought in an economic or regulatory context to which specific legislation pursuing different objectives applies, the Court must endeavour to ensure that all the legislation is applied coherently, unless the relevant measures contain a provision expressly giving one body of measures primacy over the other;

– where the specific sectoral legislation sets out its own disclosure regime, a 'general presumption' arises to the effect that documents should only be disclosed pursuant to and in the circumstances envisaged by that legislation and are otherwise to be treated as confidential for the purposes of both Article 4(2) and Article 4(3) of Regulation No°1049/2001, subject to the possibility of demonstrating, by reference to the particular circumstances of the case, that a particular document falls outside the presumption, or that disclosure under Article 4(2) of Regulation No 1049/2001 is nonetheless justified by a relevant 'overriding public interest';

– such an approach has already been recognised in the case-law;

– in the present case, Regulation No 726/2004 contains, in conjunction with other relevant regulations, specific and detailed provisions as to the information held by the EMA which is or is not to be made publicly available;

– in the context of the highly competitive and innovative pharmaceutical industry, characterised by expensive investment, Regulation No 726/2004 and the other relevant legislation strike a very careful balance between, on the one hand, the interests of transparency, legitimate public interest considerations, and the desirability of avoiding duplicative research, and, on the other hand, the need to give companies a proper incentive to invest in research and development without fear that competitors will be able to free-ride on their innovation, the interests of stimulating multiple lines of research, and the proper and open functioning of a system for the assessment of MA applications under which companies are not discouraged from providing full and frank disclosure of all relevant information;

– it is also of the very essence of the MA regime that all documents submitted as part of an MA application dossier, and in particular the studies and trial reports, including the report at issue, are entitled to the protection of a general presumption of confidentiality for the purposes of Article 4(2) or (3) of Regulation No 1049/2001;

– the general presumption of confidentiality must apply throughout the period of marketing data exclusivity and even beyond, rather than expiring once the MA decision has been made: any other interpretation would not be in accordance with the *effet utile* of the EMA Regulation;

– moreover, in the present case, only a conditional MA has been granted; that means that the decision-making process concerning the grant of a full MA has not yet been concluded; consequently, all study documents (periodic safety update reports) should be kept secret at least

until the grant of a full MA or final refusal of an ongoing conditional MA, so that the EMA can conduct its investigation into the safety and efficacy of the medicinal product in question without outside interference;

– Regulations Nos 1049/2001, 726/2004, 141/2000 and 507/2006 must be interpreted in light of the requirements of the TRIPS Agreement, and in particular Article 39(3), which reinforces the conclusion that the report at issue is covered by a general presumption of confidentiality;

– the extremely administratively burdensome nature of the line-by-line redaction task contemplated by the EMA provides yet further support for the view that on a proper interpretation of Regulation No 726/2004 preserving its useful effect the EMA would be able to rely on a general presumption of confidentiality in respect of documents submitted to it as part of MA application dossiers, including clinical study reports;

– the EMA's reasons for rejecting the application of a general presumption of confidentiality to the report at issue are inadequate.

31 The EMA disputes those arguments.

32 In the context of the first plea, the applicant submits in essence that the general presumptions of confidentiality applying to certain categories of documents also apply to the report at issue presented in the context of the MA procedure for the medicinal product Translarna, provided for in Regulations Nos 141/2000, 726/2004 and 507/2006, and, accordingly, that the disclosure of that report would in principle undermine commercial interests. Thus, the general presumption of confidentiality on which the applicant relies is based on the exception relating to the protection of its commercial interests, which is referred to in the first indent of Article 4(2) of Regulation No 1049/2001.

33 It should be borne in mind that, 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. 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).

34 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 (judgments of 29 June 2010, *Commission* v *Technische Glaswerke Ilmenau*, C-139/07 P, EU:C:2010:376, paragraph 54, of 17 October 2013, *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:671, paragraph 72, and of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 45; see also, to that effect, 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).

35 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).

36 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).

37 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.

38 First of all, it has been held that, in order for a general presumption of confidentiality 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).

39 Moreover, it follows from the case-law cited in paragraph 38 above that the application of general presumptions is essentially 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).

40 Furthermore, in all the cases which gave rise to the judgments establishing general presumptions of confidentiality, 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 29 June 2010, *Commission* v *Technische Glaswerke Ilmenau*, C-139/07 P, EU:C:2010:376, paragraphs 12 to 22; 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 75, and of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraphs 69 and 70).

41 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 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).

42 The exceptions to the right of access to documents contained in Article 4 of Regulation No 1049/2001 cannot therefore be interpreted without taking account of the specific rules governing access to those documents, which are laid down in the relevant regulations.

43 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).

44 It is also on the basis of the criterion mentioned in paragraph 41 above 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).

45 In the present case, the applicant applied, on 29 October 2012, for a conditional MA for the medicinal product Translarna, in accordance with Article 14(7) of Regulation No 726/2004. The administrative procedure relating to that application was closed, on 31 July 2014, by the granting of the AMM applied for. The request for access based on Regulation No 1049/2001 was made only on 29 July 2015 and the contested decision is dated 25 November 2015. Accordingly, the report at issue does not relate to an ongoing administrative procedure. It follows that, even if the case-law cited in paragraph 39 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 report at issue cannot alter that procedure.

46 Similarly, 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, Regulations Nos 141/2000 and 726/2004 do not restrict the use of documents in the file relating to an MA procedure for a medicinal product. They do not provide that access to the file is limited to the 'parties concerned' or to 'complainants'.

47 More specifically, Regulation No 141/2000 does not contain any specific provision on access to documents.

48 As regards Regulation No 726/2004, it provides 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.

49 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 healthcare 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.

50 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.

51 As regards Regulation No 507/2006, its legal basis being Regulation No 726/2004, that also reflects the legislature's intention that the MA procedure should be transparent. In addition, the provisions of Regulation No 507/2006 to which the applicant refers provide for the publication of certain information such as the specific obligations of the holder of a conditional MA and the timeframe for their completion (Article 5(3) of that regulation), the opinion of the CHMP given in the context of a renewal application for a conditional MA (Article 6(3) of that regulation) and the clear mention, in the patient package leaflet, of the conditional nature of the MA (Article 8 of that regulation). Those provisions, the sole purpose of which is to require the EMA to proactively publish that information, just like the provisions of Regulation No 726/2004, as was noted in paragraph above, do not relate to the regulatory scheme on access to the documents submitted in the context of an MA application and cannot therefore under any circumstances be interpreted as providing for a special scheme in that regard.

52 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 relate to those referred to in Article 4(2) of Regulation No 1049/2001, including the exception relating to commercially confidential information. In view of the requirement of a strict interpretation recalled in paragraph 36 above, it must be held that the EU legislature took the implicit view that the integrity of the MA procedure is not undermined in the absence of a presumption of confidentiality.

53 In view of all the foregoing, it must be held that there is no general presumption of confidentiality of the documents of a file submitted in the context of an MA application for a medicinal product, and in particular of clinical study reports, arising from the application of the combined provisions of Regulations Nos 141/2000, 1049/2001 and 726/2004 and 507/2006. Clinical study reports cannot therefore 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 application file for MA, 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.

54 Moreover, it should also be added that, pursuant to Article 73 of Regulation No 726/2004, the EMA adopted the detailed rules for implementing Regulation No 1049/2001, entitled 'Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents'. 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.

55 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 is added to as the EMA gains more experience in the field of requests for access to documents. That table was supplemented, first, by 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 clinical study reports, the EMA considers them to be public and publishes them as soon the MA procedure for a medicinal product has ended. Similarly, it is apparent from point 3.2 of the abovementioned joint guidance document that, '[i]n general, the data included in clinical trial study reports is considered as data that can be released as such data is not considered either commercially confidential or personal data that should be protected' and that '[i]n the case of exceptional and substantiated cases, particularly where innovative study designs and/or innovative analytical methods have been used, consideration will be given to the need for redaction'.

56 Moreover, it should be pointed out that even though Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ 2014, L 158, p. 1) is not applicable in the present case, it is also an indication that a general presumption of confidentiality is not intended by the legislature. That regulation is based on the principle, as is apparent from recital 68 thereof, that clinical study reports are in principle publicly accessible 'once [an MA] has been granted'.

57 It follows that the plea alleging that there is a general presumption of confidentiality in respect of the documents submitted in the context of an MA application, and in particular of the clinical study reports, must be rejected.

58 None of the arguments put forward by the applicant can call that conclusion into question.

59 First, the applicant asserts 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 the studies and trial reports, are protected by a general presumption of confidentiality for the purposes of Article 4(2) or (3) 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 apparent that studies and trial reports are in themselves confidential (see paragraph 53 above). Those studies and trial reports 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 that 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, to that effect and 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 applicant, that there is any recognition of the existence of a general presumption of confidentiality in respect of clinical 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 application is confidential.

60 Second, given that a general presumption of confidentiality is not applicable, the argument that, to ensure the *effet utile* of Regulation No 726/2004, the alleged general presumption of confidentiality must apply throughout the period of marketing data exclusivity and even beyond, rather than expiring once the MA decision has been made is irrelevant.

61 Third, the argument that the interpretation of Regulations Nos 1049/2001, 726/2004, 141/2000 and 507/2006 in light of the requirements of the TRIPS Agreement, and in particular Article 39(3), is an argument which supports the recognition of a general presumption of confidentiality cannot succeed.

62 It should be pointed out that, although Article 39 of the TRIPS Agreement cannot as such be relied upon to challenge the validity of the contested decision, Regulations Nos 1049/2001, 726/2004 and 141/2000 and 507/2006 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).

63 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.

64 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 principle of disclosure of the information submitted in the context of an MA application for an orphan medicinal product. To that effect, the approach advocated by the applicant of considering that the entirety of the information that it submitted is confidential amounts to disregarding the balance established by Regulations Nos 1049/2001, 726/2004, 141/2000 and 507/2006 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 those provisions in the light of Article 39(2) and (3) of the TRIPS Agreement.

65 Moreover, it is sufficient to recall, in so far as the applicant's line of argument suggests that there is no mechanism for protecting intellectual property, that, first, holders of data enjoy a period of protection of those data under Article 14(11) 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.

66 Fourth, as regards the assertion that the task of redacting confidential data is extremely burdensome in administrative terms for both the EMA and the third party originator, thus providing further support for the contention that there is a general presumption of confidentiality, it is sufficient to note that such an approach runs counter to the letter and spirit of Regulation No 1049/2001. In that regard, it should be recalled that access to documents of the institutions is an approach to be adopted in principle, whereas the power to refuse access is the exception. It is not, in principle, appropriate that account should be taken of the amount of work entailed by the exercise of the applicant's right of access and its interest in order to vary the scope of that right. In other words, it is clear from the case-law that the administrative work related to providing public access to documents cannot be used as a valid justification for refusing access to documents (see, to that effect, judgments of 13 April 2005, *Verein für Konsumenteninformation* v *Commission*, T-2/03, EU:T:2005:125, paragraphs 103 to 108, and of 10 September 2008, *Williams* v *Commission*, T-42/05, not published, EU:T:2008:325, paragraph 86). Moreover, by analogy, no evaluation can be made in the assessment of whether a document or parts of a document can be released of the amount of work that a third party originator needs to make for assessing which part of the document is covered by any of the exceptions in Article 4(1) or (2). In addition, it is in the very interest of the consulted third party originator to provide justifications with a view to assisting the EU institution seised of a request for public access in order to apply, if appropriate, the relevant exceptions.

67 Fifth, the applicant complains that the EMA failed to provide a sufficient statement of reasons, in the contested decision, for finding that the report at issue did not enjoy a general presumption of confidentiality and contests the grounds aimed at justifying that finding.

68 In so far as the applicant complains that the EMA infringed the obligation to provide a statement of reasons for the contested decision, such a complaint must be rejected. First, since the EMA carried out a specific examination of the report at issue, it was not required to mention its reasons for rejecting the existence of a general presumption of confidentiality in respect of the documents requested. Second, the EMA's reasons for finding that confidentiality could not be granted to the entirety of the document requested are clearly apparent from the contested decision, as summarised in paragraphs 8 to 13 above. Similarly, it is apparent from the contested decision that the EMA responded in detail to the observations made by the applicant in the context of the consultation referred to in Article 4(4) of Regulation No 1049/2001. More specifically, as regards the assertion of the existence of a risk of unfair use of the data, it is apparent from the contested decision that the EMA observed that data submitted in the context of an MA application are protected by a period of data exclusivity provided for in Article 14(11) of Regulation No 726/2004. 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 Regulations Nos 726/2004 and 1049/2001 cannot constitute a ground for refusing access to

documents, since otherwise, in practice, almost full paralysis of the EMA's activities 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 fulfil the requirement to state reasons laid down in Article 296 TFEU.

69 It must be stated that, in reality, the applicant takes issue with the EMA for applying Article 4(6) of Regulation No 1049/2001 and with the fact that, because of that, the EMA gave partial access to the report at issue, thus refusing to recognise the existence of a general presumption. However, inasmuch as the applicant's objection relates to the actual grounds of that finding, it cannot succeed. In that regard, it is clear from paragraph 57 that recognition of such a presumption has already been rejected.

70 Moreover, it follows from the judgment of 14 November 2013, *LPN and Finland* v *Commission* (C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 66 and 67), that the institution concerned is not required to base its decision on a general presumption, if such a presumption exists. It may always carry out a specific examination of the documents covered by a request for access and provide reasons stemming from that specific examination.

71 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 61 to 65 above. In that regard, the applicant is wrong to assert that the EMA's approach necessarily presupposes that all the applicant's competitors will behave lawfully at all times and that they will not be able to obtain a commercial advantage by using the report at issue 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 application 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.

72 The applicant also claims 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. In the applicant's submission, the EMA accepts no responsibility for interested parties' compliance with those conditions, which amounts to an acknowledgement that those conditions do not make it possible to prevent competitors securing unfair advantages. 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 documents submitted in the context of an MA application must enjoy a presumption of confidentiality.

73 In addition, the applicant submits that there are numerous ways in which its competitors might use knowledge gained from sight of the report at issue to obtain a competitive advantage at its expense. However, that in no way shows that all the information merits protection by a general presumption of confidentiality.

74 Lastly, the fact that a conditional MA was issued to the applicant has no bearing on the recognition of a general presumption of confidentiality in respect of documents submitted in the context of an MA application based on the exception relating to the protection of commercial interests, referred to in the first indent of Article 4(2) of Regulation No 1049/2001.

75 It follows from the foregoing that the first plea must be rejected.

Second plea in law, alleging that the report at issue in its entirety constitutes commercially confidential information that is protected by Article 4(2) of Regulation No 1049/2001

76 In the second plea in law, the applicant, supported by the intervener, submits that:

– the granting of access to the report at issue could specifically and effectively undermine the applicant's commercial interests given that its competitors could use the information and data in the report for various reasons and to their own advantage, thereby giving those competitors a 'road map' for obtaining their own MA for a related medicine; the EMA therefore erred in law by concluding that the report was not in fact commercially confidential in its entirety;

– furthermore, the entirety of the report at issue should be treated as confidential, even if parts of it have been disclosed in the EPAR, because the whole is more than the sum of its parts; the assembly of the trial data, study design, analysis and presentation of non-clinical information in the report at issue has been done following an inventive strategy; consequently, the report forms an 'inseparable whole with economic value' within the meaning of the case-law resulting from the orders of 25 July 2014, *Deza* v *ECHA* (T-189/14 R, not published, EU:T:2014:686, paragraph 54), and of 1 September 2015, *Pari Pharma* v *EMA* (T-235/15 R, EU:T:2015:587, paragraph 56);

– it is therefore unhelpful for the EMA to persist in its view that the applicant must demonstrate that 'each and every element' of the document is commercially confidential;

– as to the EMA's argument that potential misuse of the report at issue by a competitor is not a ground for considering that information is confidential under Regulation No 1049/2001, reference need only be made to the arguments put forward in connection with the first plea in law; the TRIPS Agreement requires the protection of documents submitted to the EMA against unfair commercial use and permits their disclosure only where steps are taken to protect them from unfair commercial use.

77 The EMA disputes all those arguments.

78 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.

79 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).

80 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 1 February 2007, *Sison* v *Council*, C-266/05 P, EU:C:2007:75, paragraph 63, 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 36, and of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 75).

81 However, the mere fact that a document concerns an interest protected by an exception to the right of access laid down in Article 4 of Regulation No 1049/2001 is not sufficient to justify the application of that exception (judgments of 3 July 2014, *Council* v *in't Veld*, C-350/12 P, EU:C:2014:2039, paragraph 51, and 13 April 2005, *Verein für Konsumenteninformation* v *Commission*, T-2/03, EU:T:2005:125, paragraph 69).

82 First, if the institution concerned decides to refuse access to a document that it has been asked to disclose, it must, in principle, explain how disclosure of that document could specifically and actually compromise the interest protected by the exception, among those provided for in Article 4 of Regulation No 1049/2001, upon which it relies. Moreover, the risk of the interest being undermined must be reasonably foreseeable and must not be purely hypothetical (see judgment of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 76 and the case-law cited).

83 Second, if an institution applies one of the exceptions provided for in Article 4 of Regulation No 1049/2001, it is for that institution to weigh the particular interest to be protected through non-disclosure of the document concerned against, inter alia, the public interest in the document being made accessible, having regard to the advantages stemming, as noted in recital 2 of Regulation No 1049/2001, from increased openness, in that 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 (judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 45; 17 October 2013, *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:671, paragraph 32; and 3 July 2014, *Council* v *in't Veld*, C-350/12 P, EU:C:2014:2039, paragraph 53).

84 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.

85 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 requested 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).

86 It is in the light of the considerations set out in paragraphs 78 to 85 that the applicant's arguments that the EMA infringed the first indent of Article 4(2) of Regulation No 1049/2001 by adopting the contested decision must be analysed.

87 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 documents submitted in the context of an MA application and, in particular, the report at issue in its entirety. It follows that, in order for it be found

that the report at issue is commercially confidential in its entirety for the purposes of Article 4(2) of Regulation No 1049/2001, it is necessary that all the data in that report constitute commercially confidential information.

88 That is not the case here.

89 In that regard, in the first place, the applicant's 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 report at issue forms an 'inseparable whole with economic value' meriting confidential treatment in its entirety cannot succeed. The expression 'inseparable whole with economic value' which appears moreover only in the order of 1 September 2015, *Pari Pharma* v *EMA* (T-235/15 R, EU:T:2015:587), was used in the context of the examination of the plea relating to the existence of a general presumption of confidentiality. However, as is apparent from the examination of the first plea, no general presumption of confidentiality was recognised in those orders in respect of the documents held by the EMA in the context of the MA procedures for medicinal products for human use. Moreover, it is not disputed that the report at issue contains a number of items of information that were disclosed in the EPAR, the latter being accessible to the public and containing data emanating directly from the report at issue. Consequently, in order to be able to claim confidential treatment in respect of the entire report at issue, it is for the applicant 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 its commercial interests. The assertion that 'the whole is more than the sum of its parts' is too vague to show that that assembly of information could produce the consequences alleged. It was all the more necessary to adduce precise and proper explanations since, as has been pointed out in paragraph 80 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.

90 In the second place, the argument that disclosure of the report at issue would provide a competitor with a 'road map' on how to file an MA application for a competing product must be rejected. The applicant has failed to show any novelty in its models, assays or methodologies. As the EMA contended, the models and methodologies used in the clinical study concerned are based on know-how of recruitment, end-points and statistical analysis which are widely available in the scientific community and that study follows the applicable Guidelines and is thus based on state-of-the-art principles. Moreover, the document does not contain any information on the composition or manufacturing of the medicinal product Translarna, given that the EMA proactively redacted references to discussions on protocol design with the US Food and Drug Administration, batch numbers, materials and equipment, explanatory assays, quantitative and qualitative description of the method for drug concentration measurement as well as start and end dates of treatment and further dates that could lead to the identification of the patients. Accordingly, disclosure of the report at issue would not provide any valuable insight to the applicant's competitors on the long-term clinical development strategy and "study design" in addition to the information already available to the public for the medicinal product Translarna.

91 In the third place, it must be held that potential misuse of the report at issue by a competitor is not in itself a ground for considering that information is commercially confidential under Regulation No 1049/2001. In that regard, it should be borne in mind that, according to the EMA's own policy, the EMA does not disclose commercially confidential information such as detailed information on the quality and manufacturing of medicinal products. In the present case, as was stated in paragraph 90 above, the EMA did not disclose such information. It must be stated that the applicant has not adduced any evidence to explain why the EMA's redactions are insufficient. Moreover, even if another undertaking were to use most of the information contained in the report at issue in the manner claimed by the applicant, that undertaking would still have to carry out its own relevant studies and trials and successfully develop its own medicinal product. Furthermore, the medicinal product

Translarna benefits, under Article 8(1) of Regulation No 141/2000, from a period of market exclusivity preventing a similar medicinal product being marketed for a ten-year period after MA has been issued. Accordingly, the claim that the report at issue must be considered confidential in its entirety on the ground that its disclosure might enable competitors to apply for MA is unfounded in law.

92 In addition, the purpose of the period of market exclusivity, which prevents a similar medicinal product being marketed, is to enable the author of the data to recover the investments made in developing the medicinal product, and disclosure of the report at issue pursuant to Regulation No 1049/2001 cannot in any way run counter to that objective. Accordingly, it is difficult to see how the use of information almost ten years after the placing on the market of the medicinal product Translarna could undermine commercial interests.

93 However, in the case of orphan medicinal products, as in the present case, that exclusivity applies only in three exceptional cases, one of which, provided for in Article 8(3)(c) of Regulation No 141/2000, is where 'the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior'. In such a case, the CHMP must evaluate the similarity of the two medicinal products and the superiority of the medicinal product in respect of which the new MA application is filed. However, contrary to the applicant's submission, it must be pointed out that publication of the report at issue would not be sufficient for a competitor to draw up a complete report in relation to its own tests and its own results merely by relying on the data which have been made public. On this view, publication of the report at issue, without moreover the commercial data, does not place competitors at an advantage.

94 In the last place, the applicant refers to a risk of immediate loss of the benefit of the period of data exclusivity in the event of disclosure of the report at issue on the ground that that report could be used by competitors in third countries that permit such use. However, apart from the fact that that argument is vague, there is nothing to permit the conclusion that access to the information — which is not confidential from the point of view of the applicant's commercial interests — in the report at issue, 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 relevant data, such as the data on the quantitative and qualitative description of the method for drug concentration measurement of the medicinal product, remain confidential. The applicant has 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 market access 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.

95 In the light of all the foregoing, the second plea must be rejected.

Third plea in law, alleging that the release of the report at issue would undermine the EMA's decision-making process

96 In support of the third plea, the applicant claims that the release of the report at issue would in any event be premature, given that the EMA has not yet made a final decision about the full MA and continues to receive data from the applicant as part of its obligations under the conditional MA. The EMA was therefore wrong to consider, in the contested decision, that the decision to grant a conditional MA and the decision to convert a conditional MA into a full MA are two separate decision-making processes. It is therefore possible that premature release of the report at issue could be used by a competitor to lobby the EMA in relation to the grant of a full MA, which is why the report must be covered by the exception provided for in Article 4(3) of Regulation No 1049/2001.

97 The EMA contends that this plea should be rejected.

98 In the context of the third plea, the applicant claims, in essence, that release of the report at issue would undermine the EMA's decision-making process and would therefore be at odds with the first subparagraph of Article 4(3) of Regulation No 1049/2001.

99 Under the first subparagraph of Article 4(3) of Regulation No 1049/2001, access to a 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, is to be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.

100 In the present case, it must be stated that the report at issue was submitted and evaluated in the context of the MA application for the medicinal product Translarna and that, subsequently, the EMA granted the applicant the MA for that product in respect of a specific therapeutic indication. Accordingly, the procedure was closed when the request for access to that report was submitted by a third party, so that the first subparagraph of Article 4(3) of Regulation No 1049/2001 is not applicable.

101 The fact that, in the present case, a conditional MA has been granted does not in any way alter this. It is only subsequently, on the basis of one or more additional studies, and in the context of a separate decision-making process, that a decision as to whether a full MA will be granted is made. In other words, two separate decision-making processes are involved which are based on different tests. The report at issue relates to a completed study forming part of a closed decision-making process which has no impact on the forthcoming decision-making process relating to whether to grant the full MA, the grant of that MA depending on various studies.

102 For that reason, the assertion that the clinical data submitted with the MA application, which led to the grant of a conditional MA, are part of an 'incomplete data-set' is incorrect and irrelevant. Similarly, the argument that the report at issue could be used by a competitor to influence the EMA in its future decision-making process cannot succeed. In that regard, as the EMA explains, there is no material difference between a conditional MA and a full MA since, at any time, even after the granting of a full MA, any interested party could submit scientifically relevant information which could be taken into consideration by the EMA in order to ensure a high level of safety and efficacy of medicinal products and for the purpose of protecting public health.

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

Fourth plea in law, alleging that the EMA failed to carry out a balancing exercise as required by law.

104 The applicant, supported by the intervener, maintains that it is for the EMA, as the party wishing to disclose, to demonstrate that there is an overriding public interest justifying disclosure of the applicant's confidential information, and it complains that the EMA failed to examine this question. More specifically, the EMA failed to consider the relevance of the specific rules of Regulation No 726/2004 governing access to documents submitted to the EMA by MA applicants, the EU's obligations under the TRIPS Agreement, and fundamental rights and the principle of proportionality.

105 The EMA disputes those arguments.

106 It is apparent from the final phrase of Article 4(2) of Regulation No 1049/2001 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 (see, to that effect, judgment of 7 October 2014, *Schenker* v *Commission*, T-534/11, EU:T:2014:854, paragraph 74).

107 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).

108 In the present case, as the EMA points out, it did not conclude that the report at issue should be protected by the exceptions 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 report at issue or to weigh it against the applicant's interest in keeping that report confidential.

109 It follows that the applicant's arguments are ineffective and that this plea must therefore be rejected.

Fifth plea in law, alleging that the outcome of a proper balancing exercise, as required by law, would have been a decision not to release any part of the report at issue.

110 In the fifth plea in law, the applicant argues that, in any event, a proper balancing exercise would clearly have produced a favourable outcome for it. It notes that adequate information regarding the medicinal product Translarna's safety and efficacy is already available to the public through the EPAR. In the applicant's opinion, disclosure is likely to harm the public interest, by undermining MA applicants' confidence in the MA procedure and the security of commercially confidential information shared with the EMA.

111 The EMA reiterates that it has noted that the whole and entire content of the report at issue cannot be considered commercially confidential and that it could not therefore have balanced any overriding interest in disclosure against the specific interest to be protected by non-disclosure of the document.

112 The fifth plea is based on the premiss that the report at issue or a part thereof is confidential. However, it is clear from the examination of the previous pleas that the EMA did not err in finding that there was no confidential information for the purposes of Article 4(2) and (3) of Regulation No 1049/2001, with the exception of the redacted passages mentioned in paragraph 8 above. The EMA was not therefore required to weigh the particular interest in confidentiality against the overriding public interest in disclosure.

113 The fifth plea in law must therefore be rejected as unfounded and, accordingly, the action must be dismissed in its entirety.

Costs

114 Under Article 134(1) of the Rules of Procedure, 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 applicant has been unsuccessful in the main proceedings, it 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.

115 Eucope must bear its own costs in accordance with Article 138(3) of the Rules of Procedure.

On those grounds,

THE GENERAL COURT (Second Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders PTC Therapeutics International Ltd to bear its own costs and to pay those incurred by the European Medicines Agency (EMA), including those relating to the application for interim measures;**

3. **Orders the European Confederation of Pharmaceutical Entrepreneurs (Eucope) to bear its own costs.**

Prek Schalin Costeira

Delivered in open court in Luxembourg on 5 February 2018.

E. Coulon President
Registrar