Federal Court  Cour fédérale

Date: 20130531

Dockets: T-1769-11
T-1934-11
T-80-12

Citation: 2013 FC 508

BETWEEN:

NOVARTIS CONSUMER HEALTH CANADA INC.

Applicant

and

HEALTH CANADA AND THE MINISTER OF HEALTH

Respondents

PUBLIC REASONS FOR JUDGMENT
(Confidential Reasons for Judgment released May 15, 2013)

HUGHES J.

[1] The Applicant Novartis Consumer Health Canada Inc (Novartis) has brought three separate applications, consolidated for the purposes of the hearing, for an Order under the provisions of section 51 of the *Access to Information Act*, RSC 1985, c. A-1, that the Respondent Minister of Health not disclose certain information described as Disputed Information provided by the Applicant to Health Canada. In particular, there are at issue three decisions of the Minister in which the Minister has indicated a determination that such Information will be disclosed. Those decisions

are dated October 11, 2012 (T-1769-11); undated, but with reference number A-2011-00185/bo (T-1934-11); and December 22, 2011 (T-80-12).

[2] For the reasons that follow, I have determined that the applications will be dismissed with costs.

EVIDENCE AND MOTION TO EXCLUDE CERTAIN PORTIONS

[3] The Applicant filed as its evidence the Affidavit of Donald Beatty, its Director of Regulatory and Scientific Affairs, together with several exhibits. He was not cross-examined.

[4] The Respondent filed the Affidavit of Maria Chabot, the Chief of Operations drug portfolio at Health Canada Access to Information and Privacy Division, together with several exhibits. She was cross-examined. The Respondent also filed the Affidavit of Jennifer Novak, the Head of Operations in the Information Management Directorate at the Health Products and Food Branch of Health Canada, together with several exhibits. She was not cross-examined.

[5] At the outset of the hearing before me, Counsel for the Applicant spoke to a motion previously filed by the Applicant, to strike out certain portions of the Chabot and Novak affidavits; in particular, Counsel requested:

1. An order striking out all or parts of paragraphs 24, 43, 47, 48, 49, 50, 52, 54, 55, 57, 58, 59, 60, 61, 62, 63, 64, 65, 67, 69, 73, 74, 75, 76, 78 and 79 of the Affidavit of Jennifer Novak sworn July 6, 2012;

2. An order striking out all or parts of paragraphs 10, 13, 16, 37, 38, 39, 40, 41, 42, 43, 45, 46, 47, 48, 49, 50, and 51 (last sentence only) of the Affidavit of Maria Chabot sworn July 6, 2012.

[6] I agree with Applicant's Counsel that these portions of these affidavits appear to be legal argument and not matters of fact known to the affiants or within their expertise. Neither of them are lawyers. These paragraphs would belong, more properly, in a Memorandum of Argument.

[7] I asked whether Chabot was cross-examined upon any of the paragraphs or the portion of paragraph 51 sought to be struck out from her affidavit, and was advised that she was not.

[8] Respondents' Counsel argued that the Applicant had not shown any prejudice arising from any of the impugned paragraphs; thus, they should not be struck out. I disagree; prejudice is not a necessary element when considering whether evidence should be struck out.

[9] In the present case, I will not strike out the impugned paragraphs or portion thereof, but I will give them no weight, as they are, in my opinion, clearly expressed as legal argument and not as factual matters or matters of opinion in respect of which the affiants have expertise. I leave them in, simply because it is more expeditious to do so and, in the event that any party seeks to appeal, the record is more complete.

FACTS

[10] The Applicant Novartis (sometimes called NCHC) develops and markets over-the-counter health products intended for the prevention or self-treatment by persons in respect of certain medical conditions and ailments. In this regard, the Applicant is subject to certain of the requirements of the *Food and Drug Act*, RSC 1985, c. F-27 and *Food and Drug Regulations*, CRC, c 870. Among those requirements are that the Applicant shall prepare an annual summary report of all information relating to adverse drug reactions and serious adverse drug reactions that it received or became aware of in the previous 12 months. Further, the Applicant may be requested to submit to the Minister of Health an issue-related summary report as described in section C.01.019 of the *Regulations*.

> *C.01.019*
> *(1) The Minister may, for the purposes of assessing the safety and effectiveness of the drug, request in writing that the manufacturer submit to the Minister an issue-related summary report.*
>
> *(2) The report shall contain a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to the drug, as well as case reports of all specified adverse drug reactions and serious adverse drug reactions to the drug that are known to the manufacturer in respect of the issue that the Minister directs the manufacturer to analyze in the report.*

[11] The Respondents have published guidelines entitled "Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products" (effective 2011-03-02) which includes the following provisions as to what is expected by the Respondents in respect of reports submitted by persons such as the Applicant:

3. Good Case Management Practices

3.1 Minimum Criteria for an Adverse Reaction Report

Complete information for the final description and evaluation of an AR report may not be available within the time frame required for reporting. Nevertheless, for regulatory purposes, AR reports must be submitted within the prescribed time, as long as the following minimum criteria are met:

(a) An identifiable reporter (source)
(b) An identifiable patient
(c) A suspect product
(d) An adverse reaction

Ideally, more comprehensive information would be available on all cases from the outset, but in practice MAHs will often have to follow up after initially submitting the report to seek additional information. Follow-up AR reports should be clearly labelled as such. The MAH is expected to exercise due diligence to collect any key data elements (see Section 3.8) that are lacking at the time of initially submitting the report.

It is important that at the time of the original report, sufficient details about the patient and reporter be collected and retained to enable follow-up in accordance with the collection, use and disclosure provisions of the Personal Information Protection and Electronic Documents Act or equivalent provincial privacy legislation.

. . .

3.3 The Role of Narratives

The objective of the narrative is to summarize all relevant clinical and related information, including patient characteristics, therapy dates, medical history, clinical course of the event(s), diagnosis, and AR(s) including the outcome, laboratory evidence (including normal ranges), and any other information that supports or refutes an AR (e.g., rechallenge information). The narrative should serve as a comprehensive, stand-alone "medical story".

Abbreviations and acronyms should be avoided, with possible exception of laboratory parameters and units. Key information from supplementary records including summarized relevant autopsy or post-mortem findings should be included in the report, and their availability should be mentioned in the narrative and supplied on request. Clinical judgement should be exercised by a qualified health care professional from the MAH to determine what information

> *should be submitted. Personal identifiers should only be submitted in accordance with the collection, use and disclosure provisions of the Personal Information Protection and Electronic Document Act or equivalent provincial privacy legislation.*
>
> *Information (e.g. ARs, indication, and medical conditions) in the narrative should be accurately reflected in appropriate data fields of the reporting form.*

[12] The Applicant and an affiliate, referred to as NCH, collate data in respect of adverse and serious adverse drug reactions (these are defined terms under the *Regulations*) as reported to them by members of the public who presumably have experienced or are associated with those who have experienced an adverse reaction. The information is prepared in a format known as CIOMS (Council for International Organizations of Medical Sciences). These reports are described in the affidavit of Donald Beatty, Director of Regulatory and Scientific Affairs of the Applicant, at paragraph 9 of his affidavit:

> *9. CIOMS reports prepared by NCH contain information regarding the affected drug, the age of the patient, the nature of the suspected adverse event, whether the affected drug was used concomitantly with any other drugs and the patient's relevant medical history. They also contain a Narrative of the suspected adverse event, which is prepared by NCH representatives. For ease of reference, I will refer to the Narrative contained in each of the records that Health Canada has decided to disclose as the "Narrative" throughout this affidavit.*

[13] Beatty summarizes the Applicant's position in these proceedings succinctly at paragraph 11 of his affidavit:

> *11. In the three decisions that are under review in these proceedings, Health Canada has decided to disclose the eighteen listed adverse event reports without redacting the Narrative.*

[14] The manner in which the CIOMS Reports, especially the Narrative, are created is described in detail by Beatty at paragraphs 12 to 26 of his affidavit:

> *a. Creation and Contents of the CIOMS Reports and Narratives*
>
> *[…]*

[15] According to paragraphs 36 and 37 of the Beatty affidavit, these narratives are used by the Applicant and its affiliates to improve their products and make their use safer for consumers; for instance, changes to product labelling may be made.

[16] The Beatty affidavit, paragraphs 27 to 35, states that these CIOMS reports are maintained by the Applicant and its affiliates as confidential and, when they are required to be submitted to Health Canada, they are submitted as being confidential with an appropriate caption on the reports to that effect.

[17] The use to which these reports is put by Health Canada is set out in their document entitled "Procedure - The Release to the Public of Information Obtained from Adverse Reaction and Medical Device Incident Reports: (issued 2011-08-11). Section 2.3 reads:

> *2.3 Use of Adverse Reaction (AR) or Medical Device Incident Information Provided from Adverse Reaction Reporting Programs in the Health Products and Food Branch (HPFB)*
>
> *The adverse reaction or medical device incident data provided by AR or medical device incident reporting programs of the Health Products and Food Branch may be used in other documents, including publications. It is requested that the author acknowledges the source of the data, the limitations of the data from spontaneous*

> *reporting systems and provides a copy of the document or publication to the AR reporting program prior to publication.*

[18] An illustration of the use of such reports is provided at Exhibit M to the Novak affidavit, which is a warning as to the use of triaminic vapour patch issued by Health Canada on May 30, 2006. I repeat this warning in part, noting that it says that *"Health Canada is aware of one adverse reaction associated with the use of Triaminic Vapour Patch…*":

> ***Health Canada warns consumers not to use Triaminic vapour patch due to potential health risks***
>
> ***Warning***
> *2006-39*
> *May 30, 2006*
> *For immediate release*
>
> ***OTTAWA*** *– Health Canada is warning consumers not to use Triaminic Vapour Patch due to the serious adverse health effects that could result if the product is accidentally ingested by children.*
>
> *Triaminic Vapour Patch contains camphor, eucalyptus oil and menthol. The reported side-effects from swallowing products containing camphor or eucalyptus oils vary from minor symptoms such as burning sensation in the mouth, headache, nausea and vomiting to more severe and life-threatening reactions such as seizures.*
>
> *Health Canada is aware of one adverse reaction associated with the use of Triaminic Vapour Patch. The adverse reaction involved a child who had a seizure after chewing on the patch.*
>
> *Triaminic Vapour Patch is advertised as a cough suppressant for children two years of age and older. The directions on the label indicate that the patch is to be applied to the throat or chest to allow the vapours to reach the nose and mouth. Once applied, the patch would be within close reach for a child to remove and ingest. An additional risk is the product's cherry scent, which could also lead a child to chew or swallow the patch.*
>
> . . .

[19] Summaries of these adverse reactions are available from Health Canada online on what is known as a CADRIS database. That database contains a warning that the information is not a scientific evaluation, and that quantitative comparisons of the health safety of various products cannot be made from the information in the database. I repeat what Novak says at paragraphs 31 and 32 of her affidavit:

> *31. Summary reports of data provided by HC based on the CADRIS database contain the following statement:*
>
> > *"This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders, each report represents the suspicion, opinion or observation of the individual reporter. The Canadian Adverse Drug Reaction Monitoring Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems.* ***Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data****. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales fore, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement."*

> *32. In describing the "outcome" field on the HC website, the following statement is made:*
>
> > *"The outcome represents the outcome of the reported cases described by the reporter at the time of reporting and does not infer casual relationship. The outcome is not based on a scientific evaluation by Health Canada."*

[20] The evidence is unclear as to whether Health Canada has ever released the actual substance of any adverse reaction report as submitted to it by Novartis. […] I find that Health Canada has not established that any previous adverse reaction reports submitted to it by Novartis have been released to the public.

[21] The evidence of both parties shows that Health Canada gave notice to Novartis that a request for release of the adverse reaction reports had been made by a third party. That third party has not been identified on the record. The motives of that third party in seeking such information are unknown. The evidence further shows that there have been considerable negotiations between the parties such that Health Canada has agreed to redact several portions of these reports, including certain identifying information and specific comments as to the particular case as made by Novartis itself. What remains in dispute is that portion referred to as the "Narrative", to which I have previously referred. This is the portion recorded by a trained Novartis person as to what was stated by the person who reported the adverse drug reaction. Health Canada wants that to be released; Novartis does not.

[22] The statutory framework respecting the release of information in the possession of a government body such as Health Canada is provided by the *Access to Information Act*, supra. Subsection 2. (1) states that the purpose is to provide a right of access to the public to such information, subject to necessary exceptions:

2. (1) The purpose of this Act is to extend the present laws of Canada to provide a right of access to information in records under the control of a government institution in accordance with the principles that government information should be available to the public, that necessary exceptions to the right of access should be limited and specific and that decisions on the disclosure of government information should be reviewed independently of government.	*2. (1) La présente loi a pour objet d'élargir l'accès aux documents de l'administration fédérale en consacrant le principe du droit du public à leur communication, les exceptions indispensables à ce droit étant précises et limitées et les décisions quant à la communication étant susceptibles de recours indépendants du pouvoir exécutif.*

[23] Section 20 of that *Act* provides that the head of the relevant government institution shall refuse disclosure in respect of information falling under certain categories. In the present application, the Applicant is relying on subsections 20 (1) (b) and (c):

20. (1) Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains	*20. (1) Le responsable d'une institution fédérale est tenu, sous réserve des autres dispositions du présent article, de refuser la communication de documents contenant :*
. . .	. . .

(b) 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;

b) des renseignements financiers, commerciaux, scientifiques ou techniques fournis à une institution fédérale par un tiers, qui sont de nature confidentielle et qui sont traités comme tels de façon constante par ce tiers;

(b.1) information that is supplied in confidence to a government institution by a third party for the preparation, maintenance, testing or implementation by the government institution of emergency management plans within the meaning of section 2 of the Emergency Management Act and that concerns the vulnerability of the third party's buildings or other structures, its networks or systems, including its computer or communications networks or systems, or the methods used to protect any of those buildings, structures, networks or systems;

b.1) des renseignements qui, d'une part, sont fournis à titre confidentiel à une institution fédérale par un tiers en vue de l'élaboration, de la mise à jour, de la mise à l'essai ou de la mise en oeuvre par celle-ci de plans de gestion des urgences au sens de l'article 2 de la Loi sur la gestion des urgences et, d'autre part, portent sur la vulnérabilité des bâtiments ou autres ouvrages de ce tiers, ou de ses réseaux ou systèmes, y compris ses réseaux ou systèmes informatiques ou de communication, ou sur les méthodes employées pour leur protection;

(c) information the disclosure of which 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; or

c) des renseignements dont la divulgation risquerait vraisemblablement de causer des pertes ou profits financiers appréciables à un tiers ou de nuire à sa compétitivité;

[24] The Applicant accepts that, in the present case, it bears the burden to prove that the documents at issue fall under one or both categories. However, Counsel for the Applicant argues, and I accept, that the burden is only the normal civil burden proof, citing the decision of the Supreme Court of Canada in *Merck Frosst Canada Ltd v Canada (Minister of Health)*, [2012] 1 SCR 23. Unanimous Reasons were provided by Cromwell J, who wrote at paragraph 162:

> *162 I agree with Merck that the Court of Appeal applied an unduly onerous standard of proof. The Court of Appeal stated that the third party opposing disclosure has a "heavy" burden to establish the s. 20(1)(b) exemption (para. 62). For reasons I have set out earlier, this is an error of law. The burden is to show on the civil standard that the exemption applies. However, I do not think the result reached by the Court of Appeal turns on its description of the standard of proof. The court's decision rested on what it concluded to be an absence of evidence responsive to the claimed exemptions in light of the [page98] extensive redactions made by Health Canada. I will explain.*

[25] At paragraph 150 of *Merck Frosst*, Cromwell J cautioned that, once the relevant legal principles are established, the question is largely one of fact in each case. One cannot draw broad principles from any particular case without knowing the particular factual circumstances:

> *150 I underline this last point. Once the relevant legal principles are established, whether or not a record is confidential is primarily a question of fact. Care must be taken, therefore, not to overgeneralize the holdings of particular cases, by failing to give due regard to the evidence which was before the court in those cases. It may be, for example, that the relevance of a particular study to a particular line of inquiry might in some cases be shown to be confidential. Similarly, as in Janssen-Ortho, [page94] express or implicit statements of the applicant's evaluation of the reliability of a study will generally meet the definition of confidential information. Of course, where the existence or contents of studies themselves meet the definition of confidential information in s. 20(1)(b), references to such studies will also generally be confidential for the purposes of the exemption.*

> *Similarly, if the fact that the applicant has evaluated or relied on the study is publicly available, that fact will not be confidential. The key point is that these principles are not self-applying and must be considered in light of the evidence in each case.*

[26] I turn first to section 20 (1) (b) and a consideration as to whether the "Narratives" contain "financial, commercial, scientific or technical information", and whether that information has been consistently treated as confidential.

[27] As to the meaning of the first set of terms, the late Justice MacKay of this Court in *Air Atonabee Ltd v Canada (Minister of Transport)*, (1989), 37 Admin LR 245, 27 FTR 194, 27 CPR (3d) 180, wrote at paragraph 36 that he found that dictionary meanings provided the best guide:

> *Nevertheless, I am not prepared to accept the respondent's submission that information must have an independent value, perhaps, from examples suggested, a market value or a cost value to the third party in acquiring it. Information is in my view essentially neutral as to value in those terms. Its value ultimately depends upon the use that may be made of it and its market value will depend upon the market place, who may want it and for what purposes, a value that may fluctuate widely over time. Questions about the application of this criterion appear to have been raised in a few cases but without definitive tests yet evolving. In the circumstances, it seems to me that dictionary meanings provide the best guide and that it is sufficient for purposes of subsection 20(1)(b) that the information relate or pertain to matters of finance, commerce, science or technical matters as those terms are commonly understood. Insofar as information of this sort may have a marketable value or its disclosure might cause loss to the third party it would seem that those aspects are protected by Parliament by subsections 20(1)(a), 20(1)(c) and 20(1)(d) of the Act.*

[28] In the Applicant's Memorandum of Argument, at paragraph 39, the following definitions from the Oxford Canadian Dictionary were provided:

> a. *"Commercial" is defined as "of, engaged in, or concerned with commerce";*
>
> b. *"Scientific" is defined as "used in, engaged in, or relating to (esp. natural) science"; and*
>
> c. *"Technical" is defined as "of or relating to a particular subject or craft etc.".*

[29] I find that these definitions are not particularly helpful and are somewhat circular in their meaning; (e.g.) commercial has to do with commerce. The evidence of Beatty, previously set out, indicates that the narratives are of limited value, possibly only resulting in changes to instructions for use. We do not know, however, whether it is the information contained in the narrative, rather than the narrative itself, that may influence a change in instructions. The evidence from Health Canada, previously reviewed, is that no scientific conclusions should be drawn from information contained in the adverse reaction reports.

[30] The Applicant has abstracted the Narratives at issue at Schedule A to the Beatty affidavit. To give a flavour of what such Narratives contain, I reproduce two of the briefer ones:

> ***Narrative for CIOMS Report #180581***
>
> *Initial consumer report was received on 23Jan2005. The patient's wife called and reported that she was concerned because her husband is still smoking while on the patch. She stated that he was applying the 21 mg Habitrol Transdermal Nicotine patch for 4*

> *weeks, while smoking 3 – 4 cigarettes every day. He is currently on his 4th week with Habitrol 14mg patch and he continues to smoke 3 – 4 cigarettes every day because of the cravings he continues to have. She stated that this Physician advised him to quit smoking because of the blood clot in his leg, but it is uncertain if Habitrol was recommended by the Physician. Therapy continues.*
>
> ***Narrative for CIOMS Report #180829***
>
> *Consumer report received on 31 Jan 2005. The patient reported that she applied a Habitrol Transdermal Nicotine patch (nicotine) on the morning of 30 Jan 2005. A couple of hours later, she experienced shortness of breath, coughing and wheezing.*
>
> *She removed the patch and fully recovered that evening. She later noticed that the patches were expired. The product was discontinued.*

[31] I am concerned that there is no evidence from a disinterested person who may have expertise in such matters, that narratives such as this have any commercial, scientific, or technical value. The basic information that could possibly be gleaned from such a narrative is already public. An example of that shown at Exhibit 7 to the Beatty affidavit:

Detailed Adverse Reaction Report Information

Health Canada Santé Canada

Canada

Home > Drugs & Health Products > MedEffect Canada > Canada Vigilance Adverse Reaction Online Database

Drugs and Health Products

Search the Canada Vigilance Adverse Reaction Online Database

Detailed Adverse Reaction Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number:	000190103
Latest AER Version Number:**	0
Market Authorization Holder AER Number:	CDN05688NICPA
Initial Received Date:	2005-09-08
Latest Received Date:	2005-09-08
Age:	56 Years
Age Group:	
Type of Report:	Spontaneous
Reporter Type:	Patient
Source of Report:	MAH
Feature of Report:	Adverse Reaction
Report Outcome:	Not recovered/not resolved
Gender:	Female
Weight:	
Height:	
Serious report?	No

Reason for Seriousness

Death: **Hospitalization:** **Life Threatening:**

Congenital Anomaly: **Disability:**

Other Medically Important Conditions:

Product Information:

Product Description	Dosage Form	Health Product Role	Route of Administration	Dose	Frequency	Therapy Duration
HABITROL	DISC (EXTENDED-RELEASE)	Suspect	Topical	7.0 Milligram		
TOBACCO	NOT SPECIFIED	Concomitant	Inhalation			

[32] In my opinion, the Narratives themselves cannot be said to contain information, not otherwise public, that is commercial, scientific or technical.

[33] As to whether the Narratives were kept confidential and intended to be kept confidential, I am satisfied that Novartis kept them confidential, and intended them to be treated as such. As previously discussed, I do not accept the Respondents' evidence as to the disclosure of one or two previous files.

[34] As a result, even if the information was confidential, it is not commercial, scientific, or technical. I find that it does not fall within the exemption afforded by subsection 20 (1) (b) of the *Access to Information Act.*

[35] Turning to subsection 20 (1) (c) of the *Access to Information Act*, the Applicant is required to show, on a civil burden of proof, that the information could reasonably be expected to result in material financial loss or gain to it, or prejudice a competitive position.

[36] This issue was substantially reviewed by Cromwell J in *Merck Frosst,* supra. He summarized what a person such as the Applicant here, must demonstrate, at paragraph 199 of his Reasons:

> *199 I would affirm the Canada Packers formulation. A third party claiming an exemption under s. 20(1)(c) of the Act must show that the risk of harm is considerably above a mere possibility, although not having to establish on the balance of probabilities that the harm will in fact occur. This approach, in my view, is faithful to the text of the provision as well as to its purpose.*

[37] At paragraph 212, he wrote that the types of harm contemplated by subsection 20 (1) (c) are expressed disjunctively, such that any one of such harm could be sufficient to claim the exemption:

> *212 To begin, it is worth noting that the list of types of harm in s. 20(1)(c) is disjunctive. It is sufficient for a third party to show that disclosure could reasonably be expected to result in any one of a financial loss or gain or in prejudice to the third party's competitive position. In other words, it is not necessary for the third party to show that the "prejudice" to his or her competitive position also results in "harm": see Brookfield Lepage, at paras. 9-10.*

[38] At paragraph 219, he wrote that a direct link must be made between the disclosure and the apprehended harm:

> *219 Third, disclosure of information, not already public, that is shown to give competitors a head start in developing competing products, or to give them a competitive advantage in future transactions may, in principle, meet the requirements of s. 20(1)(c). The evidence would have to convince the reviewing court that there is a direct link between the disclosure and the apprehended harm and that the harm could reasonably be expected to ensue from disclosure: see, e.g., AB Hassle v. Canada (Minister [page118] of National Health and Welfare) (1998), 161 F.T.R. 15, at para. 42, aff'd [2000] 3 F.C. 360 (C.A.); Wells v. Canada (Minister of Transport) (1995), 103 F.T.R. 17, at para. 9; Culver v. Canada (Minister of Public Works and Government Services), 1999 CanLII 8959 (F.C.T.D.), at para. 17; Bitove Corp. v. Canada (Minister of Transport) (1996), 119 F.T.R. 278 (F.C.T.D.), at para. 10; Coradix Technology Consulting Ltd. v. Canada (Minister of Public Works and Government Services), 2006 FC 1030, 307 F.T.R. 116, at para. 31; Canada Post Corp. v. National Capital Commission, 2002 FCT 700, 221 F.T.R. 56, at paras. 16-17; Aventis Pasteur Ltd. v. Canada (Attorney General), 2004 FC 1371, 262 F.T.R. 73, at paras. 32-33; and Prud'homme v. Agence canadienne de développement international (1994), 85 F.T.R. 302, at para. 7. Even if information taken in isolation may not seem to fall within the exemption, the information should nonetheless be examined in its entirety in order to determine the likely impact of its disclosure.*

[39] He cautioned, at paragraph 224, that a Court should be sceptical as to an argument that the public might misunderstand the information disclosed:

> *224 I do not accept the principles inherent in these submissions. The courts have often - and rightly - been sceptical about claims that the public misunderstanding of disclosed information [page120] will inflict harm on the third party: see, e.g., Air Atonabee, at pp. 280-81; Canada Packers, at pp. 64-65; Coopérative fédérée du Québec v. Canada (Ministre de l'Agriculture et de l'Agroalimentaire) (2000), 180 F.T.R. 205, at paras. 9-15. If taken too far, refusing to disclose for fear of public misunderstanding would undermine the fundamental purpose of access to information legislation. The point is to give the public access to information so that they can evaluate it for themselves, not to protect them from having it. In my view, it would be quite an unusual case in which this sort of claim for exemption could succeed.*

[40] In the present case, the only evidence offered by the Applicant as to harm of the types contemplated by subsection 20 (1) (c) of the *Act* is that contained in the Beatty affidavit. His evidence is speculative and largely based on apprehended public misunderstanding. Novartis Counsel argues that his evidence is, of necessity, speculative, since disclosure has not occurred. Up to a point, this is correct. However, I am concerned that there is no evidence from a disinterested person as to the effect or possible effect of disclosure. I find the Beatty affidavit to be insufficient to persuade me that the Applicant can claim an exception under subsection 20 (1) (c) of the *Access to Information Act*.

CONCLUSION AND COST

[41] As a result, I find that the Applicant Novartis has failed to persuade me, on a civil burden, that the Narratives are exempt from disclosure under either subsection 20 (1) (b) or (c) of the *Access to Information Act*. Thus, the three applications will be dismissed. I will provide for a period of

thirty (30) days before the dismissal is effective so that the Applicant, if so advised, may consider any steps to preserve confidence pending any appeal.

[42] Counsel for the Respondent asked for costs in the $2,000 to $2,500 range. That is more than reasonable, and I will apportion those costs at $800.00 in each application.

[43] I must conclude by commending all Counsel who appeared before me in the very professional and helpful way in which this case was presented.

Judge

Ottawa, Ontario
Public Reasons for Judgment May 31, 2013

Toronto, Ontario
Confidential Reasons for Judgment May 15, 2013

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1769-11 T-1934-11 T-80-12
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