

**IN THE SUPREME COURT OF CANADA
(On Appeal From The Federal Court of Appeal)**

BETWEEN:

MERCK FROSST CANADA LTD.

Appellant
(Appellant)

-and-

THE MINISTER OF HEALTH

Respondent
(Respondent)

-and-

BIOTECANADA

Intervener

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PART I – STATEMENT OF FACTS

1. The intervener herein takes no position on the facts as stated by the parties in view of the fact that the parties' facts are sealed.

PART II – POINT IN ISSUE

2. The intervener will argue the following issues:
 1. When is a Government Institution Required to Give a Third Party Notice and an Opportunity to Make Submissions?
 2. Was s. 20(1) of the *Act* correctly interpreted and applied by the Federal Court of Appeal?
 - A. Interpretation of s. 20(1)(a) – Trade Secret and s. 20(1)(b) – Confidential Information
 - B. Burden of Proof

PART III - ARGUMENT

Issue #1: When is a Government Institution Required to Give a Third Party Notice and an Opportunity to Make Submissions?

3. Where seeking access to documents that relate to a regulatory submission, such as a new drug submission, a third party must be given notice and an opportunity to make submissions on the release of its information, except where the information is already public. The Court of Appeal's interpretation of the notice provision is contrary to s. 27(1) of the *Access to Information Act*¹ (the "*Act*") as well as the fiduciary duty and duty of confidence that arises when trade secrets, confidential information and commercially sensitive information are filed with a governmental institution.
4. First, the Court of Appeal erred in ignoring the clear words of s. 27(1) that notice must be given where there is any reason to believe that the requested information might contain a trade secret or confidential information. The Court of Appeal did not provide an explanation as to why this statutory safeguard should be ignored.

¹ *Access to Information Act*, R.S.C. 1985, c. A-1, s. 27(1) [*Access to Information Act*].

5. There is no doubt that material filed as part of a new drug submission is generally confidential and thus there is a “reason to believe” that the information might contain confidential information or trade secrets.² Moreover, the purpose of the *Act*, to provide access to information on file with the government, is subject to “necessary exceptions,”³ which include third party confidential information.⁴ As set out in s. 2, the purpose of the *Act* specifically balances the desire to make information available to the public, while at the same time accepting that there are “necessary exceptions to the right of access”. The Court of Appeal ignored that “necessary exceptions” are part of the policy and purpose of the *Act*.⁵

6. In *Canada (Information Commissioner) v. Canada (Commissioner of the Royal Canadian Mounted Police)*, this Court confirmed that the *Act* does not favour access.⁶

The statement in s. 2 of the Access Act that exceptions to access should be “limited and specific” does not create a presumption in favour of access. Section 2 provides simply that the exceptions to access are limited and that it is incumbent on the federal institution to establish that the information falls within one of the exceptions.

7. The *Act* specifically provides for circumstances in which disclosure is not required. It is inconsistent with the purpose and spirit of the *Act* to weaken these provisions by reading in a stricter test that favors disclosure. By requiring a restrictive and high standard for s. 20(1) (a) and (b), the Court of Appeal “got off on the wrong foot”, which impacted its entire analysis of what types of information qualify as trade secrets and confidential information.

8. Moreover, concluding that the notice provision must be read restrictively ignores the common law right to notice, which is a fundamental tenet of procedural fairness that exists independently of statute. Notice is essential to the fundamental common law

² See *Merck Frosst Canada & Co. v. Canada (Minister of Health)*, [2005] 1 F.C.R. 587, 2004 FC 959 at para. 50 [*Merck Frosst, Trial Decision*].

³ *Access to Information Act*, *supra* note 1, s. 2(1).

⁴ *Ibid.*, s. 21(1).

⁵ *Merck Frosst*, [2009] F.C.J. No. 627, 2009 FCA 166 at para. 36 [*Merck Frosst, Appeal Decision*].

⁶ *Canada (Information Commissioner) v. Canada (Commissioner of the Royal Canadian Mounted Police)*, [2003] 1 S.C.R. 66, 2003 SCC 8 at para. 21.

principle of *audi alteram partem* – the right to be heard.⁷ This right transcends both the common law and the Civil Code.⁸

9. It is impossible to comply with the provisions of the *Act* or to offer a fair hearing if the Institution does not give notice to the owner of the confidential information.⁹ Notice under s. 27(1) of the *Act* is also an obvious precondition to the Institution's ability to comply with its obligation to protect third party information from disclosure. An Institution cannot know if disclosure will, for example, result in harm to a third party without consulting the third party.

10. An innovative company that submits trade secrets, confidential information and commercially sensitive information to a governmental institution is vulnerable to release of that information under the access to information regime. Thus, the innovator is dependant on the Institution to exempt third party information from disclosure. Further, this gives rise to a fiduciary obligation on the Institution to strictly comply with the obligation to give notice. As stated by this Court in *Guerin v. The Queen*,¹⁰

where by statute [...] one party has an obligation to act for the benefit of another, and that obligation carries with it a discretionary power, the party thus empowered becomes a fiduciary. Equity will then supervise the relationship by holding him to the fiduciary's strict standards of conduct.

11. In addition, there is a duty that is created by virtue of the relationship between the parties. The Institution owes the third party a duty of confidence that arises from the Institution having acquired knowledge of confidential information under circumstances in which the Institution has notice that the information is confidential. This duty of confidence exists beyond traditional categories of contractual obligation, fiduciary duty or a relationship between the parties and is based on elements of trust and reasonable expectation.¹¹

⁷ *Kanda v. Government of Malaya*, [1962] A.C. 322 at 337, Denning L.J.

⁸ *Société de l'assurance automobile du Québec v. Cyr* [2008] S.C.J. No. 13, 2008 SCC 13 (S.C.C.).

⁹ *Knight v. Indian Head School Division No. 19*, [1990] S.C.J. No. 26, [1990] 1 S.C.R. 653 (S.C.C.).

¹⁰ *Guerin v. The Queen*, [1984] 2 S.C.R. 335 at 383-84.

¹¹ *Lac Minerals Ltd. v. International Corona Resources Ltd.* (1989) 26 C.P.R. (3d); *Coco v. A.N. Clark (Engineers) Limited*, [1969] R.P.C. 41 (Ch.D.); *Saltman Engineering v. Campbell Engineering Co.*, [1963] 3 ALL E.R. 413.

12. It is submitted that the Institution cannot comply with its statutory obligations without third party consultation. The only exception to the duty to consult is where information is “public property and public knowledge”.¹²

13. Viewed through the lens of the duty of confidence, strict compliance with the notice obligations exists not only to protect the third party, but also to protect the Institution and requester from liability. The unlawful disclosure of third party information could give rise to a claim for damages against both the direct recipient of the information and any third-party recipient who has actual, imputed or constructive knowledge that the information was confidential.¹³

Issue #2: Was s. 20(1) of the Act correctly interpreted and applied by the Federal Court of Appeal?

14. The Court of Appeal erred in its interpretation of “trade secret” and “confidential information” in s. 20(1) and by failing to acknowledge the *prima facie* confidentiality of information submitted to an Institution for regulatory approval. Section 20(1) of the *Act* imposes an obligation on the Institution to refuse to disclose records containing third party confidential information. Where information is *prima facie* confidential, the Institution cannot release the information until it has evidence that overcomes the *prima facie* confidentiality.

A. Interpretation of s. 20(1)(a) – Trade Secret and s. 20(1)(b) – Confidential Information

15. There is no basis in law for the Court of Appeal’s conclusion that a trade secret ought to be “interpreted in a narrow sense” using a “high threshold” or that it must be of such “peculiar value... that harm to him would be presumed.”¹⁴ Likewise, there is no basis in law that confidential information is comprised only of information “not available

¹² See *Saltman Engineering v. Campbell Engineering Co. Ltd.* (1948), *ibid.* at p .215. To give rise to a duty of confidence, “[t]he information ... must ... have the necessary quality of confidence about it, namely it must not be something which is public property and public knowledge.”

¹³ Unlike the *Privacy Act* (see Section 74), the *Access to Information Act* does not accord protection from civil proceeding or from prosecution to the Head of an Institution or a person acting on behalf of or under the direction of a Head of an Institution.

¹⁴ *Merck Frosst, Appeal Decision, supra* note 5 at paras. 52-54.

from sources otherwise accessible by the public or that could not be obtained by observation or independent study”.¹⁵

16. There is little if any value in creating mutually exclusive definitions for trade secrets and confidential information as the boundary between the two is blurred. The two definitions are not water tight compartments. Indeed, courts often use the terms “trade secrets” and “confidential information” interchangeably.¹⁶ If a distinction is required, a reasonable distinction is that trade secrets tend toward technical and scientific information. In contrast, confidential information tends towards administrative aspects of a business or trade. For example, confidential information has been found to include lists of suppliers and customers.¹⁷ Regardless, the clear intent of the legislation is to protect both trade secrets and confidential information. An Institution should not produce confidential documents to a third party’s competition merely because they do not neatly fit into the “trade secret box” or the “confidential information box”.

17. The *Act* does not define trade secrets or confidential information. Consequently the normal meaning of these words should prevail. In *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, this Court confirmed that the threshold required to classify information as a trade secret is relatively low.¹⁸ Similarly, in *Lac Minerals Ltd. v. International Corona Resources Ltd.*, this Court suggested that the definition of a trade secret should be expansive rather than restrictive.¹⁹

18. The concept of “trade secret” is well-defined in international agreements and in the legislation of other jurisdictions. *Trade-Related Aspects of International Property Rights (“TRIPS”)* defines trade secrets as information that (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is

¹⁵ *Ibid.* at para. 65.

¹⁶ *GasTOPS Ltd. v. Forsyth*, [2009] O.J. No. 3969 at 120 [*GasTOPS*].

¹⁷ *Ibid.* at para. 119; See also *R. v. Stewart* (1983), 42 O.R. (2d) 225.

¹⁸ *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para. 75 [*Cadbury Schweppes*].

¹⁹ *Lac Minerals Ltd. v. International Corona Resources Ltd.* (1989) 26 C.P.R. (3d) at 154.

secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.²⁰

19. The United States *Uniform Trade Secrets Act*, a model law designed to ensure conformity among the enacting states, defines a trade secret as:

information, including a formula, pattern, compilation, program device, method, technique, or process, that:

(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and

(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.²¹

20. Based on these sources, the normal and usual definition of trade secrets includes the following: (1) information that is perceived as valuable by the owner; (2) information that the owner reasonably believes is secret; (3) information that the owner has undertaken reasonable efforts to keep secret; (4) information that has commercial value by virtue of it being secret; and (5) information that is of value in view of the usage and practices of the particular industry or trade.

21. In *Coco v. A.N. Clark (Engineers) Ltd.*, the following observation about confidential information was made:

Something that has been construed solely from materials in the public domain may possess the necessary quality of confidentiality: for something new and confidential may have been brought into being by the application of the skill and ingenuity of the human brain. Novelty depends on the thing itself, and not upon the quality of its constituent parts.²²

22. In *Pharand Ski Corp v. Alberta*²³ it was repeated that confidential information may consist of a compilation of publicly available information.

²⁰ *Trade-Related Aspects of International Property Rights (TRIPS)*, 1869 U.N.T.S. 332, s. 7, art. 39, online: WTO <http://www.wto.org/english/tratop_e/trips_e/t_agm3d_e.htm#7> [TRIPS].

²¹ See for example *Uniform Trade Secrets Act (California)*, Cal. Civ. Code, ss. 3426-3426.11, s. 1, online: Leginfo <<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=civ&group=03001-04000&file=3426-3426.11>>.

²² *Coco v. A.N. Clark (Engineers) Ltd.*, [1969] R.P.C. 41 at 47.

²³ *Pharand Ski Corp v. Alberta*, [1991] A.J. No. 471. See also *GasTOPS*, *supra* note 16 at para. 124.

23. Article 39(3) of *TRIPS*²⁴ specifically protects commercial vulnerability of pharmaceutical and agricultural products by protecting sensitive data from disclosure:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

24. Under this definition, manufacturing processes qualify as a trade secret. However, minor details in a manufacturing process may not be protected under the Court of Appeal's definition, yet that information could be of great value to a competitor seeking to replicate the product. This is particularly problematic for the biotechnology sector. For instance, Health Canada's 2010 Guidance on Subsequent Entry Biologics (SEBs) indicates that seemingly minor changes can produce serious alterations to biological products:

Changes to source materials, manufacturing processes, equipment, or facilities can result in significant unexpected changes to the intermediate and/or final product.²⁵

25. The definition applied by the Court of Appeal erroneously narrowed the definition of trade secrets and confidential information to exclude information that would in other situations qualify as a trade secret or confidential information. For instance, compilations of publicly available information is excluded. Further, non-public information that is not "closely guarded" is also excluded. In addition, a trade secret or confidential information whose harm is difficult to establish would not be protected. A trade secret is not defined by its commercial value. This later point is in direct conflict with this Court's ruling in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*²⁶

26. BIOTECCanada submits that the usage and practices of the biotechnology industry supports application of the normal interpretation of what is considered to be a trade secret and confidential information. Even if not "closely guarded", "of peculiar value", or if

²⁴ *TRIPS*, *supra* note 20.

²⁵ Health Products and Food Branch, Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs) (Ottawa: Minister of Public Works and Government Services Canada, 2008).

²⁶ *Cadbury Schweppes*, *supra* note 18.

compiled from publicly available sources, any information or material related to obtaining regulatory approval should not be released, unless the specific information is already public.

B. Burden of Proof

27. In *Ontario (Public Safety and Security) v. Criminal Lawyers' Association*, this Court acknowledged that both openness and confidentiality are protected by freedom of information legislation.²⁷ While there is a general right of access to information held by Institutions, some information is entitled to protection in order to promote good governance and safeguard the proper functioning of the affected institutions. Section 20(1) of the *Act* protects the confidentiality of third party information by imposing a mandatory obligation on the Institution to exempt such information from disclosure.

28. The burden of proof under s. 20(1) must be understood in light of this statutory scheme and the Institution's obligation to protect third party information. Specifically, where information falls *prima facie* within the scope of one of the s. 20(1) exemptions and is "objectively" confidential owing to the circumstances in which it was supplied by a third party, the Institution bears the burden of demonstrating why the information is not subject to protection under that exemption.

29. Given the expectations of innovators, the international framework for protection of such information and the character of the information, information disclosed to regulatory authorities for the purposes of obtaining approval falls *prima facie* within the scope of s. 20(1)(b). If information is *prima facie* confidential, the Institution should bear the onus of establishing that it is publicly available on a balance of probabilities. To hold otherwise would permit the Institution to unilaterally ignore its obligation to treat information that it received under the umbrella of confidentiality as confidential.

30. In this regard, all new drug submissions while under review are treated as confidential. Once a Notice of Compliance has issued, then publicly available portions of that submission may be accessible under the *Act*; however, the fact that the information

²⁷ *Ontario (Public Safety and Security) v. Criminal Lawyers' Association*, 2010 SCC 23.

was received in confidence means that Health Canada must maintain that confidentiality, unless and until it has sufficient information that the information is no longer confidential. The recipient of confidential information always has the obligation to establish that the information is no longer confidential before it discloses it.

31. In *Apotex Inc. v. Canada (Attorney General)*, it was highlighted that in order for the drug approval process to function effectively, the confidentiality of the information submitted to Health Canada should be honoured and maintained.²⁸

The perceived confidentiality of information flowing from a drug manufacturer to the Department of National Health and Welfare is a cornerstone of the system pertaining to the processing of new drug submissions and the issuance of notices of compliance. For this system to function effectively, the confidential nature of the relationship ought to be honoured and maintained to the extent possible.

This comment was echoed in *AB Hassle v. Canada (Minister of National Health and Welfare)* wherein it was affirmed that confidentiality is the “cornerstone of the regulatory scheme set out in the Food and Drug Regulations.”²⁹

32. In *Canadian Tobacco Manufacturers' Council v. Canada (Minister of National Revenue - M.N.R.)*, the Federal Court held that the government must consider itself bound by its undertakings to act confidentially whenever a third party has consistently treated the information as confidential”.³⁰

33. Based on the foregoing, BIOTECanada submits that if information is disclosed to an Institution as required under an approval process and the disclosure by the third party is done with the understanding that it will remain confidential, and that generally such information is considered confidential, then such information should be treated as confidential, unless the Institution has evidence that the information is available in the public domain.

²⁸ *Apotex Inc. v. Canada (Attorney General)* (1993), 48 C.P.R. (3d) 296 (F.C.T.D.) at 305.

²⁹ *AB Hassle v. Canada (Minister of National Health and Welfare)* [2000] F.C.J. No. 283, 5 C.P.R. (4th) 149 at para. 4.

³⁰ *Canadian Tobacco Manufacturers' Council v. Canada (Minister of National Revenue - M.N.R.)*, [2003] F.C.J. No. 1308, 2003 FC 1037 at para. 33.

34. The standard of proof that Health Canada should meet would not be the “high threshold” as courts have required the owner of the information to establish. Rather, the standard is the normal civil standard, a balance of probabilities. Even if the burden is on the owner of the information, there is simply no basis in law to employ a burden other than the normal civil standard.

35. Finally, BIOTECCanada submits that the Court of Appeal further erred in holding that there is a “heavy burden” of proof on the party objecting to disclosure of its information under s. 20(1)(b) of the *Act*.³¹ In civil cases there is but one burden of proof – proof on the balance of probabilities. In the words of J. Sopinka, in *The Law of Evidence in Canada*:

Since society is indifferent to whether the plaintiff or the defendant wins a particular civil suit, it is unnecessary to protect against an erroneous result by requiring a standard of proof higher than a balance of probabilities.³² [Emphasis added]

A single standard of proof in civil cases was unequivocally affirmed by this Court in *F.H. v. McDougall*, wherein it stated that “in civil cases there is only one standard of proof and that is proof on a balance of probabilities.”³³

PART IV – SUBMISSION ON COSTS

36. The intervener herein requests no costs of this appeal and asks that no costs be assessed against it.

PART V – ORDER SOUGHT, ORAL ARGUMENT AND OUTCOME

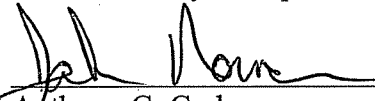
37. It is the intervener’s submission that the Appeal be allowed. Given the importance of this issue to the biotechnology industry and that the parties’ facts are sealed, BIOTECCanada respectfully request the right to make oral submissions not exceeding 20 minutes in length.

³¹ *Merck Frosst, Appeal Decision, supra* note 5 at para. 62 [*Merck Frosst*].


³² J. Sopinka, S. N. Lederman and A. W. Bryant, *The Law of Evidence in Canada*, 2d ed, (Toronto: Butterworths, 1999) at 154.

³³ *F.H. v. McDougall*, [2008] 3 S.C.R. 41, 2008 SCC 53 at para. 49.


ALL OF WHICH IS RESPECTFULLY SUBMITTED this 15th day of September, 2010.



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PART VI – LIST OF AUTHORITIES

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PART VII - LEGISLATION

DOCUMENTS

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