Reports of Cases

ORDER OF THE VICE—PRESIDENT OF THE COURT

28 November 2013*

(Appeal — Order for interim measures — Regulation (EC) No 1049/2001 — Access to documents of the institutions — Documents held by the European Medicines Agency in the context of an application for authorisation to place a medicinal product on the market — Decision to grant a third party access to the documents — Information not available to the public — Serious and irreparable damage — Evidence)

In Case C-390/13 P(R),

APPEAL under the second paragraph of Article 57 of the Statute of the Court of Justice of the European Union, brought on 5 July 2013,

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

appellant,

the other parties to the proceedings being:

InterMune UK Ltd, established in London (United Kingdom),

InterMune, Inc., established in Brisbane (United States),

InterMune International AG, established in Muttenz (Switzerland),

represented by T. de la Mare QC, and F. Campbell, Barrister, instructed by I. Dodds-Smith and A. Williams, Solicitors,

applicants at first instance,

supported by:

European Confederation of Pharmaceutical Entrepreneurs AISBL (Eucope), established in Brussels (Belgium),

represented by F. Louis and P. Gey, avocats,

intervener in the appeal,

THE VICE-PRESIDENT OF THE COURT,

having heard the First Advocate General, P. Cruz Villalón,

* Language of the case: English.

makes the following

Order

1 By its appeal, the European Medicines Agency (EMA) seeks to have set aside the order of the President of the General Court of 25 April 2013 in Case T-73/13 R *InterMune UK and Others* v *EMA* ('the order under appeal'), whereby the President of the General Court suspended the operation of EMA decision EMA/24685/2013 of 15 January 2013 ('the contested decision') granting 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 (OJ 2001 L 145, p. 43), to the documents '2.4 Non-clinical Overview', '2.5 Clinical Overview', '2.6 Non-clinical Summary', and '2.7 Clinical Summary' ('the requested documents'), submitted by InterMune UK Ltd, InterMune, Inc. and InterMune International AG (together, 'the InterMune companies') as part of an application for authorisation to place the medicinal product Esbriet on the market ('the MA'), and ordered the EMA not to disclose the requested documents in a version which is more detailed than the edited version of those documents as provided by the InterMune companies to the EMA on 8 October 2012.

Legal context and EMA administrative practice

2 The legal context and EMA administrative practice were summarised as follows in paragraphs 1 to 11 of the order under appeal:

> '1 [The 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 medicines for human and veterinary use. To that end, the EMA is responsible for the scientific evaluation of applications for European Union [MAs] for human and veterinary medicines (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.
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> 2 Under Regulation No 726/2004, certain categories of medicinal products, including medicinal products resulting from biotechnology such as Esbriet, 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 application for [an MA], which is examined by the EMA, and a decision by the European Commission on the MA. The information which an MA applicant is to provide to the EMA must include a quality dossier (particulars on product composition and description of the manufacturing processes), non-clinical data (physico-chemical, biological or microbiological and results of animal tests) and results of clinical trials (actual tests and data assessing the use of the product in humans), in support of the intended therapeutic use of the product. Once the MA has been granted, the details thereof may be amended; amendments may range from mere administrative changes to more significant amendments, such as adding a new therapeutic indication.
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> 3 The first paragraph of Article 73 of Regulation No 726/2004 states that [Regulation No 1049/2001], a regulation which is aimed at guaranteeing the broadest public access possible to documents held by the European Union administrative bodies, is applicable to documents held by the EMA.

4 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.

5 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. Thus, on 19 December 2006, the EMA adopted rules implementing Regulation No 1049/2001 on access to its documents. Article 4 of those rules provides that EMA documents are to be classified in one of the following three categories: public, restricted or confidential.

6 Under a policy governing access to its documents which the EMA applied consistently until 2007, public access to documents contained in the dossier submitted by a company for the purposes of an MA, including clinical study reports, was generally refused on the ground that such data fell under the exceptions contained in the aforementioned implementing rules, and more particularly Article 3(2)(a), which, mirroring the provisions of the first subparagraph of Article 4(2) of Regulation (EC) No 1049/2001, refers to the protection of commercial interests of a natural or legal person, including intellectual property.

7 In 2007, a research and information centre in the field of health care contacted the EMA, requesting access to clinical study reports concerning two medicinal products. The EMA refused access on the grounds that it would undermine the commercial interests of the producers of those medicinal products. The research and information centre then filed a complaint with the European Ombudsman who, following an investigation into the relevant reports, concluded that they did not contain information on the composition of the medicinal products or other commercially confidential information. In its view, their disclosure would consequently not undermine the sector's commercial interests. In its draft recommendation, the Ombudsman therefore called on the EMA to disclose the documents.

8 In its reply of 31 August 2010, the EMA stated that it had decided to grant access to those reports and committed itself to taking appropriate measures in order to implement the Ombudsman's draft recommendation. In line with the Ombudsman's recommendations, on 30 November 2010 the EMA adopted a new policy on access to its documents. In the press release accompanying the adoption of this policy, the EMA stated that documents submitted to it as part of an MA application, such as clinical trial reports, could henceforth be disclosed, provided that the decision-making process for the application in question was finalised. The policy on access to EMA documents became effective on 1 December 2010.

9 Under its new policy, the EMA drew up an output table for the various documents in its possession. More specifically, MA dossiers or updates and amendments to those dossiers, including clinical trial reports, are considered to be public, that is to say, they may be disclosed once, inter alia, the Commission's MA decision is available for the medicinal product concerned. In March 2012 the output table was complemented by guidelines from the EMA and heads of national medicines agencies regarding the types of information included in an MA application that can be publicly released after the final decision on the application. The objective is to enable a consistent approach to be adopted in order to provide guidance on the identification of commercially confidential information which must be protected after an MA has been granted.

10 According to the guidelines, the following are considered commercially confidential information: detailed information concerning the quality and manufacturing of the medicinal products; information concerning the development of the product, including detailed information on the synthesis and manufacturing of the active substance; formulation, test procedures, validation, as well as manufacturers and suppliers of the active substance and excipients; and detailed descriptions of the manufacturing and control processes for the finished product. By contrast, information encompassing clinical and non-clinical development of a medicinal product is not per se commercially confidential. Accordingly, as a rule the data included in clinical trial reports is regarded as data that can be disclosed. Non-clinical studies are intended, inter alia, to identify the pharmacological properties and to understand the toxicological profile of the medicinal product, whilst clinical trials are studies that are intended to discover or verify the effects of one or more investigational medicines. Regulation of those trials aims to ensure that the rights, safety and well-being of trial subjects are protected and the results of clinical trials are credible.

11 Consequently, since its new policy on access to documents has been in place, the EMA has been releasing documents submitted as part of MA applications, including clinical study reports, on request pursuant to Regulation No 1049/2001.'

Background to the dispute and procedure before the President of the General Court

3 The background to the dispute was set out as follows in paragraphs 12 to 15 of the order under appeal:

'12 The [InterMune companies] belong to the pharmaceutical and biotech group InterMune, founded in 1998 in the United States, whose focus is on the research and development of innovations in the field of respiratory and orphan fibrotic diseases. Since February 2011, they have held an MA from the Commission for the medicinal product Esbriet, which contains the active substance Pirfenidone and is authorised for the treatment of idiopathic pulmonary fibrosis (IPF).

13 In August 2012, the pharmaceuticals company Boehringer Ingelheim GmbH, a competitor undertaking of the [InterMune companies], requested the EMA to grant it access to documents that the [InterMune companies] had submitted as part of their MA application for the medicinal product Esbriet. The request concerned the [requested documents]. Those documents contain information relating to the trials carried out on human beings and animals to establish the safety and efficacy of the medicinal product Esbriet for the purposes of obtaining an MA.

14 After being informed by the EMA of that request for access, the [InterMune companies], by letter of 8 October 2012, set out their objections to disclosure in detail and provided an edited version of the [contested documents], adding that that version could be disclosed to Boehringer Ingelheim. It also identified data which were not yet in the public domain which they considered confidential and liable to be of value to a competitor, explaining why disclosure would harm their commercial interests.

15 Nevertheless, by [the contested decision], the EMA informed the [InterMune companies] that it was prepared to grant the request for access to the [requested documents] in their entirety under Regulation No 1049/2001 …'

4 By application lodged at the Registry of the General Court on 11 February 2013, the InterMune companies brought an action for annulment in part of the contested decision, inasmuch as it authorises the disclosure of information which is not yet publicly available. In support of that action they argue, in essence, that the contested decision infringes Article 4(2) of Regulation No 1049/2001 and their fundamental right to protection of confidential information covered by business secrecy under Article 7 of the Charter of Fundamental Rights of the European Union ('the Charter').

5 By a separate document, lodged at the Registry of the General Court on the same date, the InterMune companies made an application for interim measures, in which they claimed, in essence, that the President of the General Court should:

— suspend the operation of the contested decision, inasmuch as it envisages disclosure of information which is not yet publicly available, until the General Court has ruled on the main action;

— order the EMA to refrain from disclosing that information, until the General Court has ruled on the main action; and

— order the EMA to pay the costs.

6 In its observations on the application for interim measures, lodged at the Registry of the General Court on 5 March 2013, the EMA contended that the President of the General Court should:

— dismiss the application for interim measures; and

— order the InterMune companies to pay the costs.

7 By application lodged at the Registry of the General Court on 2 April 2013, the European Confederation of Pharmaceutical Entrepreneurs AISBL (Eucope), which represents the interests of over 900 European pharmaceutical and biotech companies, including small and medium-sized enterprises, applied for leave to intervene in support of the form of order sought by the applicants.

The order under appeal

8 In paragraphs 20 to 22 of the order under appeal, the President of the General Court observed that the dispute between the parties arises from the fact that the InterMune companies provided the EMA with a list of the data which they considered to be confidential together with an edited version of the requested documents, and the EMA, rather than expressing a position on the merits of that edited version or the actual confidential nature of the various data referred to by the InterMune companies, took the view that the disputed documents, by virtue of their very nature, had to be disclosed in their entirety. Taking into consideration the expeditiousness required in interim proceedings and the brevity of those proceedings – which according to the President of the General Court, precluded him from conducting a specific individual assessment of the clinical and non-clinical information alleged to be confidential and therefore redacted in the edited version of the requested documents ('the information redacted in the edited version of the requested documents') – the President of the General Court decided to examine whether that information should enjoy temporary protection because of its very nature, since it had been provided to the EMA as part of an MA application for a medicinal product. Consequently, he decided that his examination would focus on the nature of that information as a whole, as presented in the InterMune companies' letter of 8 October 2012.

9 The President of the General Court, referring to his order of 11 March 2013 in Case T-462/12 R *Pilkington Group* v *Commission* [2013] ECR, paragraphs 24 and 25, observed, in paragraphs 23 to 27 of the order under appeal, that the grant of interim measures is subject to two cumulative conditions relating, first, to the urgent nature of their grant, in so far as it is necessary, in order to avoid serious and irreparable harm to the interests of the party applying for the measures, that those measures be ordered and take effect before a decision is reached in the main action, and, secondly, to the determination that the grant of those interim measures is justified, prima facie, in fact and in law (*fumus boni juris*). Moreover, the President of the General Court indicated, that, where appropriate, the judge hearing an application for interim measures must also weigh up the interests involved. He pointed out that the judge hearing such an application enjoys a broad discretion and is free to determine the manner in which those various conditions are to be examined and, considering that he

had all the information needed to rule on the application without its being necessary to hear oral argument from the parties, he decided first to examine together the questions relating to the weighing up of interests and to urgency.

10 In paragraphs 28 and 29 of the order under appeal, the President of the General Court, referring to paragraphs 28 and 29 of the order in *Pilkington Group* v *Commission*, noted that the weighing up of the various interests involved requires the judge hearing the application for interim measures to determine whether or not the applicant's interest in obtaining those measures outweighs the interest in immediate application of the contested measure by examining, in particular, whether annulment of that measure by the court ruling on the main application would allow the situation which would have been brought about by its immediate operation to be reversed, and, conversely, whether suspension of its operation would prevent it from being fully effective in the event of the main application being dismissed. The President of the General Court added that the decision made by the judge hearing an application for interim measures is, by its nature, interim in the sense that it must not prejudge the future decision on the substance of the case, nor render it illusory by depriving it of its effectiveness.

11 The President of the General Court continued by pointing out, in paragraphs 31 and 32 of the order under appeal, that in order to protect the effectiveness of a judgment annulling the contested decision, the InterMune companies had to be able to ensure that the EMA would not allow access to the information redacted in the edited version of the requested documents, because such a judgment and accordingly its enforcement, would be deprived of effectiveness if the application for interim measures were to be dismissed, since the consequence of that dismissal would be that the EMA would be free to grant immediate access to that information, notwithstanding the fact that even if that information were actually to be disclosed, it would probably not deprive the InterMune companies of an interest in bringing proceedings for the annulment of the contested decision.

12 Consequently, in paragraph 33 of the order under appeal, the President of the General Court, weighing up the interests involved, considered that the interest defended by the InterMune companies prevailed over the EMA's interest in the dismissal of the application for interim measures. The fact that the party requesting disclosure of the information redacted in the edited version of the requested documents had a right of access to documents under Article 15(3) TFEU did not call that conclusion into question, since the exercise of that right would merely be delayed if the interim measures were granted, whilst the competing right of the InterMune companies to protection of the confidentiality of that information would be reduced to nothing if the application for interim relief were dismissed.

13 In paragraph 34 of that order, the President of the General Court found that since the balance of interests involved was in the InterMune companies' favour, there was a clear urgency, from that perspective, in protecting the interest defended by them, but that it remained to be determined whether those parties were likely to suffer serious and irreparable harm in the event of their application for interim measures being dismissed. In that regard, the InterMune companies maintained that the situation that would result from disclosure of the requested documents would be irremediable.

14 The President of the General Court noted, in paragraph 35 of the order under appeal, that the InterMune companies, referring to the order of the President of the General Court of 16 November 2012 in Case T-345/12 R *Akzo Nobel and Others* v *Commission* [2012] ECR, claimed that if the information redacted in the edited version of the requested documents were to be disclosed before a decision is given on the main action, those companies would risk finding themselves without any effective remedy for the infringement of their fundamental rights, including the right to protection of their business secrets. The harm likely to be caused to the InterMune companies, which manufacture and market only a single medicinal product, by the disclosure of that information, would be particularly serious. The fact that the disclosure is sought by a competitor of those companies for

what can only be use intended to improve irreversibly its competitive position could only strengthen that analysis. If that information were authorised for release into the public domain, any subsequent annulment of the contested decision would be ineffective.

15 In paragraphs 36 and 37 of that order, the President of the General Court held that the condition relating to urgency was, in principle, satisfied. He found that disclosure of the information redacted in the edited version of the requested documents would irreparably infringe the InterMune companies' right to the protection of their business secrets under Article 339 TFEU, Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950 ('the ECHR'), and Article 7 of the Charter. Moreover, the InterMune companies' fundamental right to an effective remedy, enshrined in Article 6 of the ECHR and Article 47 of the Charter, was likely to be jeopardised if the EMA were to be authorised to disclose that information before the General Court adjudicates on the main action.

16 In paragraph 38 et seq. of the order under appeal, the President of the General Court rejected the EMA's arguments to the contrary. In that respect, he found, in paragraph 39 of that order, that the EMA's assertion that the grant of the interim measures sought by the InterMune companies would confer a 'confidential', as opposed to a 'public', nature on the information redacted in the edited version of the requested documents, was irrelevant to the examination of the requirement of urgency, since it related rather to the requirement that there be a prima facie case. He also found, in paragraphs 40 and 41 of that order, that the EMA's arguments concerning the purely financial nature of the damage could not succeed, since, in the area of disclosure of allegedly confidential information, an approach that reduces the breach of professional secrecy to a purely financial loss is not appropriate inasmuch as it disregards the fundamental rights relied upon. Referring to paragraph 53 of the order in *Pilkington Group* v *Commission*, the President of the General Court stated in that regard that, at least since the entry into force – on 1 December 2009 – of the Treaty of Lisbon, which raised the Charter to the level of primary European Union law and which, under the first subparagraph of Article 6(1) TEU, provides that it is to have the same legal value as the Treaties, an imminent risk of a serious and irreparable breach of the fundamental rights conferred by Articles 7 and 47 of the Charter in that field has had to be regarded, in itself, as harm justifying the grant of the interim protection requested.

17 In paragraph 43 et seq. of the order under appeal, the President of the General Court examined the condition that there be a prima facie case. Having noted, in paragraph 43, that the condition in question 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, to be relevant and in any event not unfounded, he observed, in paragraph 44 of that order that, in the specific context of interim protection for information alleged to be confidential, such as the information redacted in the edited version of the requested documents, the judge hearing the application for interim measures – if he is not to disregard the intrinsically ancillary and provisional nature of proceedings for interim measures and the imminent risk of negation of the fundamental rights relied on by the party seeking interim protection of those rights – may, as a rule, conclude that there is no prima facie case only where the information in question is obviously not confidential.

18 It was on the basis of those considerations that the President of the General Court examined, in paragraphs 45 to 47 of the order under appeal, the arguments raised by the InterMune companies in support of their main action. According to those companies, the information redacted in the edited version of the requested documents is covered by business secrecy and industrial property rights. The EMA failed to make a detailed assessment of the arguments and evidence submitted by those companies concerning the confidential nature of that information and did not carry out a proper weighing up as required under Article 4(2) of Regulation No 1049/2001, in order to determine whether there was a public interest in disclosure of that information which took priority over the need to protect their commercial interests against the harm resulting from that disclosure. The InterMune companies emphasised the requirements for protecting business secrets resulting, inter alia, from Article 80 of Regulation No 726/2004, under which information on supervision of medicinal

products is to be made available to the public, provided that that information is not confidential, and noted that in its recent case-law the Court of Justice has insisted on the need to interpret the exceptions provided for in Article 4(2) of Regulation No 1049/2001 in such a manner as to ensure coherence with the interests protected by other European Union legal measures.

19 In paragraphs 48 and 49 of the order under appeal, the President of the General Court noted that, according to the EMA, the disclosure of allegedly confidential information was based solely on its new policy on access to documents, which became effective on 1 December 2010. The EMA submitted, moreover, that there is no provision in European Union law indicating that the documents submitted by an MA applicant containing information on the results of a clinical trial must be deemed to be confidential. The EMA did not dispute that some parts of the extensive documentation submitted by MA applicants do contain information which is commercially confidential, but submitted that it is unreasonable to claim that allegedly confidential information concerning the safety or efficacy of the medicinal products on human health and the environment, should enjoy the same level of protection.

20 It was on the basis of those considerations, set out in paragraphs 45 to 49 of the order under appeal, that the President of the General Court held, in paragraphs 50 to 53 of that order, that the documents in the case did not support the conclusion that there was clearly no prima facie case. He observed that there was no case-law enabling an answer to be given easily to the question on which judgment would have to be delivered subsequently on the substance, that is to say, whether the contested decision, based on the EMA's new disclosure policy, infringes the InterMune companies' right to professional secrecy, as guaranteed by Article 339 TFEU, Article 8 of the ECHR and Article 7 of the Charter, on the ground that the information redacted in the edited version of the requested documents is confidential and must therefore be protected against any disclosure. The President of the General Court concluded that such a question of principle could not be ruled on for the first time by a judge hearing an application for interim measures, but rather required an in-depth examination in the context of the main proceedings.

21 The President of the General Court also held, in paragraph 54 of the order under appeal, that, in any event, it was for the court adjudicating on the substance of the case to decide whether an overriding public interest justifies disclosure of the information redacted in the edited version of the requested documents, by weighing the InterMune companies' commercial interest in not having that information disclosed against the general interest guaranteeing the broadest public access possible to documents held by the European Union. Lastly, the President of the General Court observed, in paragraph 56 of the order under appeal, that inasmuch as the EMA emphasised the importance of transparency in the decision-making process in the assessment and supervision of medicinal products in order to ensure efficient pharmacovigilance, it did not set out the reasons why the question of principle which is the subject-matter of the main proceedings should receive a particularly expeditious answer. In that respect, the President of the General Court added that it was open to the EMA to include in its statement of defence an application for an expedited procedure under Article 76a of the Rules of Procedure of the General Court.

22 It is on the basis of all of those considerations that the President of the General Court decided to grant the interim measures sought by the InterMune companies, without ruling on the application for leave to intervene lodged by Eucope. Paragraphs 1 and 2 of the operative part of the order under appeal are worded as follows:

'1. The operation of [the contested decision] is suspended.

2. The EMA is ordered not to disclose the [requested documents] in a version which is more detailed than the edited version of those documents as provided by [the InterMune companies] to the EMA on 8 October 2012.'

The procedure before the Court of Justice and the forms of order sought

23 The EMA claims that the Court should:

— set aside the order under appeal; and

— order the InterMune companies to pay all the costs of the proceedings, including those incurred before the General Court.

24 The InterMune companies contend that the appeal should be dismissed and the EMA ordered to pay the costs of the appeal.

25 By a document lodged at the Court Registry on 12 August 2013, Eucope sought leave to intervene in support of the form of order sought by the InterMune companies. The arguments relied on by Eucope in support of its application to intervene reveal, prima facie, that it has an interest in the outcome of the present appeal proceedings. It appears that Eucope represents a considerable number of companies in the pharmaceutical industry, including one of the InterMune companies, and that one of the aims laid down in its statutes is the protection of its members in proceedings before the institutions of the European Union. Moreover, the present proceedings raise significant issues concerning the treatment of allegedly confidential information by the EMA and could therefore have a direct and significant effect on the interests of Eucope's members, at least until the General Court's decision on the substance in Cases T-44/13 and T-73/13. Accordingly, Eucope's application for leave to intervene was granted and Eucope was notified of this by letter of the Court Registry of 11 September 2013.

26 In its statement in intervention of 23 September 2013, Eucope contends that the Court should reject the appeal and order the EMA to pay the costs, including those incurred by Eucope as a result of its intervention. The EMA and the InterMune companies submitted their written observations on that statement in intervention on 9 October 2013.

27 On 14 October 2013, the parties presented oral argument and replied to questions put to them by the Court at a joint hearing with Case C-389/13 P(R) *EMA* v *AbbVie*, pending before the Court.

The appeal

28 In support of its appeal, the EMA relies on two grounds, alleging respectively:

— an error of law in the assessment of the weighing up of interests and the urgency condition; and

— a failure to state reasons and a manifestly incorrect assessment of the condition that there be a prima facie case.

29 It is appropriate to begin by examining the first ground of appeal, relating to the weighing up of interests and to urgency. By that ground of appeal, which is composed of two parts, the EMA claims, in particular, that the President of the General Court erred in his application of the case-law, thereby vitiating the order under appeal by an error of law, in so far as that judge found, first, that the balance of interests was in favour of the InterMune companies and that the condition relating to urgency was met and, secondly, that the interests claimed by the InterMune companies were protected by the fundamental right to private life under Article 8 of the ECHR and Article 7 of the Charter.

30 More specifically, it is appropriate to examine, in the first place, the first branch of the first ground relied on by the EMA in support of its appeal, in so far as it is based on an error of law allegedly made by the President of the General Court in finding that the condition relating to urgency was met in the present case.

Arguments of the parties

31 The EMA claims, in essence, that in the order under appeal, in assessing whether the condition relating to urgency was satisfied, the President of the General Court erred in law in his assessment inasmuch as, in particular, he failed to examine whether the InterMune companies had demonstrated that the harm resulting from the alleged potential loss of a competitive and commercial advantage could not be sufficiently compensated in the context of an action for damages. It submits that, contrary to settled case-law, the President of the General Court did not take into account the fact that the harm resulting from the loss of an advantage would, in any event, be of a purely financial nature.

32 At the hearing, the EMA added, in reply to questions put to it by the Court, that the order under appeal is vitiated by the same error of law as the order of the President of the General Court in *Pilkington Group* v *Commission*, for the reasons set forth in the order of the Vice-President of the Court of 10 September 2013 in Case C-278/13 P(R) *Commission* v *Pilkington Group* [2013] ECR. It submitted, at that hearing, that the InterMune companies can establish a risk of damage affecting them only if they can prove that the disclosure of the requested documents is liable to provide a commercial advantage to their competitors, and they have not demonstrated that this is the case. In any event, even if such damage were established, it would not be irreparable since it would be pecuniary damage, which could be remedied in the context of an action for damages. Such damage, resulting from the disclosure of scientific evidence to third parties, is not comparable to that which was at issue in the *Commission* v *Pilkington Group* case, which arose from the publication on the Internet of specific commercial information, in particular to the extent that, in contrast to that at issue in abovementioned case, the damage invoked in the present case may be identified and quantified.

33 At the hearing, the InterMune companies acknowledged that, in the light of the order in *Commission* v *Pilkington Group*, the existence of a risk of serious and irreparable harm cannot be regarded as arising from the mere alleged infringement of certain fundamental rights such as the right to property or the right to protection of confidential information.

34 The InterMune companies indicate that the financial damage that they are liable to suffer cannot be identified and quantified, within the meaning of paragraph 54 of the order in *Commission* v *Pilkington Group*. That damage would arise both from the future use of the information redacted in the edited version of the requested documents by the InterMune companies' competitors – and specifically by Boehringer Ingelheim GmbH, which has already requested that the EMA disclose that information – in order to develop a medicinal product which would compete with the medicinal product Esbriet, and from the InterMune companies' loss of the opportunity to obtain future patents, since that information would henceforth constitute prior art if the EMA were to disclose it. The InterMune companies note, in that respect, that their patents strategy is focused on obtaining patents relating to the use of chemical substances which are already known, including that of pirfenidone, the active substance in the medicinal product Esbriet, for new therapeutic purposes, and that it is not always possible to submit an application for such patents before submitting the application for an MA to the EMA. They also maintain that information contained in the requested documents could be used by their competitors for the purposes of obtaining MAs for medicinal products which would subsequently compete with the medicinal product Esbriet, not only in Europe but throughout the world, including countries where the rules governing both access to public documents and intellectual property rights are not the same as in Europe.

Findings of the Court

35 It must be pointed out, first of all, that, in accordance with Article 278 TFEU, actions brought before the Court of Justice of the European Union are not to have suspensory effect, but the Court may, if it considers that circumstances so require, order that application of the contested act be suspended or, in accordance with Article 279 TFEU, adopt other necessary interim measures. Thus, the grant of interim measures represents an exception to the general rule that the acts adopted by the European Union institutions enjoy a presumption of legality and are, in principle, enforceable.

36 Article 104(2) of the Rules of Procedure of the General Court provides that applications for interim measures must state 'the subject-matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the interim measures applied for'. Thus, the judge hearing an application for interim relief may order the suspension of operation of an act, or other interim measures, if it is established that such an order is justified, prima facie, in fact and in law (*fumus boni juris*) and that it is urgent in so far as, in order to avoid serious and irreparable harm to the applicant's interests, it must be made and produce its effects before a decision is reached in the main action. Those conditions are cumulative, so that an application for interim measures must be dismissed if either of them is absent (order in *Commission* v *Pilkington*, paragraph 35 and the case-law cited). Where appropriate, the judge hearing such an application must also weigh up the interests involved (order of the President in Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73).

37 In that respect, it must be noted that the purpose of interlocutory proceedings is to guarantee the full effectiveness of the final future decision in order to ensure that there is no lacuna in the legal protection provided by the Court of Justice. To attain that objective, urgency must be assessed in the light of the need for an interlocutory order in order to avoid serious and irreparable damage to the party seeking the interim relief (see, to that effect, order of the President of 14 December 2001 in Case C-404/01 P(R) *Commission* v *Euroalliages and Others*, ECR I-10367, paragraphs 61 and 62). It is for that party to prove that it cannot wait for the outcome of the main proceedings without suffering damage of that nature (see order of the President of 12 October 2000 in Case C-278/00 R *Greece* v *Commission* ECR I-8787, paragraph 14).

38 Although in order to establish the existence of serious and irreparable damage it is not necessary for the occurrence of the damage to be demonstrated with absolute certainty, it being sufficient to show that damage is foreseeable with a sufficient degree of probability, the party seeking an interim measure is nevertheless required to prove the facts forming the basis of its claim that serious and irreparable damage is likely (order of the President of 14 December 1999 in Case C-335/99 P(R) *HFB and Others* v *Commission* ECR I-8705, paragraph 67).

39 It must be pointed out that, according to the order under appeal, the damage invoked by the InterMune companies in the present case is that which would arise from the disclosure, in their entirety and to a competitor, of documents which contain allegedly confidential information capable of being used by that competitor, or by other competitors as the case may be, in order to produce and obtain marketing approval for their own medicinal products. Those documents, and in particular the information redacted from the edited version of the requested documents, concern the clinical and non-clinical trials, including those conducted on animals and human beings, carried out by the InterMune companies in order to prove the safety and effectiveness of the medicinal product Esbriet in the context of an MA application for that medicinal product.

40 In order to assess whether there was a risk of serious and irreparable damage, and without prejudice to the examination of the condition that there be a prima facie case, which is linked to but distinct from that assessment, the President of the General Court necessarily had to start from the premiss that the

information redacted in the edited version of the requested documents was indeed confidential, as claimed by the InterMune companies, both in the main action and in the proceedings for interim relief.

41 In that respect, it must be pointed out that, in paragraphs 36 and 37 of the order under appeal, the President of the General Court inferred the existence of a risk of serious and irreparable damage from the fact that the InterMune companies' fundamental right to the protection of their business secrets, as well as their fundamental right to an effective remedy, were liable to be seriously and irreparably breached by the immediate disclosure of their alleged confidential information. It is apparent from paragraphs 40 and 41 of that order that the President of the General Court held that, in the area of disclosure of allegedly confidential information, an approach that reduces the breach of professional secrecy to a purely financial loss is not appropriate inasmuch as it disregards the fundamental rights relied upon by the person seeking interim protection for that information. In support of that line of reasoning, the President of the General Court referred, inter alia, to the entry into force of the Treaty of Lisbon and the resulting enhanced protection of the rights enshrined in the Charter.

42 However, according to the settled case-law of the Court of Justice, the argument that harm is, by definition, irreparable because it falls within the scope of fundamental freedoms cannot be accepted since it is not sufficient to allege infringement of fundamental rights in the abstract for the purpose of establishing that the harm which could result would necessarily be irreparable (see, to that effect, the order of the President in Case C-43/98 P(R) *Camar* v *Commission and Council* [1998] ECR I-1815, paragraphs 46 and 47). That case-law is not called into question by the enhanced protection of fundamental rights brought about by the Treaty of Lisbon, since those rights, in particular the rights invoked in the present case, already enjoyed protection under European Union law before the entry into force of that treaty (order in *Commission* v *Pilkington Group*, paragraph 40).

43 It is true that the infringement of certain fundamental rights, such as the prohibition of torture and inhuman or degrading treatment or punishment, enshrined in Article 4 of the Charter, is liable, because of the very nature of the right infringed, to give rise by itself to serious and irreparable harm. Nevertheless, in accordance with the case-law referred to in paragraphs 37 and 38 of the present order, it is still for the party seeking an interim measure to set forth and establish the likelihood of such harm occurring in its particular case.

44 That is the case, in particular, where one undertaking seeks the adoption of interim measures in order to prevent the disclosure of information allegedly covered by the obligation of professional secrecy. The extent to which the disclosure of such information causes serious and irreparable harm depends on a combination of circumstances, such as, inter alia, the professional and commercial importance of the information for the undertaking which provides it and the utility of that information for other undertakings which are liable to examine and use it subsequently.

45 It follows from all of the foregoing considerations that the President of the General Court erred in law in finding, in particular in paragraphs 36 and 37 of the order under appeal, that the alleged infringement of the InterMune companies' fundamental right to the protection of their business secrets, enshrined in Article 339 TFEU, in Article 8 of the ECHR, and in Article 7 of the Charter, and of their right to an effective remedy, enshrined in Article 6 of the ECRH and Article 47 of the Charter, was sufficient in itself to establish the risk of serious and irreparable harm in the circumstances of the present case.

46 As regards the inferences that should be drawn from that error of law, it must be noted that, according to the InterMune companies, the harm that they are liable to suffer is serious and irreparable despite its commercial and financial nature. They submit that the harm resulting from the future use by competitors of information redacted in the edited version of the requested documents, and in particular by the competitor which has already requested the EMA to disclose that information, in order to develop a medicinal product intended to compete with the medicinal product Esbriet, and

the loss of the opportunity to obtain patents since that information would henceforth be in the public domain, cannot be identified and quantified within the meaning of paragraph 54 of the order in *Commission* v *Pilkington Group*. It is necessary to examine whether those arguments, relating to financial harm, may justify a substitution of grounds, as in *Commission* v *Pilkington Group*.

47 As regards the irreparable nature of that harm, it is undisputed that if the General Court were to annul the contested decision in the main action, it would not eliminate the harm already suffered and bring about a *restitutio in integrum*. Indeed, if the disclosure of the requested documents is not prohibited until the decision in the main action has been delivered, the harm arising from the potential use of those documents by competitors of the InterMune companies during the course of the main proceedings could no longer be reversed.

48 However, damage of a pecuniary nature cannot, otherwise than in exceptional circumstances, be regarded as irreparable since, as a general rule, pecuniary compensation is capable of restoring the aggrieved person to the situation that obtained before he suffered the damage. Any such damage could be recouped by the applicant's bringing an action for compensation on the basis of Articles 268 TFEU and 340 TFEU (order in *Commission* v *Pilkington Group*, paragraph 50 and the case-law cited).

49 Nevertheless, it must be pointed out that harm of a financial nature may be considered to be serious and irreparable if the harm, even when it occurs, cannot be quantified (order of the Vice-President of the Court of 7 March 2013 in Case C-551/12 P(R) *EDF* v *Commission* [2013] ECR, paragraph 60 and the case-law cited).

50 It is true that the uncertainty of obtaining compensation for pecuniary damage if an action for damages is brought cannot in itself be regarded as a factor capable of establishing that such damage is irreparable within the meaning of the case-law of the Court of Justice. At the interlocutory stage, the possibility of subsequently obtaining compensation for pecuniary damage if an action for damages is brought following annulment of the contested measure is necessarily uncertain. Interlocutory proceedings are not intended to act as a substitute for an action for damages in order to remove that uncertainty, since their purpose is only to guarantee the full effectiveness of the final future decision that will be made in the main action (in this case an action for annulment), to which the interlocutory proceedings are an adjunct (order of the President of 14 December 2011 in Case C-446/10 P(R) *Alcoa Trasformazioni* v *Commission*, paragraphs 55 to 57).

51 However, the situation is different where it is already clear, when the assessment is carried out by the judge hearing the application for interim measures, that, in view of its nature and the manner in which it will foreseeably occur, the harm alleged, should it occur, may not be adequately identified or quantified and that, in practice, it will not therefore be possible to make good that harm by bringing an action for damages (order in *Commission* v *Pilkington Group*, paragraph 54).

52 In that respect, it must be noted that the risk of the financial harm alleged by the InterMune companies in the present case, concerning the use of the information redacted in the edited version of the requested documents by competitors of those companies following the disclosure of that information and the loss of the opportunity to obtain future patents since the information would henceforth constitute prior art, is not comparable, in principle, particularly as regards its nature and the manner in which it will foreseeably occur, to the risk arising in the case which gave rise to the order in *Commission* v *Pilkington Group* from the publication on the Internet of specific and purportedly confidential commercial information relating to matters such as the identity of customers, the number of parts supplied, price calculations and price changes. The financial harm invoked in the present case would allegedly arise from the future use by a competitor of the information redacted in the edited version of the requested documents, or from the failure to obtain patents relating to therapeutic uses of chemical substances for which no application has yet been made.

53 As noted in paragraph 38 of the present order, although it is not necessary for the occurrence of the damage to be demonstrated with absolute certainty, it must be foreseeable with a sufficient degree of probability and, moreover, the party seeking an interim measure is required to prove the facts forming the basis of its claim that serious and irreparable damage is likely.

54 However, in the present case, it cannot be excluded, in the light of the foregoing considerations, so far as concerns information contained in the edited version of the requested documents, considered individually or as a whole, the disclosure of which, according to the InterMune companies, is liable to cause them serious and irreparable harm, that they will be able to establish the existence of such a risk with regard to some of that information, while ultimately being unable to do so with regard to the potential disclosure of other such information.

55 In that respect, and contrary to the President of the General Court's conclusion in paragraph 21 of the order under appeal, the expeditiousness required in interim proceedings was not in itself such as to preclude the judge hearing an application for interim measures from examining one by one in the present case, the arguments and evidence put forward at first instance by the InterMune companies and intended to prove the necessity of maintaining the confidentiality of information redacted in the edited version of the requested documents in order to prevent serious and irreparable harm to those companies. Moreover, it is clear from the case-law, of both the Court of Justice and the General Court, that the judge hearing an application for interim relief may, where he considers it appropriate, adopt temporary solutions, in particular by granting an application seeking the suspension in part of the operation of an act (see, to that effect, orders of the President of the Court in Case 71/74 R and BR *Nederlandse Vereniging voor de Fruit- en Groentenimporthandel and Nederlandse Bond van Grossiers in Zuidvruchten en ander Geimporteerd Fruit* v *Commission* [1974] ECR 1031, paragraphs 5 to 8, and in Joined Cases 43/82 R and 63/82 R *VBVB and VBBB* v *Commission* [1982] ECR 1241, paragraphs 9 to 12, and the order of the President of the General Court in Joined Cases T-24/92 R and T-28/92 R *Langnese-Iglo and Schöller Lebensmittel* v *Commission* [1992] ECR II-1839, paragraphs 30 to 35 and points 1 and 2 of the operative part).

56 In the event that the InterMune companies produce such proof with regard to certain information redacted in the edited version of the requested documents, the principle of effective legal protection, enshrined in Article 47 of the Charter, requires that the interim measure sought be granted to them, in respect of that information only.

57 It should be pointed out in that respect that, in the part of their application for interim relief before the General Court concerning the condition that there be a prima facie case, and more particularly, by reference to their first plea in law in support of their application for annulment, the InterMune companies noted that, in their letter of 8 October 2012 and in the annex to that letter, they set out in detail their objections specifically with regard to the disclosure of information redacted in the edited version of the requested documents. It was therefore for the President of the General Court to examine, in the light of those proposals, whether it was possible to authorise access to some of that information, without that authorisation's creating a sufficiently probable risk of serious and irreparable damage to the InterMune companies.

58 In those circumstances, the order under appeal must be set aside and, since the state of the proceedings does not permit final judgment to be given, it must be referred back to the General Court for judgment, in accordance with Article 61 of the Statute of the Court of Justice of the European Union.

On those grounds, the Vice-President of the Court hereby orders:

1. The order of the President of the General Court of the European Union of 25 April 2013 in Case T-73/13 R *InterMune UK and Others* v *EMA* is set aside.

2. The case is referred back to the General Court of the European Union.

3. The costs are reserved.

[Signatures]