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Accessing Competitor Information in Canadian Government Files

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Supreme Court of Canada sets low threshold for companies to be notified of competitor requests for information. The need to protect confidential information is reaffirmed.

The Canadian government allows the public to request access to information in government files. Access must be provided by law, as a way of ensuring government openness and transparency. Drug companies often make access to information requests with the Canadian government to obtain information about their competitors, for example, information in a competitor's regulatory submission for drug approval. Much of the information in the submission is highly confidential, such as the drug manufacturing process. Other information is not confidential, such as the drug Product Monograph for an approved drug (ie. drug company document given to physicians and pharmacists describing the scientific background, use, side effects of the drug).

The company that provided the information to the government is called the "Information Provider" in this article. The Canadian government cannot give out confidential information or information that would harm the Information Provider. The exempted categories of information may be summarized as:

a. trade secrets;
b. financial, commercial, scientific or technical confidential information;
c. information that, if disclosed, could result in material financial loss or gain, or prejudice the competitive position of the Information Provider; or
d. information that, if disclosed, could interfere with the Information Provider's contractual or other negotiations.

The government may disclose such information in the interest of public health, public safety or protection of the environment, which should be rare.

The access laws must provide for a careful balance between broad rights of access and protection of third party information.

The bottom line in Canada, following the decision, remains that the government will not knowingly disclose trade secrets to competitors.

The Supreme Court of Canada reviewed the access to information rules in the context of the drug industry. The just-released decision is a very important precedent for future *access to information requests (Merck Frosst Canada Ltd. v. Canada* (Health), [2012] SCC 3). The case arose after Merck asked for judicial review to stop Health Canada from releasing information to a competitor.

The bottom line in Canada, following the decision, remains that the government will not knowingly disclose trade secrets to competitors. The pharmaceutical company should receive notice before any potential disclosure of a trade secret. However, Information Provider must be diligent and provide clear justification when responding to Health Canada about whether a particular piece of information is a trade secret.

The decision is positive overall because the Supreme Court disagreed with the Court of Appeal judgment that had interpreted trade secrets restrictively and applied a high threshold to qualify as exempted information. The Supreme Court set a fairly low threshold to trigger the obligation to give notice to

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an Information Provider before making a disclosure in response to an access to information request. The low threshold ensures fairness and reduces the risk of mistaken disclosure of confidential information. The Court decided that disclosure without notice is only permitted when there is no reason to believe that the disclosed information might contain confidential information. When in doubt or when redacting documents (ie. severing confidential information from non-confidential information), the government must give notice to the Information Provider.

Although the standard set by the Court is reasonable and protects confidential information, the outcome was not favourable to Merck. It was not able to show that any of the pages to be disclosed (redacted by Health Canada), contained any confidential information that should be exempted from disclosure.

Details of the Decision

Trade Secrets & Confidential Information

The Court defined a "trade secret" for the purposes of as the access to information law as:

> a plan or process, tool, mechanism or compound, which possesses the following characteristics: the information must be secret in an absolute or relative sense (is known only by one or a relatively small number of persons); the possessor of the information must demonstrate he or she has acted with the intention to treat the information as secret; the information must be capable of industrial or commercial application, and; the possessor must have an interest (e.g. an economic interest) worthy of legal protection.

The Court said that its approach was consistent with definitions in prior court cases. In the context of the access laws, it also takes account of the legislative intent that a trade secret is something different from the broader category of confidential commercial information protected under the access laws.

Although the Court decision is positive in requiring a low standard for the government to give notice to the information owner, the Court disagreed that the redacted documents continued to contain confidential information. The information in those documents did not qualify for the "confidential information" exemption because it was not i) financial, commercial, scientific or technical information; ii) confidential and consistently treated in a confidential manner by the third party, and iii) supplied to a government institution by a third party. Health Canada provided evidence that the unredacted material is in the public domain and was not confidential. The Court said that Merck did not provide evidence showing that the information to be disclosed was confidential.

In addition, Health Canada reviewers' notes will only fall under the exemption if they contain exempted information communicated to them by a drug company.

With respect to the drug submission itself, the choice about how information is presented or the precise organization and ordering of sections of a document is not exempted information. Formatting and structure of new drug submissions, did not qualify for exemption as confidential information. These are often based on publicly available Health Canada guidelines so there must be something more substantive to qualify for exemption. This part of the decision will not impact the ability of drug companies to protect the trade secret content in their new drug submissions.

Public domain articles and studies in the submission were also not exempted information that could be exempted in this case. Merck had referred to many of the studies in its published Product Monograph and elsewhere.

Harm to the Information Provider

The exemption from disclosure applies if disclosure could reasonably be expected to harm the third party. The Court approved the current test for harm:

> the test to establish the degree of likelihood that harm will result from disclosure is "a reasonable expectation of probable harm". This long-accepted formulation is intended to capture that, while the third party need not show on a balance of probabilities that the harm will in fact come to pass if the records are disclosed, the third party must nonetheless do more than show that such harm is simply possible. The important objective of access to information would be thwarted by a mere possibility of harm standard. Exemption from disclosure should not be granted on the basis of fear of harm that is fanciful, imaginary or contrived. There is no reason to reformulate the test.

Disclosing information that is already in the public domain will not be considered harm except in cases where the way in which publicly available information has been compiled for a particular purpose is not, itself, publicly known, giving rise to the risk of harm by disclosure. The Court provided the example of information, not already public, would give competitors a head start in developing competing products, or a competitive advantage in future transactions.

Disclosure of information such as dates, numbering and location of information within a new drug submission or the manner of its presentation, as well as lists of studies or acknowledgement that certain studies have been consulted, and information about how the regulatory process works, usually does not give rise to harm or competitive prejudice.

Severance of Information

The Supreme Court agreed with the Court of Appeal assessment of when severance of information will be appropriate. Redacting will be done where disclosure of the unexcised portions of the record would reasonably fulfill the purposes of the access law, having regard to whether what is left after excising exempted material. Where severance leaves only disconnected snippets of releasable information, disclosure is not required.