

E-ALERT

December 5, 2013

VICE-PRESIDENT OF THE CJEU UNABLE TO GIVE FINAL JUDGMENT ON EMA'S APPEAL IN CASE C-389/13 P(R)

On 28 November 2013, the Vice-President of the Court of Justice of the European Union (CJEU) handed down his Appeal Order in [Case C-389/13 P\(R\) European Medicines Agency \(EMA\) v AbbVie](#). The Vice-President held that he could not provide a final judgment on the EMA's appeal and has referred the matter back to the General Court for further consideration. Accordingly, the court proceedings continue and AbbVie's application for injunctive relief remains pending.

Case T-44/13 (R)

In T-44/13(R), the President of the General Court granted interim relief to AbbVie to prevent the EMA granting a third party access to clinical study reports (CSRs) submitted by AbbVie to the EMA in support of a marketing authorisation for its product, Humira. The President held that AbbVie's request for interim measures satisfied the requirement of urgency and was justified in fact and law. The President considered that the disclosure of the CSRs may irreparably infringe AbbVie's right to protection of its business secrets and its right to a private life. These fundamental rights would be likely jeopardised if the EMA was allowed to disclose the CSRs before the General Court decides on the main action. Further, the President held that the alleged infringement of AbbVie's fundamental rights was sufficient to establish the risk of serious and irreparable harm. Moreover, the President said that AbbVie's right to an effective legal remedy would have been jeopardized if the EMA disclosed the CSRs before the General Court ruled on the main action as the harm could not be undone.

Order of the Vice-President of the Court of Justice

In Case C-389/13 P(R), the EMA sought to have the President's Order in Case T-44/13(R) set aside by the CJEU. However, in his Appeal Order of 28 November 2013, the Vice-President of the CJEU was unable to provide a final judgment on the EMA's appeal.

The Vice-President of the CJEU concluded that the President of the General Court had failed to conduct a sufficiently robust assessment of the merits of AbbVie's application for interim relief. The Vice-President stated that the President of the General Court was correct to assume that the CSRs do contain commercially confidential information, but he had concerns over the President's assessment of whether there was irreparable harm.

According to the Appeal Order, the President of the General Court should have granted the injunction only once he had satisfied himself that serious and irreparable harm was reasonably foreseeable. He had erred by focussing on the infringement of fundamental rights as evidence for irreparable harm and should have assessed "*the professional and commercial importance of the information for the undertaking which provides it and the utility of the information to other undertakings*" (para. 42).

The President should also have given more consideration to whether the harm was irreparable. The Vice-President accepted that financial loss may be serious and irreparable if the harm cannot be identified or quantified.

Finally, the Vice-President indicated that the President of the General Court should have considered whether there might be alternatives to granting an injunction, including whether the EMA might have released redacted documents without causing serious and irreparable harm to AbbVie.

AbbVie and the EMA now have the opportunity to make further submissions to the General Court before the President of the General Court reconsiders AbbVie's application for interim relief. In the meantime, the CSRs remain undisclosed by the EMA.

The outcome of the EMA's appeal against the injunction granted to InterMune under similar circumstances was almost identical. See [Case C-390/13 P\(R\) EMA v InterMune](#).

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

Peter Bogaert	+32.(0).25495243	pbogaert@cov.com
Grant Castle	+44.(0)20.7067.2006	gcastle@cov.com
Brian Kelly	+44.(0)20.7067.2392	bkelly@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2013 Covington & Burling LLP, 265 Strand, London WC2R 1BH. All rights reserved.