Reports of Cases

ORDER OF THE PRESIDENT OF THE GENERAL COURT

1 September 2015*

(Application for interim measures — Access to documents — Regulation (EC) No 1049/2001 — Documents held by the EMA concerning information submitted by an undertaking as part of its application for authorisation to place a medicinal product on the market — Decision to grant a third party access to the documents — Application for suspension of operation of a measure — Urgency — Prima facie case — Weighing up of interests)

In Case T-235/15 R,

Pari Pharma GmbH, established in Starnberg (Germany), represented by M. Epping and W. Rehmann, lawyers,

applicant,

v

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

defendant,

supported by

Novartis Europharm Ltd, established in Camberley (United Kingdom), represented by C. Schoonderbeek, lawyer,

intervener,

APPLICATION, in essence, for the suspension of operation of Decision EMA/271043/2015 of the EMA of 24 April 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 certain documents containing information submitted in the context of an application for marketing authorisation for the medicinal product Vantobra,

THE PRESIDENT OF THE GENERAL COURT

makes the following

* Language of the case: English.

Order [1]

Background to the dispute, procedure and forms of order sought

1 The European Medicines Agency (EMA), established by 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), has as its main responsibility the protection and promotion of public and animal health, through the evaluation and supervision of medicinal products for human and veterinary use. To that end, the EMA is responsible for the scientific evaluation of applications for European Union marketing authorisations ('MAs') for human and veterinary medicinal products (centralised procedure). Under the first subparagraph of Article 57(1) of Regulation No 726/2004, the EMA is to provide the Member States and the institutions of the European Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it.

2 Under Regulation No 726/2004, certain categories of medicinal products, such as Vantobra, which is the subject-matter of the present proceedings, must be approved under the centralised procedure pursuant to that regulation. That procedure entails the submission, by the pharmaceutical company concerned, of an MA application, which is examined by the EMA, and a decision by the European Commission on the MA. The documentary information which an MA applicant is to provide must allow the EMA, in the interest of public health, to take its decision on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, in order to assess the risk-benefit balance of that product. Exclusive responsibility for preparing the EMA's opinions on all questions concerning medicinal products for human use is to be vested in a Committee for Medicinal Products for Human Use ('CHMP').

3 Under Article 13(3) of Regulation No 726/2004, the EMA is to publish the European Public Assessment Report ('EPAR') on the medicinal product for human use drawn up by the CHMP, namely a summary of the product's characteristics that is understandable to the public, and the reasons for its opinion in favour of granting the MA, after deletion of any information of a commercially confidential nature. In addition, under the first paragraph of Article 80 of Regulation No 726/2004, the EMA is to adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

4 The first paragraph of Article 73 of Regulation No 726/2004 states that 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), a regulation which is aimed at ensuring the widest possible public access to documents held by the European Union administrative bodies, is applicable to documents held by the EMA.

5 Article 4(2) of Regulation No 1049/2001 provides that the institutions are to refuse access to a document where disclosure would undermine, inter alia, the protection of commercial interests of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure of the document in question. As regards third-party documents, Article 4(4) of Regulation No 1049/2001 provides that the institution is to consult the third party with a view to assessing whether an exception in paragraph 2 is applicable, unless it is clear that the document must or must not be disclosed. Pursuant to Article 4(6) of Regulation No 1049/2001, if only parts of the requested document are covered by any of those exceptions, the remaining parts of the document are to be released.

1 — Only the paragraphs of this order which the Court considers it appropriate to publish are reproduced here.

6 On 19 December 2006, the EMA adopted rules for the implementation of Regulation No 1049/2001 on access to its documents. In addition, in an effort to further enhance its transparency, the EMA amended its policy on access to EMA documents ('the EMA's access policy') in November 2010, in order to ensure the widest possible access to EMA documents concerning any matter related to the policies, activities and decisions falling within the EMA's remit and responsibilities, prioritising access to documents containing essential scientific information concerning the safety and efficacy of an authorised medicinal product.

7 The applicant, Pari Pharma GmbH, is a pharmaceutical company belonging to the PARI Group, which has approximately 550 employees worldwide and which focuses on the optimisation of aerosol delivery platforms with established or new liquid medicines for inhalation use. The PARI Group is primarily in the business of developing and commercialising nebuliser devices and drug formulation methodologies, and has developed its proprietary 'eFlow' nebulisation technology for tailored inhalation therapies in respiratory diseases. The applicant also holds an MA for its own medicinal products in the field of respiratory diseases, which are marketed together with its proprietary nebuliser.

8 The MA for Vantobra, a 170 mg nebuliser solution (tobramycin), which is the subject-matter of the present proceedings, was granted by the Commission on 18 March 2015 following completion of the centralised authorisation procedure in accordance with Regulation No 726/2004. Vantobra is intended for the treatment of chronic pulmonary infection due to Pseudomonas aeruginosa in patients aged 6 years and older with cystic fibrosis. It is a hybrid medicinal product to the TOBI 300 mg/5 ml nebuliser solution ('TOBI'). According to the applicant, through the use of its 'eFlow' technology, Vantobra has a therapeutic advantage over TOBI due to a significantly reduced treatment time.

9 As regards TOBI, the intervener, Novartis Europharm Ltd, is the holder of an MA granted by the Commission, on 20 July 2011, under Regulation No 726/2004, for the medicinal product TOBI Podhaler, a tobramycin dry powder for inhalation. TOBI Podhaler was classified as an 'orphan medicinal product', within the meaning of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 18, p. 1), that is to say, medicinal products intended for the diagnosis, prevention or treatment of rare conditions. In order to promote the development of effective treatments for patients affected by rare conditions, that regulation introduces a system of incentives to encourage pharmaceutical companies to invest in research, development and bringing to the market of orphan medicinal products.

10 According to recital 8 of Regulation No 141/2000, the strongest incentive for the pharmaceutical industry to invest in the development and marketing of orphan medicinal products is where there is a prospect of obtaining market exclusivity for a certain number of years during which part of the investment might be recovered.

11 In that respect, Article 8(1) of Regulation No 141/2000 provides that orphan medicinal products in respect of which an MA has been granted enjoy market exclusivity, in that 'the Community and the Member States shall not, for a period of 10 years, accept another application for a [MA], or grant a [MA] or accept an application to extend an existing [MA], for the same therapeutic indication, in respect of a similar medicinal product'.

12 However, under Article 8(3) of Regulation No 141/2000, by way of derogation from paragraph 1, 'a [MA] may be granted, for the same therapeutic indication, to a similar medicinal product if:

(c) 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'.

13 Under Article 8(1) of Regulation No 141/2000, TOBI Podhaler therefore enjoys a period of market exclusivity which, following the grant of a two-year extension, will expire on 20 July 2023.

14 As regards the MA in respect of Vantobra (see paragraph 8 above), it was granted to the applicant, by way of derogation as regards TOBI Podhaler, pursuant to Article 8(3) of Regulation No 141/2000. That authorisation by way of derogation was granted following the procedure described below.

…

23 On the basis of the additional compilation of clinical trial data and related calculations provided by the applicant, the CHMP concluded, on 22 January 2015, that the applicant's claim of clinical superiority of Vantobra in terms of greater safety in a substantial portion of the target population was substantiated by sufficient evidence and that an MA should therefore be granted for Vantobra. That favourable opinion is based on two CHMP reports issued on the same day, namely the Assessment Report for Vantobra on similarity with Cayston and TOBI Podhaler (EMA/CHMP/702525/2014; 'the Similarity Report') and the Assessment Report on clinical superiority to TOBI Podhaler, (EMA/CHMP/778270/2014; 'the Superiority Report'). Those reports were drawn up on the basis of the information provided by the applicant. The Commission followed the EMA's recommendation and granted the MA for Vantobra on 18 March 2015 (see paragraphs 8 and 14 above).

24 On 13 April 2015 the EMA informed the applicant by e-mail that it had received a request for access to documents concerning the medicinal product Vantobra, in particular the Similarity Report and the Superiority Report (together, 'the reports at issue'). It emerged in the course of the proceedings that the party requesting access was the company Novartis Europharm, the holder of an MA granted for the medicinal product TOBI Podhaler (see paragraph 9 above). The EMA expressed its intention to disclose those documents with a few redactions concerning personal data, and set a deadline for the applicant to apply for additional redactions. On 20 April 2015 the applicant responded to the EMA, requesting it not to disclose the reports at issue. As a precautionary measure, the applicant asked for additional redactions to the documents in question.

25 On 24 April 2015, the EMA decided to disclose the documents in question ('the contested decision'). As regards, in particular, the reports at issue, the EMA stated that, with a few exceptions, they did not constitute 'commercially confidential information'. According to the EMA, the information which the applicant claimed to be confidential was for the most part publicly accessible, or could be easily inferred from public information. In any event, even if that information were to be considered confidential, there was an overriding public interest justifying its disclosure. The contested decision was based, inter alia, on the EMA's access policy, in accordance with which documents containing scientific information, including the opinions and the assessment reports issued by the CHMP in relation to orphan medicinal products, are released once the MA procedure concerning a medicinal product has come to an end.

26 By an application lodged at the Court Registry on 15 May 2015, the applicant brought an action seeking, in essence, the annulment of the contested decision in so far as it grants a third party access to the reports at issue. In support of that action it argues, in essence, that the contested decision infringes Regulation No 1049/2001 and Article 339 TFEU and that it breaches the applicant's fundamental rights as regards private life and confidentiality under Article 7 of the Charter of Fundamental Rights of the European Union and Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950 ('the ECHR').

27 By a separate document, lodged at the Court Registry on the same date, the applicant brought the present application for interim measures, in which it claims, in essence, that the President of the General Court should:

— suspend the operation of the contested decision, in so far as it grants a third party access to the reports at issue;

— order the EMA not to disclose those reports;

— in the alternative, as a precautionary measure, order the EMA not to disclose:

  — the Superiority Report without additional redactions on page 9 (Superior Respiratory Tolerability of Vantobra over TOBI Podhaler), pages 11, 12 and 14 (Extrapolation of tolerability from TOBI to Vantobra), pages 17 to 19 (applicant's position on question 1 and assessment of the response) and pages 19 to 23 (applicant's position on question 2 and assessment of the response, Conclusion and Recommendation), as set out in Annex A 1 to the application for interim measures;

  — not to disclose the Similarity Report, without additional redactions on pages 9 and 10, Section 2.3 (Therapeutic indication, Data from field survey) and pages 11 and 12, Section 2.3 (Therapeutic indication, Interview of physicians in cystic fibrosis centres), as set out in Annex A 2 to the application for interim measures;

— order the EMA to pay the costs of the proceedings for interim measures.

28 In its observations on the application for interim measures, lodged at the Court Registry on 1 June 2015, the EMA contends that the President of the General Court should:

— dismiss the application for interim measures;

— order the applicant to pay the costs.

…

30 By order of 22 June 2015, the President of the General Court granted the company Novartis Europharm leave to intervene in the present proceedings for interim measures in support of the form of order sought by the EMA. The main parties having requested that certain documents in the file be regarded as confidential and having produced a non-confidential version of the documents in question, for the purpose of notification to the intervener, the President ordered that the provision to the intervener of the procedural documents served or to be served on the parties be restricted to a non-confidential version, stating that a decision as to whether the application for confidentiality was well founded would be taken at a later stage in the light of any objections submitted on that issue by the intervener.

31 By a written pleading of 26 June 2015, the intervener expressed objections in respect of most of the documents which had been provisionally classified as confidential in the order of 22 June 2015. Nevertheless, it lodged a statement in intervention on 30 June 2015, in which it asked the President of the General Court to dismiss the application for interim measures and to order the applicant to pay all the costs. The main parties expressed their views on that statement on 8 and 9 July 2015.

32 Prior to this, on 28 May 2015, the intervener had brought an action before the Court seeking the annulment of the decision of 18 March 2015, by which the Commission had granted the MA for Vantobra (see paragraphs 8 and 14 above), on the ground that that decision infringed the market exclusivity it enjoyed, under Article 8(1) of Regulation No 141/2000, for its medicinal product TOBI Podhaler (Case T-269/15 *Novartis Europharm* v *Commission*).

Law …

Whether there is a prima facie case

37 It must be noted that a number of different forms of wording have been used in the case-law to define the condition relating to the establishment of a prima facie case, depending on the individual circumstances (see, to that effect, order in *Commission* v *Atlantic Container Line and Others*, cited in paragraph 35 above, EU:C:1995:257, paragraph 26).

38 Thus, that condition is satisfied where at least one of the pleas in law put forward by the applicant for interim measures in support of the main action appears, prima facie, not unfounded. That is the case, inter alia, where one of the pleas relied on reveals the existence of difficult legal issues the solution to which is not immediately obvious and therefore calls for a detailed examination that cannot be carried out by the judge hearing the application for interim measures but must be the subject of the main proceedings, or where the discussion of issues by the parties reveals that there is a major legal disagreement whose resolution is not immediately obvious (see order of 10 September 2013 in *Commission* v *Pilkington Group*, C-278/13 P(R), EU:C:2013:558, paragraph 67 and the case-law cited).

39 In that context, it must be borne in mind that the interim relief procedure, which is based on a prima facie examination, is not designed to establish the truth of complex and much debated facts. The judge hearing an application for interim measures does not have the means necessary in order to carry out such examinations and in numerous instances he would have difficulty doing so in sufficient time (see, to that effect, order of 24 April 2008 in *Commission* v *Malta*, C-76/08 R, EU:C:2008:252, paragraph 36).

40 In the present case, the applicant submits that disclosure of the reports at issue would ignore their confidential nature and would infringe the applicant's right to professional secrecy, guaranteed by Article 339 TFEU, Article 8 of the ECHR and Article 7 of the Charter of Fundamental Rights. Moreover, that disclosure would not be justified by Regulation No 1049/2001, by Article 15(3) TFEU or by the EMA's access policy.

…

47 The EMA contends that the applicant has failed to demonstrate the existence of a prima facie case. It submits that the claims made by the applicant closely resemble the claims previously made by other pharmaceutical companies alleging the illegality of the EMA's decisions to release clinical and non-clinical information contained in the dossier accompanying MA applications, namely Case T-44/13, *AbbVie* v *EMA* (EU:T:2014:694), removed from the register on 17 July 2014, and Case T-73/13, *InterMune UK and Others* v *EMA* (EU:T:2015:531), removed from the register on 29 June 2015, in both of which the applicants withdrew their actions for annulment. As the EMA submitted in those cases, the general claim made by the applicant in this case that the whole content of the reports at issue should enjoy confidential treatment is unfounded. In particular, a substantial part of those reports is freely available in the public domain since it is published on widely known websites, including the EMA's own website, and is included in the EPAR. Consequently, the claim that the whole content of the reports at issue is protected by the provisions of Article 4(2), first indent, of Regulation No 1049/2001 must be rejected.

…

51 In that respect, it must be noted that the two reports at issue which the applicant claims are confidential, and which consist of, respectively, 27 and 24 pages, contain the CHMP's assessment of the similarity between two medicinal products, Vantobra and TOBI Podhaler, and of the clinical superiority of the former over the latter. That assessment relates to a very specific pharmaceutical

sector, that of orphan medicinal products, and deals, inter alia, with clinical pharmacokinetic and bioequivalence studies. It therefore raises issues involving highly technical scientific evaluations addressing quality, safety and efficacy, with a view to the grant of an MA for the medicinal product Vantobra, including the assessment of its therapeutic characteristics that are capable of justifying, through the use of its 'eFlow' nebulisation technology, the view that Vantobra offers an advantage over TOBI Podhaler. In examining the reports at issue and, inter alia, the question whether the EMA made errors in rejecting the applicant's confidentiality requests, the judge hearing the application for interim measures is thus confronted with complex scientific issues which cannot be immediately resolved in the context of proceedings for interim measures, but rather call for a detailed examination in the main proceedings.

52 The EMA and the intervener emphasise that large parts of the reports at issue are already accessible to the public. In that respect, it is true that confidential treatment cannot be claimed in respect of a specific element, such as a figure of financial significance for an undertaking, which has already been published and made accessible to interested persons. In the present case, however, the issue of confidentiality raised in that context does not concern a particular figure, but rather several complete passages of text, which the applicant submits are not, in the precise configuration and assembly of their components, generally known among the public or among operators in the pharmaceutical sector. The question therefore arises whether the fact that the applicant compiled scientific data known to the public and added secret scientific data in order to produce a body of complex information which, as such, is not readily accessible may justify treating that body of information as confidential. That question also raises issues which cannot be immediately resolved in the context of proceedings for interim measures (see, to that effect, order of 25 July 2014 in *Deza* v *ECHA*, T-189/14 R, EU:T:2014:686, paragraph 53).

53 There are no reasonable grounds for ruling out, at this stage, that the Court, when it adjudicates on the substance, may hold that the applicant's specific use of confidential and non-confidential information for the purposes of the EMA's assessment of the applicant's MA application for the medicinal product Vantobra should be treated as confidential, inasmuch as an inventive strategy of that kind bestows a scientific added value on the non-confidential elements taken in isolation (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 54 and the case-law cited).

54 While it is true that the sources used by the applicant are widely accessible to the public, the fact remains that their evaluation and compilation on the basis of a market study that it carried out in order to demonstrate the existence and significant size of a target patient population for Vantobra due to those patients' intolerance to dry powder inhalation were necessary to establish, before the EMA and the Commission, the similarity and the clinical superiority of Vantobra over TOBI Podhaler. The results of that market study were never disclosed to the public and were used only in the context of the MA application procedure for Vantobra, with the exception of a short summary presented to a limited public of specialised physicians during a scientific conference in June 2014. The same is true of the compilation of clinical trial data which was included, inter alia, in the Superiority Report. It is for the Court adjudicating on the substance of the case to evaluate, if necessary, whether the degree of novelty and the scale of the investment made by the applicant in terms of time and cost for that purpose are sufficient to justify the confidential treatment sought.

55 Furthermore, should the Court, when it adjudicates on the substance, uphold the applicant's argument alleging the confidential nature of the reports at issue as such, taken as a whole, and consider that those reports constitute a specific category of information enjoying a general presumption of confidentiality, the question of partial disclosure of the public data contained therein would not arise, given that documents covered by such a presumption are not subject to the obligation of partial disclosure (see, to that effect, judgments of 28 June 2012 in *Commission* v *Éditions Odile Jacob*, C-404/10 P, ECR, EU:C:2012:393, paragraph 133, and 27 February 2014 in *Commission* v *EnBW*, C-365/12 P, ECR, EU:C:2014:112, paragraph 134). Moreover, it would not be appropriate to carry out an individual examination of each of the elements in the reports at issue, in order to verify whether

disclosure of that element in particular could specifically and actually undermine the applicant's business interests (see, to that effect, judgment in *Commission* v *EnBW*, EU:C:2014:112, paragraph 93 and the case-law cited).

56 The question of whether the reports at issue constitute a specific category of information enjoying, on account of their very nature, a general presumption of confidentiality should lead the Court adjudicating on the substance to evaluate whether, as the applicant claims, the public and non-public elements of the reports at issue form an inseparable whole with economic value which is, as such, exempt from Article 4(6) of Regulation No 1049/2001. In any event, for the purposes of the present procedure, it would be pointless, and of no use to the intervener, which requested the EMA to grant it access to the reports at issue, to allow, by way of proceedings for interim measures, disclosure that is strictly limited to data already in the public domain. The intervener, which belongs to the professional circle concerned by that type of information, should easily be able to access those passages of the reports at issue by means of the appropriate online search tools (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 56).

57 The Court hearing the main action must also take into account the fact that the applicant relies on the fundamental right of an undertaking to privacy, laid down in Article 8 of the ECHR, the wording of which corresponds to that of Article 7 of the Charter of Fundamental Rights: the applicant maintains that disclosure of the reports at issue would undermine its business secrets, the Court of Justice having recognised that it may be necessary to prohibit the disclosure of information which is classified as confidential, in order to protect the fundamental right of an undertaking to respect for 'private life', enshrined in Article 8 of the ECHR and Article 7 of the Charter of Fundamental Rights (see, to that effect, judgment of 14 February 2008 in *Varec*, C-450/06, ECR, EU:C:2008:91, paragraphs 47 and 48). As the applicant rightly submits, the protection granted by those provisions of primary law cannot be undermined by a mere administrative practice, such as the EMA's access policy.

58 Moreover, even if the reports at issue could be regarded as being covered by the exception laid down in Article 4(2) of Regulation No 1049/2001, the question whether an overriding public interest nevertheless justifies their disclosure will require the applicant's commercial interest in the reports not being disclosed to be weighed against the general interest in guaranteeing the widest possible public access to documents held by the European Union. Such a weighing up of the various interests involved will call for delicate assessments which must be a matter for the Court adjudicating on the substance of the case (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 61), particularly since account must be taken of the fact that the intervener also invokes a fundamental right, namely its right to an effective remedy laid down in Article 47 of the Charter of Fundamental Rights, asserting that it must have access to the reports at issue in order to support its action for annulment of the decision granting the applicant the MA for Vantobra and thus to be able to protect the market exclusivity of TOBI Podhaler (see paragraph 32 above). Incidentally, that weighing up of interests, to be carried out by the Court adjudicating on the substance of the case, should not be confused with that carried out for the purpose of the present interim proceedings (see paragraphs 64 to 73 below).

59 In so far as the EMA and the intervener again emphasise the importance of transparency in the interest of human health as well as that of doctors and of patients, it is possible that such considerations may be taken into consideration for the purpose of resolving the dispute in the main proceedings. However, those parties fail to explain the particular urgency which would require the immediate disclosure of the reports at issue, because of a danger — not merely potential, but real — posed by the medicinal product Vantobra, and which would therefore preclude the grant of the requested interim measures. In any event, it seems more appropriate that any danger that Vantobra may pose should be considered in the examination, in Case T-269/15 (see paragraph 32 above), of the lawfulness of the decision granting the applicant the MA for Vantobra.

60 In view of the foregoing, it must be held, without prejudice to the merits of the arguments put forward by the EMA and by the intervener, the substance of which will be examined in the main proceedings, that the present case raises complex issues which cannot, prima facie, be considered to be manifestly of no relevance, and whose resolution calls for thorough examination within the main proceedings, particularly since the specific confidentiality issues mentioned above, as well as the EMA's new access policy, have not yet been adjudicated on by the Courts of the European Union, as the EMA acknowledged in paragraph 78 of its observations of 1 June 2015.

…

62 Accordingly, there is no case-law that would make it possible to give a ready answer to the questions of confidentiality that fall to be decided in the present case by the future judgment on the substance. They are novel questions of principle which cannot be resolved, for the first time, by the judge hearing an application for interim measures; rather they require thorough examination within the main proceedings (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 63).

63 It must therefore be found that there is a prima facie case as regards the reports at issue.

The weighing up of interests

64 According to settled case-law, the weighing up of interests requires the judge hearing an application for interim measures to determine whether or not the applicant's interest in obtaining the measures sought outweighs the interest in the immediate application of the contested measure, by examining, more specifically, whether the possible annulment of that measure by the Court when ruling on the main application would allow the situation that would have been brought about by its immediate operation to be reversed and, conversely, whether suspension of operation of the measure would prevent it from being fully effective in the event of the main application being dismissed (see, to that effect, orders of 11 May 1989 in *Radio Telefis Eireann and Others* v *Commission*, 76/89 R, 77/89 R and 91/89 R, ECR, EU:C:1989:192, paragraph 15, and 26 June 2003 in *Belgium and Forum 187* v *Commission*, C-182/03 R and C-217/03 R, ECR, EU:C:2003:385, paragraph 142).

65 As regards more particularly the condition that the legal situation created by an interim relief order must be reversible, it must be recalled that the purpose of the procedure for interim relief is to guarantee the full effectiveness of the future decision on the main action (see, to that effect, order of 27 September 2004 in *Commission* v *Akzo and Akcros*, C-7/04 P(R), ECR, EU:C:2004:566, paragraph 36). Consequently, that procedure is merely ancillary to the main action to which it is an adjunct (order of 12 February 1996 in *Lehrfreund* v *Council and Commission*, T-228/95 R, ECR, EU:T:1996:16, paragraph 61), and accordingly the decision made by the judge hearing an application for interim relief must be provisional in the sense that it cannot either prejudge the future decision on the substance of the case or render it illusory by depriving it of practical effect (orders of 17 May 1991 in *CIRFS and Others* v *Commission*, C-313/90 R, ECR, EU:C:1991:220, paragraph 24, and 12 December 1995 in *Connolly* v *Commission*, T-203/95 R, ECR, EU:T:1995:208, paragraph 16).

66 It necessarily follows that the interest defended by a party to interim relief proceedings does not merit protection where that party's request is that the judge hearing the application should adopt a decision which, far from being a merely interim measure, would serve to prejudge the future decision on the main action and to render it illusory by depriving it of practical effect.

67 In the present case, the Court will have to adjudicate, in the main proceedings, on whether the contested decision — by which the EMA rejected the applicant's confidentiality request and stated its intention to disclose the reports at issue to a third party — must be annulled for disregarding the confidential nature of those reports, in that their disclosure would constitute an infringement of, inter

alia, Article 8 of the ECHR, Article 7 of the Charter of the Fundamental Rights and Article 339 TFEU. In that respect, it is clear that, in order to preserve the effectiveness of a judgment annulling the contested decision, the applicant must be able to ensure that the EMA does not unlawfully disclose those reports. A judgment ordering annulment would be rendered illusory and deprived of practical effect if the present application for interim measures were to be dismissed, since the EMA would then be free to disclose the reports at issue immediately, thereby effectively prejudging the future decision in the main action, namely that the action for annulment would be dismissed.

68 It follows that the interest defended by the applicant must prevail over the EMA's interest in the dismissal of the application for interim measures, *a fortiori* since the grant of the interim measures requested would amount to no more than maintaining the status quo for a limited period, while the EMA, far from alleging that disclosure of the reports at issue is necessary to meet an overriding need to protect public health, merely invokes, inter alia, the general principle of transparency (see paragraph 59 above).

69 As regards the interest of the intervener, which requested the EMA to disclose the reports at issue, it is true that it may invoke a right of access to the documents of the European Union's institutions, bodies, offices and agencies under Article 15(3) TFEU. However, the exercise of that right would merely be delayed if the interim measures were granted; that would entail a temporal restriction on the exercise of that right, whilst the applicant's right to protection of the confidentiality of those reports would be reduced to nothing if the application for interim relief were dismissed.

70 In so far as the intervener invokes its right to an effective remedy, laid down in Article 47 of the Charter of Fundamental Rights, maintaining that it must have access to the reports at issue in order to be able to protect the market exclusivity of its medicinal product TOBI Podhaler and to support its action for annulment of the decision by which the Commission granted the applicant the MA for Vantobra (Case T-269/15, see paragraph 32 above), it cannot be denied that such access could be useful for that party, since the grant of the MA for Vantobra was in fact justified by the EMA's favourable opinion based on the reports at issue. However, whether and, as the case may be, to what extent the intervener may be granted access to the reports at issue is best decided by the Court adjudicating on the dispute in Case T-269/15.

71 Should the Commission, in the dispute in Case T-269/15, rely on the reports at issue in order to justify the similarity and clinical superiority of Vantobra over TOBI Podhaler, it would be for the intervener to request access to those documents and for the Court deciding on the substance to assess whether it would be appropriate to grant the access sought, in order to respect the intervener's right to an effective remedy, the assumption being that, if the intervener were granted access to those reports, it could not use them for any inappropriate purpose, since it would be entitled to use them only for the purpose of pursuing its own case in Case T-269/15 and for no other purpose (see, to that effect, order in *Commission* v *Pilkington Group*, cited in paragraph 38 above, EU:C:2013:558, paragraph 57; judgment of 17 June 1998 in *Svenska Journalistförbundet* v *Council*, T-174/95, ECR, EU:T:1998:127, paragraphs 135 to 137; and order of 28 April 1999 in *Van Parys and Others* v *Commission*, T-11/99 R, ECR, EU:T:1999:86, paragraph 22). Conversely, if the reports at issue were disclosed pursuant to Regulation No 1049/2001 in the context of the present proceedings, that disclosure would have an *erga omnes* effect, in that those documents could be communicated to other applicants for access and any person would have the right to access them (see, to that effect, judgment of 21 October 2010 in *Agapiou Joséphidès* v *Commission and EACEA*, T-439/08, EU:T:2010:442, paragraph 116). Such an *erga omnes* effect would clearly go beyond the scope of the legitimate interests of the intervener, which seeks only to exercise its right to an effective remedy for the purposes of Case T-269/15.

72 Moreover, it is possible that the intervener may obtain its objective in Case T-269/15, namely the annulment of the decision to grant the MA for Vantobra, without having recourse to the reports at issue, if it succeeds in persuading the Court that the decision in question is vitiated by a failure to state reasons, precisely because the Commission did not disclose the relevant content of those reports to the intervener.

73 It follows that the applicant's interest must, in the context of the present proceedings, also prevail over that of the intervener.

Urgency …

84 It should be noted that, in the present case, the alleged damage would result from the disclosure of information claimed to be confidential. For the purpose of assessing the existence of serious and irreparable damage, the judge hearing an application for interim measures is necessarily required to start from the premiss that the information alleged to be confidential is in fact confidential, as claimed by the applicant both in the main action and in proceedings for interim relief (see, to that effect, orders in *Commission* v *Pilkington Group*, cited in paragraph 38 above, EU:C:2013:558, paragraph 38, and *EMA* v *AbbVie*, cited in paragraph 79 above, EU:C:2013:794, paragraph 38).

85 Consequently, for the purposes of the present appraisal of the urgency condition, the reports at issue must be regarded as being confidential. It follows that the arguments by which the EMA contests that confidentiality must be rejected.

86 It must be pointed out, next, that although the damage caused by the publication on the Internet of allegedly confidential information is not comparable, in principle, particularly as regards its nature and the manner in which it will foreseeably occur, to the damage linked to the disclosure of such information to a third party, particularly in relation to its use for commercial purposes (see, to that effect, order in *EMA* v *AbbVie*, cited in paragraph 79 above, EU:C:2013:794, paragraph 50), it cannot be ruled out, inevitably and logically, that the damage resulting from such disclosure to a third party may be classified as serious and irreparable (order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 81).

87 In any event, the extent to which the disclosure of allegedly confidential information causes serious and irreparable damage depends on a combination of circumstances, such as, inter alia, the professional and commercial importance of the information for the undertaking seeking its protection and the utility of that information for other market participants which are liable to examine and use it subsequently (see, to that effect, orders in *Commission* v *Pilkington Group*, cited in paragraph 38 above, EU:C:2013:558, paragraph 42; *EMA* v *AbbVie*, cited in paragraph 79 above, EU:C:2013:794, paragraph 42; and *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 82).

88 As regards more specifically the damage invoked by the applicant in the present case, it has been held that financial damage which is objectively considerable, or even not insignificant, may be considered 'serious', without it being necessary in every case to relate that damage to the turnover of the undertaking concerned (see, to that effect, order of 7 March 2013 in *EDF* v *Commission*, C-551/12 P(R), ECR, EU:C:2013:157, paragraphs 32 and 33; see also, by analogy, order of 8 April 2014 in *Commission* v *ANKO*, C-78/14 P-R, ECR, EU:C:2014:239, paragraph 34).

89 The reports at issue, relating to pharmacology, contain highly technical scientific evaluations concerning quality, safety and efficacy and justify the grant of an MA for the applicant's medicinal product Vantobra on the ground that it presents a therapeutic advantage over another similar product. Those reports therefore concern the applicant's manufacturing and commercial activity. Moreover, in view of the market share that Vantobra, as a superior medicinal product to TOBI Podhaler, could achieve in competition with that product (see paragraph 76 above), they are

objectively liable to be used for competitive purposes. The financial value of the reports at issue is attested to by the authorisation procedure for Vantobra before the EMA: after an approximately 30-month procedure and thanks to continuous dialogue with the CHMP (see paragraphs 15 to 23 above), the applicant was able — by combining and analysing publicly available information with data from its new market study — to convince the CHMP and the Commission of the similarity and clinical superiority of Vantobra over TOBI Podhaler, bearing in mind that both the public and non-public elements compiled by the applicant were included in the reports at issue. Those elements may also be relevant for the applicant's future development and planning as regards bringing the medicinal product Vantobra to many different markets. It follows that the reports at issue, the confidential nature of which must be presumed in the context of the urgency assessment (see paragraphs 84 and 85 above), are an intangible asset that may be used for competitive purposes, whose value could be seriously reduced, or even eliminated, if the reports did not remain secret (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 85).

90 Moreover, the serious nature of the damage invoked by the applicant is also established on the following ground: first, the existence of a prima facie case has been shown, in the present case, by the fact that the confidentiality request submitted by the applicant raises complex questions which call for a thorough examination that can be carried out only by the Court when it adjudicates on the substance, and, secondly, the judge hearing an application for interim measures is required to start from the premiss that the information alleged to be confidential is in fact confidential (see paragraph 84 above). Information of an economic nature is classified as confidential only if its disclosure is liable to cause serious damage to the commercial and financial interests of the holder of that information (see, to that effect, judgments of 18 September 1996 in *Postbank* v *Commission*, T-353/94, ECR, EU:T:1996:119, paragraph 87; 30 May 2006 in *Bank Austria Creditanstalt* v *Commission*, T-198/03, ECR, EU:T:2006:136, paragraph 71; and 12 October 2007 in *Pergan Hilfsstoffe für industrielle Prozesse* v *Commission*, T-474/04, ECR, EU:T:2007:306, paragraph 65). It follows that the assessment of whether disclosure of the reports at issue would cause the applicant 'ordinary' or 'serious' damage cannot be separated from the thorough examination to be carried out by the Court when ruling on the main action. In view of his ancillary role vis-à-vis that of the Court adjudicating on the substance, the judge hearing an application for interim measures is therefore, in any event, required to assume, for the purposes of the present proceedings, not only that the reports at issue are confidential, but also that the damage that may be caused to the applicant by disclosure of those reports is serious (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 86).

91 Consequently, the applicant has established, to the requisite legal standard, the serious nature of the financial damage it is liable to suffer if the reports at issue are disclosed.

92 That conclusion is not called into question by the fact that the applicant claimed, in the alternative, that the Court should order the EMA not to disclose in any event certain specific elements in the reports at issue (see paragraph 27 above). That alternative head of claim was made only as a precaution, should the judge hearing the application for interim measures consider that the reports at issue were not confidential in their entirety. It cannot be inferred from this that only the disclosure of those specific elements would be liable to cause the applicant serious damage, since, otherwise, it would be penalised for having chosen, as a precautionary measure, a procedural strategy aimed at protecting itself as much as possible. In those circumstances, the applicant's procedural approach must be interpreted as meaning that disclosure of the reports at issue, as a whole, would cause it 'serious' damage, whereas the damage suffered in the event of disclosure of the particularly sensitive elements, identified in the alternative head of claim, would be 'extremely serious'.

93 As regards the irreparable nature of the damage invoked, it is appropriate to examine, first of all, the foreseeability of the damage liable to be caused to the applicant by disclosure of the reports at issue to the third party which made a request to that effect to the EMA.

94 It is true that such disclosure of information to a single person is of a different nature from a publication of information online, such as that at issue in the order in *Commission* v *Pilkington Group*, cited in paragraph 38 above (EU:C:2013:558). In the latter case, the immediate cause of the damage feared by the undertaking concerned is not the online publication as such. The persons potentially interested in the information in question, in particular competitors, must also be informed of that publication and take cognisance of the information, in order to use it for purposes harmful to the undertaking concerned. Such online publication therefore merely places the undertaking concerned in a situation of general vulnerability; that situation may be exploited at any time by interested persons, which is liable to cause damage to that undertaking (see, to that effect, *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 88).

95 Disclosure of the reports at issue to the third party which made a request to that effect to the EMA pursuant to Regulation No 1049/2001, namely the intervener, would place the applicant in a vulnerable situation as least as threatening as that examined in the order in *Commission* v *Pilkington Group*, cited in paragraph 38 above (EU:C:2013:558). That third party would immediately take cognisance of those reports and could use them straightaway for any purpose it deemed useful, since Article 6(1) of Regulation No 1049/2001 does not require the party requesting access to give reasons explaining that request. The applicant would thus have to expect that the disclosure of those reports would be liable to weaken its competitive position. It would therefore be in a vulnerable situation which would entail, for it, a risk of damage (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 89).

96 Moreover, the disclosure of a document, under Regulation No 1049/2001, has an *erga omnes* effect in that the document may be communicated to other applicants for access and any person has the right to access it (see paragraph 71 above). Consequently, if the reports at issue were disclosed, not only would the intervener be free to use them, but all the applicant's competitors could themselves apply — if necessary through individuals acting on their behalf — to the EMA in order to obtain that information directly. The aforementioned *erga omnes* effect would even allow the EMA to publish the reports at issue online, on its own initiative, a step which is far from hypothetical, since, in the context of the present case, the EMA forcefully argues that the reports at issue must be made publicly accessible (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 90).

97 Once the reports at issue are disclosed, it is highly likely that current or potential competitors of the applicant with a genuine interest in exploiting those reports would attempt to obtain them, in order to use them for their own scientific and commercial needs, particularly with a view to producing a medicinal product similar to Vantobra and obtaining authorisation to market that product on many different markets within or outside the European Union. Although the EMA appears to doubt the usefulness of the reports at issue for the purposes of competition, it is sufficient to note that the judge hearing an application for interim measures is not particularly well placed to make an informed and accurate prediction as to the manner in which the applicant's competitors could exploit that scientific information, following its disclosure, according to their individual interests as regards research, development and marketing (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 91).

98 Consequently, the possibility of the applicant sustaining financial damage as a result of such future exploitation of the reports at issue by its competitors cannot be characterised as purely hypothetical. Rather, it is foreseeable with a sufficient degree of probability that the vulnerable situation in which the applicant would be placed in the event of disclosure of those reports would become one entailing financial damage to it (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 92).

99 Furthermore, since the taking cognisance and use, by interested persons, of information published online were not considered to be hypothetical in the order in *Commission* v *Pilkington Group*, cited in paragraph 38 above (EU:C:2013:558), the same must be true of the taking cognisance and use, by interested persons, of information which, after being disclosed to a third party, would become freely accessible to all the competitors of the undertaking holding that information. From that perspective, the difference between the two modes of access consists solely in the means of communication actually used (order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 93).

100 As to whether the financial damage that the applicant would be likely to suffer in the event of disclosure of the reports at issue may be quantified, it should be noted that the applicant would have to expect that an undetermined and potentially unlimited number of current and potential competitors all over the world will obtain those reports in order to exploit them in numerous ways, which, depending on the status of their research and development programmes, could entail harmful effects in the short, medium or long term, liable to thwart any expansion strategy on the applicant's part. Those reports, once publicly accessible, might even be obtained by competitors without the applicant being informed. That would be the case, in particular, if the EMA published those documents on its website or if those competitors obtained the disclosure of those documents by means of applications made by individuals acting on their behalf, whose identity and intended use of the documents would not be revealed to the applicant. The applicant would therefore be confronted with the insurmountable difficulty of setting up a monitoring system to detect, at a global level, how its competitors were exploiting the reports at issue in the short, medium or long term so as to derive competitive advantages, particularly so as to market, with or without authorisation, the medicinal product at issue in third countries (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 94).

101 It is therefore impossible to assess the actual impact that disclosure of the reports at issue could have on the applicant's economic and financial interests. Accordingly, the damage that the applicant is liable to suffer in the event of disclosure of those reports cannot be quantified adequately.

102 In view of the foregoing considerations, it must be found that the condition relating to urgency is met in the present case, since the likelihood of the applicant suffering serious and irreparable damage has been established to the requisite legal standard. Having regard to the particular features of proceedings for the protection of allegedly confidential information, the applicant is not required to establish, in addition, that it would be in a position that would imperil its financial viability or that its market shares would be seriously and irreparably affected if the measures applied for were not granted (see, to that effect, and by analogy, order in *Commission* v *ANKO*, cited in paragraph 88 above, EU:C:2014:239, paragraph 26 et seq.).

103 In any event, even if the damage alleged by the applicant could not be classified as irreparable, the judge hearing the application for interim measures could not examine the confidentiality of each individual piece of data in the reports at issue with a view to possibly upholding the application for interim measures only in part (see, to the effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 98).

104 Although it was held, in paragraph 53 of the order in *EMA* v *AbbVie*, cited in paragraph 79 above (EU:C:2013:794), that the expeditiousness required in interim proceedings was not 'in itself' such as to preclude the judge hearing the application for interim measures from carrying out such an individual examination, it must be stated that it is not only that need for expeditiousness, but above all the purely ancillary, and therefore limited, nature of his powers, which prevents the judge hearing an application for interim measures from carrying out such an examination in the context of his assessment of the condition relating to urgency (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 99).

105 First of all, it would be inconsistent for the judge hearing an application for interim measures to find that there is a prima facie case on the basis of the nature of the information covered by a confidentiality request as well as the complex nature of the confidentiality issues raised, stating that the resolution of those issues calls for a thorough examination to be carried out by the Court when it adjudicates on the substance (see, to that effect, order in *Commission* v *Pilkington Group*, cited in paragraph 38 above, EU:C:2013:558, paragraphs 67 and 70), but then reverse that result in the context of the urgency assessment by allowing the disclosure of certain specific pieces of data, when it cannot be excluded that the Court when it adjudicates on the substance may refuse to carry out such a specific and individual examination of the confidential nature of the individual pieces of information and prefer to examine whether the categories of information invoked by the applicant must, by their very nature, enjoy a general presumption of confidentiality (see paragraph 55 above).

106 Next, the judge hearing an application for interim measures must also take into account, in the context of the urgency assessment, the intrinsically ancillary and provisional nature of proceedings for interim relief by comparison with the main action, as well as the need to avoid prejudging, at the stage of the proceedings for interim relief, the outcome of the main action. Since those considerations concerning the nature of proceedings for interim measures are decisive for the outcome of those proceedings, they cannot be confined solely to the examination of whether there is a prima facie case and the weighing up of interests. The prohibition on the judge hearing an application for interim measures from rendering illusory, by an order for interim measures, the future judgment in the main proceedings by depriving it of practical effect (order in *CIRFS and Others* v *Commission*, cited in paragraph 65 above, EU:C:1991:220, paragraph 24) is intended, inter alia, to ensure that the consequences of the decision to be given subsequently on the substance of the action are not neutralised in advance (order of 20 July 1981 in *Alvarez* v *Parliament*, 206/81 R, ECR, EU:C:1981:189, paragraph 6).

107 The consequences and practical effect of any judgment annulling the contested decision and bringing the main proceedings to an end would not be limited to a finding that the reports at issue are confidential and that their disclosure would be unlawful. Rather, in the event that the contested decision is annulled, the consequences and practical effect of that judgment would consist for the applicant in the assurance that no data in the reports found to be confidential by the Court ruling on the main action would be disclosed, irrespective of whether such disclosure would cause it reparable or irreparable damage. To the same effect, in the area of restrictive measures, the President of the Court of Justice envisaged the practical consequences of the future judgment on the substance, holding that the grant of suspension of operation of the measure freezing the funds of an undertaking could be such as to prevent that measure being 'fully effective' in the event of the action for its annulment being dismissed, since such a suspension of operation would allow that undertaking to withdraw immediately all the funds deposited at the banks which were obliged to ensure that they were frozen and to empty its bank accounts before judgment was delivered on the substance (order of 14 June 2012 in *Qualitest FZE* v *Council*, C-644/11 P(R), EU:C:2012:354, paragraphs 72 to 74).

108 Thus, a clear distinction must be made between the present proceedings, which relate to the protection of allegedly confidential information, and proceedings relating to the lawfulness of payment obligations imposed by a decision of the Commission, such as a fine or the obligation to reimburse State aid. In the latter category of proceedings, the dismissal of an application for interim measures on the ground that the serious and irreparable damage condition is not met cannot neutralise in advance the consequences of a future annulment of the contested decision, since the applicant would obtain repayment of the sum paid or reimbursed, including interest, and would therefore be fully restored financially (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 103).

109 Nor is it appropriate, in view of the specific features of proceedings seeking the protection of allegedly confidential documents, for the judge hearing an application for interim measures to consider a partial solution consisting in protecting only certain pieces of information, while allowing access to others. If

the Court adjudicating on the main action accepted that the reports at issue were covered by a general principle of confidentiality, those reports would not be subject to an obligation of partial disclosure (see paragraph 55 above). A judge of the Court hearing an application for interim measures, given his purely ancillary powers — which remain largely less extensive than those entailed by the far more autonomous role granted to some national judges by their respective domestic law —, cannot therefore authorise partial access without depriving the judgment on the substance of practical effect (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 104).

110 Lastly, the judge hearing an application for interim measures must not apply mechanically and rigidly the condition relating to the irreparable nature of the financial damage pleaded. Rather, he must take account of the factual and legal circumstances specific to each case (see, to that effect, order of 28 April 2009 in *United Phosphorus* v *Commission*, T-95/09 R, EU:T:2009:124, paragraph 74 and the case-law cited), particularly since that condition, which arises solely from the case-law and is set out in neither the Treaties nor the Rules of Procedure, must not be applied if it is irreconcilable with the need to provide effective provisional protection (see, to that effect, order of 23 April 2015 in *Commission* v *Vanbreda Risk & Benefits*, C-35/15 P(R), ECR, EU:C:2015:275, paragraph 30). Article 278 TFEU and Article 279 TFEU, which are primary law provisions, authorise the judge hearing an application for interim measures to order the suspension of operation of a measure if he considers 'that circumstances so require' and to prescribe any 'necessary' interim measures (order of 24 February 2014 in *HTTS and Bateni* v *Council*, T-45/14 R, EU:T:2014:85, paragraph 51). As mentioned above, those conditions are met in the present proceedings relating to the protection of allegedly confidential information, particularly since — the existence of a prima facie case having been established — the introduction of both the main action and the application for interim measures cannot be qualified as a delaying tactic on the part of the applicant aimed at postponing, without good reason, disclosure of the reports at issue (see, to that effect, order in *Deza* v *ECHA*, cited in paragraph 52 above, EU:T:2014:686, paragraph 105).

111 Accordingly, since all the necessary conditions are met, the application to suspend the operation of the contested decision must be granted. In addition, the EMA must be ordered not to disclose the reports at issue.

The confidentiality issues raised by the intervention of Novartis Europharm …

114 In so far as the intervener requests access to the reports at issue, it suffices to point out that, in the main proceedings, it is precisely the question of whether those reports may be regarded as being confidential and, accordingly, whether the contested decision must be annulled, that arises. In those circumstances, the reports in question must, at this stage of the procedure, be kept secret from the intervener, if the action for annulment is not to become devoid of purpose and the consequences of the decision to be given subsequently on the substance are not to be neutralised (see, to that effect, orders of 16 November 2012 in *Akzo Nobel and Others* v *Commission*, T-345/12 R, ECR, EU:T:2012:605, paragraph 26 and the case-law cited, and 12 June 2015 in *Deza* v *ECHA*, T-189/14, EU:T:2015:400, paragraph 34).

115 As regards the other procedural documents, the redacted data in the non-confidential versions of those documents relates to the market study carried out by the applicant, the sources of information that it had used in order to establish the superiority of Vantobra over TOBI Podhaler and the description of the groups of patients benefiting from the application of Vantobra. Those are elements which are also set out in the reports at issue, the confidential nature of which has been noted above. It follows that, at this stage and pending the decision on the substance, those elements must be kept secret from the intervener.

116 Furthermore, both the main proceedings, and the proceedings for interim relief which are ancillary thereto, concern, ultimately, whether the reports at issue must be disclosed to the intervener or whether, because of the potentially confidential nature of that type of documents, disclosure must be refused. In those circumstances, it is necessary to preclude, so far as possible, that the intervener may prematurely obtain access to the data that may be covered by that confidentiality. Accordingly, the intervener must, in the proceedings for interim measures, merely defend its interest in the outcome of the dispute on a general basis and by relying on arguments of principle, which, moreover, it did in its statement in intervention of 30 June 2015.

117 Consequently, the intervener's request seeking to obtain access to the full case file must be rejected.

On those grounds,

THE PRESIDENT OF THE GENERAL COURT

hereby orders:

1. **The operation of Decision EMA/271043/2015 of the European Medicines Agency (EMA) of 24 April 2015 is suspended, in so far as that decision grants a third party access, 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, to the assessment report (EMA/CHMP/702525/2014) concerning the similarity of Vantobra with Cayston and TOBI Podhaler and the assessment report (EMA/CHMP/778270/2014) concerning the clinical superiority of Vantobra over TOBI Podhaler.**

2. **The EMA is ordered not to disclose the two reports mentioned in point 1.**

3. **Novartis Europharm Ltd's request for access to the full case file is rejected.**

4. **The costs are reserved.**

Luxembourg, 1 September 2015.

E. Coulon
Registrar

M. Jaeger
President