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Data Protection for Drug Innovators Comes Under Attack

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A decision released by the Federal Court of Appeal in *Minister of Health v. Merck Frosst Canada Ltd.* represents a blow to innovative drug manufacturers under Canada's access to information regime. The decision was released in English last week, following an earlier publication in French issued last year.

The Federal Court of Appeal's decision concerns two separate third party requests filed with the Minister of Health for the release of information contained in drug submissions on file with the Minister relating to Merck's drug product Singulair. In response to these requests, the Minister disclosed certain information without prior notification to Merck and further advised of his intention to release other information, despite receiving representations from Merck that the information was exempt from release under section 20 of the *Access to Information Act*¹ (Act). Merck challenged the Minister's decisions through two judicial review applications (heard by the same judge). Though Merck was successful in the court at first instance, both decisions were reversed on appeal.

The Court of Appeal concluded that the application judge had erred in law in holding that prior notice must always be given before release of third party information. The Court also rejected Merck's arguments regarding the application of the exemptions to disclosure set out in section 20 of the Act. As regards section 20(1)(a), the Court ascribed a very narrow meaning to the term "trade secret" and found that Merck had failed to establish that the information proposed to be disclosed (which included summaries of research data, and technical details about the manufacture, analysis, control and specifications of the active substance and the final product) constituted trade secrets. While the Court accepted that much of the information proposed to be disclosed constituted scientific or technical information belonging to Merck, it found that section 20(1)(b) of the Act was not engaged because there was no direct and objective evidence regarding the information's confidentiality or its treatment by Merck. Finally, as regards section 20(1)(c) of the Act, the Court found that Merck had presented statements that were vague, speculative and "silent" as to specifically how and why disclosure of the disputed information would harm Merck.

¹ Section 20 of the Act creates certain exceptions to the release of information, including trade secrets of a third party (section 20(1)(a)); financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party (section 20(1)(b)); and information whose disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party (section 20(1)(c)).

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The decision of the Court of Appeal appears to be based, at least in part, on the Court's uncertainty about the state of the arguments and the documents being considered for release. Merck's arguments referred to an earlier version of the documents, which contained additional information that had subsequently been redacted. These arguments could not be reconciled with the documents that the Minister was proposing to release.

The decision underscores, however, the importance of, and confirms the challenges in, establishing that information contained in a drug submission constitutes a trade secret or confidential information. This decision also means that it is insufficient for drug innovators to simply mark a drug submission or other information submitted to the government as "Confidential" and expect to receive prior notice of any proposed disclosure. The decision highlights the need to present direct and objective evidence of confidentiality, at the very least, in response to any proposed disclosure and possibly even at the time of submitting the information to the government.

Merck has obtained leave to appeal to the Supreme Court of Canada and a hearing has been tentatively scheduled for later in 2010. In the meantime, companies affected by this decision may wish to adopt a more aggressive approach in protecting their confidential information. They will be eagerly awaiting clarification of this area of the law by the country's highest court. **1**