SIDLEY

Transparency vs. Confidentiality of Commercially Sensitive Information — A New Chapter Before EU Courts

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The saga of access to documents (ATD) cases in the European pharmaceutical legal landscape continues, this time with two promising opinions of Advocate-General (AG) Gerard Hogan in the appeals in cases C-175/18P *PTC Therapeutics v. EMA* and Case C-178/18P *MSD Animal Health Innovation GmbH (Intervet) v. EMA* delivered on September 11, 2019. In summary, AG Hogan opined that the General Court (GC) had erred in law in its conclusions that (a) there was no general presumption of confidentiality and (b) access to the study reports submitted in a marketing authorization (MA) application dossier at issue would not compromise the applicants' commercial interests. This development on the European level could well have implications for the interpretation of the Swiss Freedom of Information Act with regard to freedom of information requests concerning the access to MA submitted to Swissmedic, the Swiss regulator for therapeutic products.

This was an appeal to the GC's judgments of February 5, 2018, in which the GC sided with the European Medicines Agency (EMA) approach, taking a very restrictive position as to what information may be exempted from disclosure under the Transparency Regulation (1049/2001) and EMA Policy 43, holding that:

(a) The provisions of Article 39(2) and (3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) do not create a general presumption of confidentiality for information contained in an MA application.

(b) Additional evidence is required to show that the information should reflect an inventive strategy and provide added value to merit commercial confidential information (CCI) protection.

(c) The need for a balancing exercise between competing interests requiring the demonstration of an overriding public interest in the provision of the documents arises only once the EMA determines that an exception to ATD applies.

The GC thus imposed a high standard of proof on companies seeking to prevent disclosure and required that the companies provide actual and specific evidence of harm stemming from disclosure. The GC excluded from the scope of CCI any information that is not new or that could be inferred by other publicly available information.

With regard to similar requests for transparency addressed to Swissmedic and disputed by the concerned MA holder, the Swiss Federal Administrative Court and the Swiss Supreme Court took the same stance as the GC (although without explicitly referring to the GC's decision in the matters at hand).

The importance of these cases and AG Hogan's opinions cannot be understated. When recent case law seemed to be inclined toward the erosion and extreme restriction of what may constitute CCI, these opinions put into question the GC's interpretation of the exception afforded to private companies by law. Crucially, they recognize that the CCI exception may apply when there may be insufficient protection of fundamental commercial data, the disclosure of which may be abused in non-EEA countries. In addition, the presumption of general confidentiality would give companies the right to an injunction, as the courts cannot automatically disregard claims for CCI protection but would instead need to look at the merit of the case and its facts.

When the underlying information is of such high value to a company, every day of protecting this information counts. Whether the Court of Justice follows the AG's opinion in its judgment and sets aside the GC's decisions, or refers the cases back to the GC (as in the AG's view, the General Court must re-examine the complex issues of fact that arise), it is hoped that European Union (EU) jurisprudence takes on board the AG's concerns and the views long expressed by the innovative industry when applying the CCI exception and that the Swiss Courts may follow this lead. This would therefore allow Swissmedic to continue its previous policy of refusing access to clinical studies as far as CCI is concerned.

Another case on the same matter is pending before the GC: Case T-377/18 *Intercept Pharmaceuticals v. EMA.*