GOVERNMENT OF CANADA CANNOT DISCLOSE CONFIDENTIAL INFORMATION RELATING TO NEW DRUG SUBMISSIONS

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INTRODUCTION

On judicial review of a decision by the Minister of Health ("Health Canada") to disclose information regarding Merck Frosst Canada's ("Merck") application for a Notice of Compliance, the Federal Court ruled that the information should not have been disclosed as Merck's record with Health Canada was confidential. (*Merck Frost Canada & Co.* v. *The Minister of Health Canada*,(2004) FC 959, Harrington J. July 6, 2004)

THE FACTS

Further to Merck's development and study of the drug SINGULAIR® for the treatment of asthma, the company applied for a Notice of Compliance in order to market the product in Canada. Merck supplied Health Canada with all of the known information concerning its new drug. Health Canada thereafter received a request from a third party for documents and information which formed part of Health Canada's file for SINGULAIR®. After reviewing the request, Health Canada disclosed some information to the third party without notifying Merck of the request or the disclosure.

Upon learning of the nature and scope of the disclosure, Merck initiated an Application for Judicial Review in order for the Court to decide whether or not the information was in fact exempt for disclosure in accordance with the provisions of the Canadian *Access to Information Act* (R.S.C. 1985, c. A-1).

THE FEDERAL COURT JUDGEMENT

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Justice Harrington first proceeded to review the nature and contents of a new drug submission for the issuance of a Notice of Compliance. In particular, he analysed the contents of the Comprehensive Summary, which often contains trade secrets, financial, commercial, scientific and technical information concerning the drug. The Court recognized that this document was generally considered confidential.

The Court then proceed to review the relevant provisions of the *Access to Information Act*. The guiding principle of this law is that when a person requests information, it is normally entitled to this information unless same is specifically exempted from disclosure by law. For example, Section 20 *Access to Information Act* lists the type of information that is normally exempt from disclosure. In this regard, the Court noted that Merck's file with Health Canada, taken as a whole, was confidential as it contained the type of information that Merck itself would not habitually release to the public, or to its competitors.

Health Canada's position was that it had acted in good faith and that it had disclosed information without breaching its confidentiality duty towards Merck. Health Canada had initially determined that only 32 pages of the 534 page record were in fact confidential. However, the Court noted at the time of review, Health Canada now admitted that at least 425 pages of the record should have been considered confidential!

Although Merck agreed that there must be some form of disclosure of governmental records, it took issue with Health Canada's position that all that is publicly known should be disclosed, even if it forms part of a confidential record. Merck argued that the more information is disclosed to competitors, the more it looses its competitive advantage on the market and is unable to recoup its investment in the development of the new drug.

After reviewing the documents disclosed by Health Canada, Justice Harrington concluded that all the information requested by the third party, including the Comprehensive Summary, that would not otherwise exist had it not been for Merck's disclosure to Health Canada, was in fact confidential. The Court ruled that Health Canada should have first consulted with Merck before disclosing any part of the record. Health Canada was therefore under the obligation to give Merck prior notice that it intended to release all, or part, of the documents contained in the record. Relying on prior case law, the Court also concluded that if excerpts from the record are meaningless out of context, then there should be no disclosure of said excerpts.

The confidentiality of a document depends on the document's contents, its purpose and the circumstance under which it was compiled and communicated. Justice Harrington noted that the information which Merck sent Health Canada was always treated as confidential and Merck could legitimately expect that the information would remain confidential. The Court recognized that some of the information contained in Merck's file was already of public record, but ruled that it is the nature of the record as a whole which determines whether or not a document is confidential.

The Court therefore granted the application for judicial review with costs.

CONCLUSION

This case raises the interesting question of third party access to otherwise confidential information. Healthy competition remains the cornerstone of our Canadian economy, as well as a recognised incentive for research and development. If companies do not have the assurance that the results of their efforts and investments are not adequately protected, the development of new products may be jeopardised in the future. A certain balance must be struck between the interests of the public and those of private companies in order to encourage future innovations.