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Interim relief granted in challenge to EMA's decision to disclose pre-clinical and clinical information from an application for a centralised marketing authorisation

Summary

- InterMune UK Ltd and its associated companies have challenged a decision of the European Medicines Agency (EMA) to disclose to a third party competitor, under EU freedom of information (transparency) rules, detailed pre-clinical and clinical data contained in the dossier supporting its successful application for an EU marketing authorisation for its product Esbriet (pirfenidone).
- On 25 April 2013, the President of the General Court of the European Union granted InterMune's application for an interim injunction preventing the EMA from releasing the contested information pending the Court's decision on the substantive issues.
- InterMune maintains that the disclosure of such information would damage its legitimate commercial interests and is, therefore, exempt from disclosure under such rules. It also contends that there is no demonstrable public interest in disclosure of the information in question when there has already been substantial disclosure about the research, including the European Public Assessment Report.
- Whilst InterMune's substantive arguments have yet to be considered by the Court, the President notes that the case raises "complex and delicate" issues that require full examination, including whether the EMA's new (post-2010) policy on disclosure infringes the fundamental rights of companies, which would affect the functioning of the pharmaceutical and biotechnology sectors in Europe and worldwide.
- This case has important implications for the pharmaceutical industry, and is also relevant to the broader debate surrounding proactive disclosure of clinical trial data.

InterMune's application

InterMune's product Esbriet (pirfenidone) is the first product authorised in the EU to treat idiopathic pulmonary fibrosis, a fatal disease of unknown aetiology, characterised by progressive scarring of the lungs. Its marketing authorisation was granted in early 2011, and the product has orphan drug designation.

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Article 2 of Regulation 1049/2001/EC[1] provides EU citizens and natural or legal persons residing in the EU a general right of access to documents held by various EU institutions, including the EMA. However, this general right is subject to certain exceptions. In particular, Article 4(2) of the Regulation exempts information from disclosure where this is necessary in order to protect commercial interests, unless there is an overriding public interest in disclosure.

Since December 2010, the EMA has operated a controversial policy[2] in relation to requests received under Regulation 1049/2001/EC, pursuant to which it treats clinical and non-clinical information as being non-confidential, in principle, after a final decision on an application or its withdrawal. In September 2012, the EMA notified InterMune that it had received a request pursuant to Regulation 1049/2001/EC from one of InterMune's competitors, seeking access to documents relating to Esbriet. The requested documentation comprised a number of sections of InterMune's marketing authorisation application, including data derived from InterMune's clinical and non-clinical trials. InterMune's view was that the disclosure of certain specific parts of this information would damage its commercial interests within and outside the EU. Nevertheless, applying its policy, the EMA rejected InterMune's arguments.

InterMune believes that its commercial interests will be damaged for various reasons, including by facilitating competitor applications, by undermining its ability to obtain patent rights based in part on such data, and by preventing it from obtaining regulatory data protection in countries where prior public disclosure precludes such rights. It argues that, under the exemption from disclosure contained in Article 4(2) Regulation 1049/2001/EC, access to the information should be refused, as disclosure would damage these legitimate commercial interests. InterMune believes that the disclosure of the information was sought by a competitor, presumably to advance its private, rather than public, interests and there is no issue of concealing data from the competent regulatory authorities.

InterMune also argues that there is no basis for saying that full disclosure in response to this request is needed to protect patient safety, and that the general public interest in transparency is already well served through the publication of the European Public Assessment Report (which contains detailed information on the research underlying the grant of the marketing authorisation and how the product has been assessed by the EMA as meeting the requirements for efficacy and safety).

InterMune, therefore, applied to the General Court for annulment of the EMA's decision to disclose, insofar as it related to those specific parts of the documents it viewed as being confidential.[3] It also applied for an interim order preventing the EMA from disclosing that information pending the Court's decision. On 25 April 2013, the President of the General Court granted InterMune's application for interim relief, with the result that the EMA may not disclose the contested parts of the requested documents pending the hearing of the substantive application.

The decision

The test for grant of interim relief in the EU courts is onerous. In this case, however, having considered the interests of the respective parties, the President of the Court noted that without an interim injunction, any subsequent decision in InterMune's favour would be of little practical benefit, as the damage caused by disclosure of the information in issue could not be undone. Moreover, the President noted that the EMA had not demonstrated that disclosure was urgently required in the public interest.

The President noted that disclosure of information classified as confidential engages fundamental rights enshrined in Article 7 (Respect for privacy and professional secrecy, including concerning commercial activity) and Article 47 (Right to an effective remedy and to a fair trial) of the Charter of Fundamental Rights. An imminent risk of a serious and potential breach of these rights in itself was found to justify the grant of the interim protection requested by InterMune. The EMA's argument that damages would be an adequate remedy was not accepted because fundamental rights were in issue.

1 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.

2 European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) EMA/110196/2006 30 November 2010.

3 Case T-73/13, Action brought on 11 February 2013 — *InterMune UK and Others v EMA* (OJ C 114 from 20.4.2013 p.38). Arnold & Porter (UK) LLP represents InterMune in this case.

The President found that InterMune's application raises "complex and delicate questions" that call for a detailed examination in the main action rather than being decided in an interim application. He noted that the case raises principles "affecting the functioning of the pharmaceuticals and biotechnology sector in Europe and worldwide," and that the Court has not yet had the opportunity to examine the lawfulness of the EMA's new policy. InterMune's application for interim measures was, therefore, successful. The EMA is considering whether to appeal the President's decision.

Implications

Pharmaceutical companies will welcome the President's recognition that the EMA's assertion that the disclosure of pre-clinical and clinical information and reports can never be commercially damaging, requires careful and full examination. The President noted that if it were found that disclosure could be damaging to the company concerned, consideration would have to be given to whether an overriding public interest might still justify disclosure. However, the President found that it was not obvious from the documents that, following such a weighing up of potentially conflicting interests, the balance would clearly favour a public interest in complete disclosure.

Access to documents and disclosure of clinical trial data is an important topic at present, with ongoing discussions in the European Parliament, at the EMA and across industry. InterMune's case opens another forum for discussing the appropriate balance between access to data and confidentiality. Given the difficulties being experienced elsewhere, any guidance from the Court as to the appropriate balance to strike will be welcome.

InterMune's case is likely to be heard together with a case brought slightly earlier, and independently, by AbbVie.[4] AbbVie made an application to the General Court for an interim injunction on similar grounds relating to disclosure of clinical reports for one of its products, which was also successful. The Court's final decision will not, however, be quick – the cases are unlikely to be heard until 2014 at the earliest, although the EMA may apply for the hearing to be expedited.

4 Case T-44/13, Action brought on 29 January 2013 – *AbbVie v EMA* (OJ C 79 from 16.03.2013, p.31) and Case T-29/13, Action brought on 17 January 2013 – *AbbVie e.a. v EMA* (OJ C 79 from 16.03.2013, p.26).

We hope you have found this Advisory useful. If you would like more information or assistance in addressing the issues raised in this Advisory, please feel free to contact:

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