

**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)

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**MEMORANDUM OF ARGUMENT OF BIOTECANADA  
(Motion by BIOTECanada for Leave to Intervene)**

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**PART I – STATEMENT OF FACTS**

**Overview**

1. This is a motion by BIOTECanada, the country's national biotechnology industry association, for leave to intervene in this appeal.
2. BIOTECanada's members are innovators in the field of biotechnology who rely upon Health Canada and other government institutions to protect the trade secrets, confidential information and commercially sensitive information that is required to be disclosed to these agencies.
3. The decision appealed from departs from the prior framework governing the disclosure of trade secrets, confidential information and commercially sensitive information filed with Health Canada and other government institutions by innovative

companies. Left undisturbed, the decision will have a tremendous negative impact on BIOTECanada's members.

4. Specifically, upholding the decision of the Court of Appeal will eliminate or significantly reduce the ability of innovators to keep trade secrets, confidential information and commercially sensitive information out of the hands of competitors. This will diminish the incentive for biotechnology investment in Canada and place BIOTECanada members at a disadvantage in comparison to innovators in other countries.

5. This is particularly important to the biotechnology community given the unique nature of biotechnology products. Unlike many other products, changes to the source materials, manufacturing process and even equipment can significantly effect biological products. This illustrates the extreme importance of propriety information to this industry.

6. BIOTECanada's submissions for this appeal will be relevant, useful and distinct from those of the other parties. BIOTECanada is uniquely positioned to describe the direct effect of the decision appealed from on its broad membership base, which includes emerging and established companies in all aspects of biotechnology, including healthcare, agriculture, food, bioinformatics, research and industrial biotechnology.

7. If granted leave, BIOTECanada will take the position that:

- (a) notice must be given to third parties under s. 27(1) of the *Access to Information Act* ("the *Act*") whenever records deemed responsive to an access to information request contain information that was supplied by or relates to a third party;
- (b) the exemptions in s. 20(1) of the *Act* must be interpreted in conformity with the presumption of compliance with Canada's treaty obligations, which require Canada to provide the legal means to protect against disclosure of trade secrets, and to protect against disclosure of undisclosed tests or other data submitted to regulatory authorities to prove safety and

efficacy of pharmaceutical or agricultural chemical products that utilize new chemical entities; and

- (c) The exemptions in s. 20(1) of the *Act* require only that the third party present evidence that is sufficient to show that it is more likely than not (i.e., on a balance of probabilities) that the information is:
  - (a) a trade secret;
  - (b) confidential; or
  - (c) commercially sensitive, the disclosure of which could cause a reasonable expectation of harm.

### **BIOTECanada and Its Members**

8. BIOTECanada is a nation-wide, not-for-profit, non-government association with over 250 members. Founded in 1987, its mandate is to promote the sustainable development of biotechnology in Canada. To this end, it acts as a voice for BIOTECanada's community of researchers and innovators on public policy issues.

*Affidavit of Peter Brenders sworn June 29, 2010 ("Brenders Affidavit")*, Motion Record, Tab 2, para. 10.

9. One of BIOTECanada's key roles is to act for its members on protection of trade secrets, confidential information and commercially sensitive information in Canada. For example, in *Canadian Generic Pharmaceutical Association v. Canada (Health)*, 2009 FC 725, BIOTECanada President and CEO Peter Brenders submitted an affidavit attesting to the capital investment, time and effort expended to generate confidential data provided to health authorities to establish safety and efficacy of biologic products, and the consequent need for an effective data protection regime in Canada.

*Brenders Affidavit*, Motion Record, Tab 2, para. 11.

10. BIOTECanada's members work in all sectors of biotechnology; however, the majority of its members are small, emerging, entrepreneurial start-up companies, such as Lignol Energy, Agrisoma, Allon Therapeutics and Variation Biotechnologies. BIOTECanada's membership also includes academic and research institutions.

*Brenders Affidavit, Motion Record, Tab 2, para. 12.*

11. Proprietary information, trade secrets, confidential information and commercially sensitive information are an important asset of BIOTECanada's members. It is through these assets that BIOTECanada's members market themselves to venture capital firms and other sources of external funding. This external funding is critical to many of BIOTECanada's smaller members as it is needed to continue the development and commercialization of their initial ideas. It is this continued development and commercialization that is the incentive for external funding sources to invest in BIOTECanada's members.

*Brenders Affidavit, Motion Record, Tab 2, para. 13.*

12. Without appropriate protection of this information many of BIOTECanada's members will receive less, or no external funding as the incentives to investment are no longer present. This will prevent them from conducting research or carrying out business in Canada. It may also result in certain biotechnology products being unavailable to Canadians.

*Brenders Affidavit, Motion Record, Tab 2, para. 13.*

13. BIOTECanada frequently works with all levels of government, international bodies, and interest groups on initiatives that affect the protection of biotechnology industry in Canada. Such activities include:

- (a) making representations on biotechnology-related Intellectual Property issues, before various provincial and federal government organizations and committees, such as the House of Commons Standing Committees on Agriculture and Agri-Food, on Health and on Finance;
- (b) on-going consultations with the Ministers of Industry, Health, Agriculture, International Trade, and Natural Resources, Deputy Ministers and other officials, and the submission of position papers on a wide spectrum of biotechnology protection reform issues; and

- (c) Partnering with Industry Canada to create the Biorefinery Knowledge Network, partnering with AAFC to create the National BioProducts Roundtable, and working with DFAIT to establish the Canadian Life Sciences Database, which is used by the government to promote Canadian biotechnology and innovations on a global scale.

*Brenders Affidavit*, Motion Record, Tab 2, para. 15.

14. BIOTECanada has also acted as an intervener in two cases heard by this Court. It was an intervener in *Apotex Inc. v. Sanofi* 2008 SCC 61, which considered the validity of selection patents. In addition, BIOTECanada was an intervener in *Monsanto Canada Inc. v. Schmeiser*, [2004] S.C.J. No. 29, which considered the patentability of genes and cells.

*Brenders Affidavit*, Motion Record, Tab 2, paras. 13, 14.

## **PART II – STATEMENT OF QUESTIONS IN ISSUE**

15. This application for leave to intervene raises the following issues that comprise the test for leave to intervene established by this Court:

- (a) whether the Applicant has a real interest in the subject-matter of the appeal, and
- (b) whether the Applicant's submissions will be useful to the Court and different from those of other parties.

*R. v. Finta*, [1993] 1 S.C.R. 1138 at 1142

## **PART III – ARGUMENT**

### **BIOTECanada's Interest**

16. The issue of the proper scope of protection for information filed with Health Canada by third party innovative companies is a matter of immediate and practical importance to BIOTECanada. This Court's determination of issues relating to the obligations imposed on government agencies to not disclose information to competitors

directly and significantly affects many of BIOTECanada's members who have or will file information with government agencies that contain trade secrets, confidential information and commercially sensitive information.

*Brenders Affidavit*, Motion Record, Tab 2, para. 19.

17. The Court's decision will become the leading decision in the interpretation of the *Act* and will impact upon disclosure of trade secrets, confidential information and commercially sensitive information of BIOTECanada's members or prejudice their ability to protect such information from disclosure to competitors. The change in the framework adopted by the Federal Court of Appeal will have a profound impact on BIOTECanada's members, many of which have minimal operating capital and for whom intellectual property and trade secrets are their most valuable asset.

*Brenders Affidavit*, Motion Record, Tab 2, paras. 19 and 20.

18. The Court's decision will also impact the Canadian biotechnology industry as a whole. Two-thirds of BIOTECanada's members do not earn a positive revenue stream. Instead, they invest in research, which requires access to capital. In deciding whether to invest in Canada, investors will consider the risk that this information will be disclosed to a competitor by government agencies. Accordingly, if the Court's decision reduces protection of this type of information, investors may choose to invest in more innovation-friendly jurisdictions.

*Brenders Affidavit*, Motion Record, Tab 2, para. 21.

#### **Submissions That are Useful and Different**

19. BIOTECanada has a different perspective than the parties. While Merck is a pharmaceutical company, BIOTECanada's members operate in all areas of biotechnology, including the agriculture, food, aquaculture and industrial biotechnology industries, which are wholly unrelated to the pharmaceutical industry. Since BIOTECanada's members operate in different industries, they also operate in different

regulatory<sup>1</sup>, economic and technological environments. This affords BIOTECanada a unique perspective from those of the parties.

*Brenders Affidavit*, Motion Record, Tab 2, para. 22.

20. Filing of confidential information with government agencies is not limited to the pharmaceutical industry. Part of BIOTECanada's role as an intervener will be to assist the Court in understanding the consequences of the changes to non-pharmaceutical stakeholders. The law of access has a far broader reach than the particular facts at issue and the pharmaceutical industry in this appeal. If the Court is to consider that law, BIOTECanada respectfully asks for an opportunity to participate.

*Brenders Affidavit*, Motion Record, Tab 2, para. 23.

21. BIOTECanada has no interest in the disclosure of the specific information at the center of this appeal. Thus, BIOTECanada will assist the Court by addressing the issues from a broader perspective, distinct from the immediate factual context.

*Brenders Affidavit*, Motion Record, Tab 2, para. 24.

22. If granted leave to intervene, BIOTECanada proposes to address the following points under the issues as raised by the Appellant.

### **BIOTECanada's Proposed Submissions**

#### ***Federal Court of Appeal Decision at Odds with Policy Rational of ATI***

23. In *Ontario (Public Safety and Security) v. Criminal Lawyers Association*<sup>2</sup>, this Court acknowledged that not every demand for information held by government serves the purpose of furtherance of discussion on matters of public importance or the meaningful exercise of free expression on matters of public or political interest. This Court further acknowledged that certain government functions and activities require

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<sup>1</sup> From a regulatory perspective, it is important to note that non-pharmaceutical biotechnology companies are not involved in litigation under the *Patented Medicines (Notice of Compliance) Regulations*.

<sup>2</sup> This decision was released after the Appellant filed its factum. Consequently, if granted leave, BIOTECanada will be able to make representations on this decision that Merck could not.

privacy and that certain types of documents may remain exempt from disclosure because disclosure would impact the proper functioning of affected institutions.

*Ontario (Public Safety and Security) v. Criminal Lawyers Association*, 2010 SCC 23, paras 36-37, 40.

24. BIOTECanada will submit that access to the type of information in issue in this appeal does not serve the democratic purposes of the *Act*. The *Act* does not exist to permit competitors to obtain confidential commercially sensitive information about how innovative companies manufacture products sold in the market place. The information in issue is the type of information that is exempt from disclosure. It is derived by each individual member, for each individual product, after many years of research and at great expense. The inability of Health Canada and other government institutions to obtain such information from innovators due to fear of disclosure would surely impact the proper functioning of these institutions.

*Brenders Affidavit*, Motion Record, Tab 2, para. 27.

25. The precipitous disclosure of this confidential information to any competitor who requests it undermines the policy rationale that underlies the legal requirement for its submission. If the information was simple to obtain, Health Canada and other agencies would not require innovators to research, compile and present the information as required, but rather would be capable of collecting it on their own initiative. The information submitted by BIOTECanada members to government is not publically available and cannot be derived from sources available to the public, and cannot be treated as such.

*Brenders Affidavit*, Motion Record, Tab 2, para. 28.

26. Indeed, as Health Canada's 2010 Guidance on Subsequent Entry Biologics (SEBs) indicates, even changes to equipment or facility can have significant and unexpected changes on biological products.

Biologic drugs, unlike pharmaceutical drugs which are synthesized, are derived through the metabolic activity of living organisms and are variable and structurally complex. They are typically manufactured from animals,

microorganisms, or through the use of animals or microorganisms. Biologics tend to be labile and sensitive to changes in manufacturing processes. Biological source materials, production cells, or their fermentation media can present risks, such as the initial presence of pathogens or the growth of adventitious agents such as viruses. Because of this, careful attention is paid to raw material controls, viral/bacterial inactivation or clearance during product purification, and product testing. Changes to source materials, manufacturing processes, equipment, or facilities can result in significant unexpected changes to the intermediate and/or final product. [Emphasis added]

*Brenders Affidavit*, Motion Record, Tab 2, para. 29.  
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) at p. 4.

This shows that even the type of equipment that an innovator uses to prepare a biologic drug can be valuable information to a competitor.

27. Why would a competitor invest in research and development if a request will generate the answer much more easily? Surely this is well beyond the purpose of the *Act*. Indeed, if the information is so easily disclosed, why would the innovative third party invest in it? They would more likely take the research and the new products to a country that is more protective of its investments.

***Proper Interpretation of Section 20(1)***

28. BIOTECanada will submit that the exemptions in s. 20(1) of the *Act* must be interpreted in conformity with the presumption of compliance with Canada's treaty obligations.

29. It is by now well established that, in choosing among possible interpretations of legislation, courts are to avoid an interpretation that would put Canada in breach of its international obligations. When applying legislation in the context of a given fact situation, courts must strive to give legislation a fair and liberal interpretation with a view to fulfilling Canada's international obligations.

*Zingre v. R.*, [1981] S.C.J. No. 89, at para. 237; *R. v. Hape*, [2007] 2 S.C.R. 292.

30. TRIPS Article 39 and NAFTA Article 1711 require Canada to provide the legal means to protect against disclosure of trade secrets, and to protect against disclosure of undisclosed tests or other data submitted to regulatory authorities to prove safety and efficacy of pharmaceutical or agricultural chemical products that utilize new chemical entities. BIOTEC Canada will submit that when s. 20(1) is interpreted in light of these obligations, the only accurate construction is that the initial presumption of the agency should be that information submitted to government institutions should not be disclosed.

*North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (entered into force 1 January 1994).

*Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 (Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994, 1867 U.N.T.S. 3).

31. In addition, if the agency, after a thorough review, is of the opinion that the information does not fall within any of exemptions under the *Act* advise the third party of this finding and request submissions. If the third party submits that the information falls under s. 20(1) the agency should operate under the assumption that the requested information is a trade secret, confidential information or commercially sensitive information until it decides on a balance of probabilities that it is not.

*Brenders Affidavit*, Motion Record, Tab 2, para. 33.

32. Government agencies require third parties to disclose information to meet certain regulatory or statutory guidelines. Without those regulations or statutes, there would be no reason for the third party to disclose the information to anyone. The third party would not voluntarily make such a disclosure, as it is confidential, commercially sensitive or trade secret information. Without those regulations or statutes, the government agency would be abusing its oversight powers by requiring the third party to submit information that is not in the public domain.

*Brenders Affidavit*, Motion Record, Tab 2, para. 34.

33. In addition, BIOTECanada's members, are generally smaller than Merck. Much of Merck's argument addresses the great deal of time and effort required to review each of the documents requested by the outside party. In order to perform the same sort of review, BIOTECanada's smaller members will be subjected to a great deal more hardship as they do not have the same resources as Merck or the government agencies to devote to this type of document review.

*Brenders Affidavit*, Motion Record, Tab 2, para. 35.

34. Thus, the starting point for any ATI request should be that the third party information that was required to be submitted to the government agency meets one of the exemptions enumerated under s. 20(1) and notice of any request should be provided to the third party.

***Burden of Proof In Section 20(1)***

35. BIOTECanada's position is that the exemptions in s. 20(1) of the *Act* require only that the third party present evidence that is sufficient to show that it is more likely than not (i.e., on a balance of probabilities) that the information is: (1) a trade secret; (2) confidential; or (3) commercially sensitive, the disclosure of which could cause a reasonable expectation of harm. BIOTECanada will submit that there is no justification for imposing a "heavy" burden of proof where access to the information does not further democratic activity and is furthermore incompatible with the obligation of the institution to protect valuable third party information against disclosure.

*Brenders Affidavit*, Motion Record, Tab 2, para. 37.

36. It is not appropriate for the courts to read in a higher burden of proof that that imposed by the wording of the exemption in the context of a request to obtain competitive third-party information held by a government institution. In line with this Court's decision in *Ontario (Public Safety and Security) v. Criminal Lawyer's Association*, it will be submitted that there is no justification for imposing a "heavy" burden of proof where access to the information does not further democratic activity and

is furthermore incompatible with the obligation of the institution to protect valuable third party information against disclosure.

37. This is also consistent with this Court's decision in *F.H. v. McDougall* [2008], S.C.J. No. 54, wherein this Court rejected the notion of "shifting standards" of probability and held that the only way to reach a factual conclusion in civil cases is "to decide whether it is more likely than not that the event occurred".

*F.H. v. McDougall* [2008], S.C.J. No. 54 at para. 44.

#### ***Approaches in Other Jurisdictions***

38. The law of other countries such as the United States also contemplates protection of trade secrets, confidential information and competitively sensitive information filed with government agencies. Should BIOTECCanada be granted leave to intervene, it will set out the approaches taken in other major common-law jurisdictions and argue that these approaches are better suited to accomplish the objectives of the *Act*.

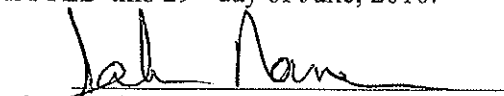
#### **PART IV – SUBMISSIONS ON COSTS**


39. BIOTECCanada proposes that there be no costs of this motion.

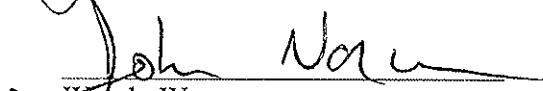
#### **PART V – ORDER SOUGHT**

40. BIOTECCanada respectfully requests that it be granted leave to intervene, that it be permitted to file a factum of no more than 20 pages, and that it be granted leave to make oral submissions on the hearing of the appeal for a maximum of 20 minutes.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 29<sup>th</sup> day of June, 2010.

  
Anthony G. Creber

  
John Norman

  
Wendy Wagner

Counsel for the Moving Party,  
BIOTECanada