Client Alert

October 2013

EU Court Judgment Weakens Protection of Confidential Business Information

In a recent decision, the General Court of the Court of Justice of the European Union ruled that an NGO is entitled to information on the composition of plant protection products submitted to a Member State agency in connection with an approval procedure, even though the information was regarded as confidential under the plant protection products legislation. This ruling raises questions extending beyond the plant protection products laws to other regulatory regimes, such as REACH.

The Facts

An NGO requested access to several documents, including test documents and a draft assessment report on an active substance issued by Germany pursuant to the Plant Protection Products Directive 91/414/EEC. This request was rejected because the information requested was deemed confidential since it involved intellectual property rights, namely the detailed chemical composition of the active substance, information on impurities and the composition of the finished products.

The NGO appealed the rejection to the General Court. It invoked its rights under Regulation 1367/2006, which implements the Aarhus Convention, and argued that there is an overriding public interest in disclosure where information relates to emissions into the environment. In an opinion dated 8 October 2013, the Court granted the NGO's appeal, and made two findings that may have far-reaching consequences.

- First, the Court ruled that the public interest in access to information on emissions into the environment overrides any private interest, including trade secrets and intellectual property rights. The EU's obligation to comply with the TRIPS Agreement's provisions on the protection of regulatory information for plant protection products and the specific confidentiality regime set forth in the EU plant protection products legislation were found not to vary the overriding interest in disclosure.
- Second, rejecting the European Commission's position, the Court ruled that information on environmental emissions is not limited to information on the direct or indirect release of substances from installations. Rather, such information includes data on purity, identity and quantity of impurities, and the analytical profile of the batches used for the tests and studies in view of obtaining regulatory approval. According to the Court, any information that relates "sufficiently directly" to emissions into the environment must be disclosed. This is the case with respect to information on active substances included in a plant protection product, which will be released into the environment.

Impact of the Ruling

The Court ruling creates a challenge for the protection of confidential business information (CBI), including trade secrets on product composition. Although the case dealt with plant protection products, there is no reason to believe that the Court would have ruled differently had the case involved other chemical substances or products that release chemical substances. The case therefore raises questions

for all companies placing regulated products on the market, including, in addition to plant protection products, biocides and other products.

Importantly, the Court effectively set aside the CBI protection regime established by Directive 91/414/EEC. If that regime can be overridden by the Aarhus regulation, CBI protection regimes in other regulatory programs, such as REACH, may no longer be safe. Whether the fact that a fee is payable to ECHA in connection with confidentiality claims would change the analysis is an open question.

Further, the Court's ruling raises broader issues about the scope of the information to which NGOs or other persons (including competing companies) may seek access, where the data is covered by confidentiality claims or intellectual property rights. If the right of access to information is interpreted broadly, any information relating to the composition and properties of substances in a product could be deemed to be "sufficiently directly" related to emissions into the environment. The key question is whether any actual or potential release, no matter when it might occur (e.g. only upon disposal) or how small it is (e.g. below the toxicological thresholds), suffices for CBI to be accessible.

The ruling thus has substantial implications for corporate strategies for the protection of CBI. Companies placing regulated products on the EU market are well advised to review their strategies and potential exposure in the light of this ruling. In particular, they should assess which CBI could eventually end up in the hands of others, and what can be done to mitigate any resulting risks.

Upcoming EU trade secrets and CBI legislation?

The Court's ruling comes a few weeks before the European Commission is expected to release a legislative proposal on trade secrets and CBI. The proposal is intended to (i) enhance innovation and growth within the internal market by facilitating cross-border cooperation between innovative companies, and (ii) protect trade secrets and CBI from misappropriation and misuse by third parties. Whether EU action will involve legislation, however, is an open issue, as the Commission has left the option of a recommendation open.

EU trade secrets and CBI legislation might provide an opportunity to address the issues caused by the Court's ruling. It could provide specific rules on how to balance the protection of CBI and access to information. Indeed, the Court's ruling has made such rules desirable. For this to happen, however, the scope of EU legislation should be broadened beyond the Commission's current thinking.

The Commission proposal is due this year. If it smoothly moves through the process, it could be adopted before the elections for the European Parliament in May 2014. Short of legislation that remedies the problem, the Court of Justice may be asked to review the judgment, as the General Court's ruling is not yet final. If it is appealed, the Court of Justice will have a chance to establish a regime that gives more deference to CBI protection.

How Hunton & Williams Can Help

The Regulatory Team of Hunton & Williams has extensive experience in assisting clients with REACH and regulations regarding plant protection products, biocides and industrial facilities. The team advises clients on a wide range of regulatory matters, including compliance management, liability assessment, product stewardship audits, product defense, specific compliance issues, consortium and SIEF management, data rights, contracts, inspections and enforcement, and legal remedies. Providing tailored advice in policy, compliance, enforcement, and transactional areas, we work closely with our clients and with regulatory and technical experts so that clients' interests are protected effectively by professionals best placed to assist.

Hunton & Williams is a global law firm with a strong focus in regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh and Washington D.C., and also in its Asian offices, including Beijing.

For a comprehensive calendar of all processes ongoing under REACH and an overview with a summary of all court cases, see www.reachpsforum.eu.

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