ALBERTA

OFFICE OF THE INFORMATION AND PRIVACY COMMISSIONER

ORDER 2001-022

December 17, 2001

ALBERTA HEALTH & WELLNESS

Review Number 1965

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Summary: The Applicant made a request to Alberta Health and Wellness ("AHW") under the *Freedom of Information and Protection of Privacy Act* for access to correspondence from Ciba-Geigy Canada Ltd. ("Ciba") to Alberta Blue Cross relating to the listing of two drugs on the Alberta Formulary. Ciba objected to the disclosure. The only information at issue was a three-page letter dated November 3, 1994, from Ciba to AHW. The Acting Commissioner found that this information met all requirements of section 15(1) of the Act. Therefore, the Acting Commissioner ordered AHW not to disclose the information to the Applicant.

Statutes Cited: AB: *Freedom of Information and Protection of Privacy Act*, S.A. 1994, c. F-18.5, ss. 15(1), 68; *Nova Scotia Freedom of Information and Protection of Privacy Act*, s. 21(1).

Authorities Cited: AB: Orders 2000-017, 96-013; **NS**: Report FI-00-87.

Cases Cited: (*Canada (Information Commissioner) v. Canada (Prime Minister*), {1991} F.C.J. No. 1054 (Fed. T.D.).

I. BACKGROUND

[Para 1.] In a letter dated April 14, 2000, the Applicant made an access request through its legal counsel under the *Freedom of Information and Protection of Privacy Act* (the "Act") to the Public Body ("Alberta Health & Wellness" and "AHW"). The Applicant has not been identified in these proceedings. The request was for correspondence between Ciba-Geigy Canada Ltd. ("Ciba") and Alberta Blue Cross regarding the listing of two drugs on the Alberta Formulary.

[Para 2.] The Applicant requested:

> Copies of any correspondence between Ciba-Geigy Canada Ltd. and the Alberta Blue Cross dealing with the listing on the Alberta Formulary of:
>
> (i) Novo-Difenac SR (DIN #02158582 and 02048698) and
> (ii) Apo-Diclo SR (DIN #02162814 and 02091194)
>
> for the 75 mg and 100 mg dosages. We are interested in the period from 1990 to present.

[Para 3.] AHW notified Ciba of the request and Ciba objected to disclosure. AHW advised the Applicant that it was refusing access after considering the representations received from Ciba. The entity previously known as Ciba-Geigy Canada Ltd. has subsequently merged with Sandoz Canada Inc. and is now known as Novartis Pharmaceuticals Canada Inc. ("Novartis"). Novartis is a Third Party in these proceedings.

[Para 4.] On July 19, 2000, the Applicant made a request for review of AHW's decision to not disclose the information. Mediation was unsuccessful and the matter was set down for a written inquiry. The Applicant, AHW and Novartis provided written submissions. AHW submitted part of its written submission 'in camera'. The Applicant and AHW also provided written rebuttal submissions.

II. RECORDS AT ISSUE

[Para 5.] The information at issue is a three-page letter dated November 3, 1994, from Ciba to AHW.

III. ISSUE

[Para 6.] There is one issue in this inquiry: Does section 15(1) apply to the information at issue?

IV. DISCUSSION: Does section 15(1) apply to the information at issue?

A. General

[Para 7.] Section 15(1) of the Act says:

> *15(1) The head of a public body must refuse to disclose to an applicant information*
>
> *(a) that would reveal*
> *(i) trade secrets of a third party, or*
> *(ii) commercial, financial, labour relations, scientific or technical information of a third party,*
>
> *(b) that is supplied, explicitly or implicitly, in confidence, and*
>
> *(c) the disclosure of which could reasonably be expected to*
> *(i) harm significantly the competitive position or interfere significantly with the negotiating position of the third party,*
> *(ii) result in similar information no longer being supplied to the public body when it is in the public interest that similar information continue to be supplied,*
> *(iii) result in undue financial loss or gain to any person or organization, or*
> *(iv) reveal information supplied to, or the report of, an arbitrator, mediator, labour relations officer or other person or body appointed to resolve or inquire into a labour relations dispute.*

[Para 9.] Section 15(1) is a mandatory exception. This means that if the head of the public body determines that the information falls within the exception, the head must refuse access. For section 15(1) to apply, the third party must satisfy the following three-part test:

> Part 1: The information must reveal the trade secrets of a third party, or commercial, financial, labour relations, scientific or technical information of a third party (section 15(1)(a));
> Part 2: The information must be supplied, explicitly or implicitly, in confidence (section 15(1)(b)); and
> Part 3: The disclosure of the information must reasonably be expected to bring about one of the outcomes set out in section 15(1)(c).

B. Does the information reveal trade secrets of a third party, or commercial, financial, labour relations, scientific or technical information of a third party (section 15(1)(a))?

[Para 10.] Novartis says that the information contains, and that disclosure of the information would reveal, its scientific, technical and commercial information under section 15(1)(a). Novartis says this is its own information about analysis and data, whether about its own products or the products of another company.

[Para 11.] Novartis says that the information is 'on its face, scientific and/or technical'. Novartis says the information involves descriptions and analysis of certain testing results and criteria and includes information about the incidence and nature of certain effects of the described preparations, adverse effect profiles, bio-equivalence parameters and data from case records and technical trials. Bio-equivalence deals with the relationships between products.

[Para 12.] AHW says the information contains, and that disclosure would reveal, scientific and commercial information of Ciba. AHW says that this information constitutes and that disclosure would reveal trade secrets of Ciba. AHW has provided an affidavit in its 'in camera' submission in support of its arguments.

[Para 13.] The Applicant says that the information requested is not the information of a third party, as it has requested correspondence from Ciba relating to drug products that are not products of Ciba. The Applicant says that the information does not contain and would not reveal scientific, technical or commercial information or trade secrets of a third party.

[Para 14.] In Order 2000-017, the Commissioner said that 'scientific information' is information exhibiting the principles or methods of science, and 'technical information' is information relating to a particular subject, craft or technique.

[Para 15.] Nova Scotia Report No. FI-00-87 involved an access request for the same information involved in this request, from the Nova Scotia formulary at the Nova Scotia Department of Health. In that report, the review officer considered section 21(1) of the *Nova Scotia Freedom of Information and Protection of Privacy Act*, which is very similar to section 15(1) of the Act. The Review Officer found that the documents at issue in that review contained scientific and commercial information.

[Para 16.] After a review of the information at issue and the submissions of the parties, I find that the information at issue contains and would reveal scientific or technical information of Novartis. The information at issue consists of comparison, evaluation and analysis of studies including bioequivalence testing, adverse effect profiles and findings about interchangeability of particular drugs. The information of Novartis is essentially competitive intelligence.

[Para 17.] Disclosure of the intelligence of Novartis, notwithstanding that this intelligence involves a drug manufactured by another entity, would reveal scientific and technical information of Novartis. As I have already decided that the information contains and would reveal the scientific or technical information of a third party, I do not find it necessary to decide whether the same information reveals commercial information or trade secrets of a third party.

C. Was the information supplied explicitly or implicitly in confidence, as provided by section 15(1)(b)?

[Para 18.] Section 15(1)(b) implies that the information is to be supplied to a public body. Ciba supplied the information contained in the letter to AHW, a public body.

[Para 19.] Section 15(1)(b) requires that the information must be supplied, implicitly or explicitly, in confidence. Novartis says the information was supplied to AHW implicitly in confidence. Novartis says that it is a well understood practice amongst regulators that pharmaceutical manufacturers' submissions regarding the approval, marketing and listing of products whether their own products or the products of others, is made in circumstances of 'utmost confidence'.

[Para 20.] Novartis says the submissions contain sensitive information and analysis which 'could only reasonably be provided in a confidential setting'. Novartis says that its expectation has always been that submissions of this kind are provided and received in confidence and that this is evident from the context of the situation.

[Para 21.] AHW says the information was provided in confidence and that this is evident in Ciba's letter of objection. The 'in camera' affidavit describes policies and practices of AHW that ensure a high degree of confidentiality for information involved in this process.

[Para 22.] Nova Scotia Report No. FI-00-87 involved a request for the same information from the Nova Scotia Department of Health that had been provided by a pharmaceutical company in the same circumstances as this request. In that report, the review officer found that the third party had supplied the information to the public body in confidence.

[Para 23.] After a review of the information and the submissions of the parties, I find that the information at issue was communicated to AHW on a confidential basis. Although the information is not marked confidential, the nature and context of the situation and the evidence before me support the finding that the information was submitted implicitly in confidence.

D. Could disclosure of the information reasonably be expected to bring about one of the outcomes set out in section 15(1)(c)?

[Para 24.] Novartis says that the pharmaceutical industry is 'highly competitive'. This applies to manufacturers of generic products as well as to manufacturers of innovative products. They are all in competition with other pharmaceutical entities. Obtaining information from a competitor may save extensive time and resources for the manufacturer.

[Para 25.] Novartis says that disclosure of the information would harm significantly the competitive position of Novartis and result in undue loss to itself and gain to its competitors. Novartis says that disclosure of the information contained in the letter could reasonably be expected to cause harm and that this harm is predictable due to the context of the pharmaceutical industry.

[Para 26.] Novartis says that undue loss and gain still arises in this situation where patent protection has long since expired for the diclofenac product and where generic competitors are already in the market. The impact is not in the specific market of diclofenac. Novartis says the main impact of disclosing this information is the competitive advantage this information would provide to a competitor. Obtaining this information from Novartis would shorten the time it takes for competitors to market competing products.

[Para 27.] Novartis says the advantage for competitors arises when competitors can analyze the Novartis strategy and tactics and revamp an application to deflect or preempt an originator's criticism. Novartis says that assessing the scientific and technical data and analysis contained in the information would allow a generic manufacturer to change its testing and analysis protocols and learn how to better analyze and present its products at the expense of Novartis. Novartis says that a one-month head start could easily result in a million dollars of extra revenue for a competitor and a corresponding million-dollar reduction in revenue for a company such as Novartis.

[Para 29.] AHW says that disclosure of the information would reasonably be expected to harm significantly the competitive position of the Third Party. AHW provides further arguments and evidence on this point in the letter of objection provided in its 'in camera' submission. AHW says that disclosure of this information could reasonably be expected to result in similar information no longer being provided to the public body.

[Para 30.] AHW says that it is in the public interest that such information continues to be supplied to AHW due to the significant cost savings when generic drugs can be interchanged with brand name drugs. AHW says it is essential that this type of information continue to be supplied to the Expert Committee and that if this information was disclosed, drug manufacturers would no longer provide this type of information.

[Para 31.] AHW says that the failure to receive this type of information would result in undue financial loss to the government, society and the public who are members of various drug coverage plans. AHW says that the information is so intertwined with third party information protected under section 15(1) that none of the information can be disclosed without revealing the content of the protected information.

[Para 32.] The Applicant says that none of the results described in section 15(1)(c) would occur with disclosure of the information. The Applicant says that disclosure of a record from Ciba that makes reference to these drugs should not harm the competitive position of Ciba or result in similar information no longer being supplied. The Applicant says that disclosure would not result in undue financial loss or gain to any person or organization since the information requested relates to products of parties other than Ciba.

[Para 33.] The Applicant says that the pharmaceutical products mentioned are not products of Ciba, but are products of other drug manufacturers. It says that the pharmaceutical products mentioned no longer have patent protection. The Applicant

says the type of information requested could not enhance the competitive position of a generic manufacturer, as there are already a number of generic products on the market.

[Para 34.] In Nova Scotia Report No. FI-00-87, the review officer found that disclosure of similar information in similar circumstances to this request would cause significant harm to the third party's financial interests.

[Para 35.] Would disclosure of the information contained in the letter reasonably be expected to harm significantly the competitive position of a third party? In Order 96-013, the Commissioner said that the harm or interference must be 'significant'. In order to meet the 'harm' test under section 15(1)(c)(i):

> …[The] evidence must demonstrate a probability of harm from disclosure and not just a well-intentioned but unjustifiably cautious approach to the avoidance of any risk whatsoever because of the sensitivity of the matter at issue. (*Canada (Information Commissioner) v. Canada (Prime Minister*), {1991} F.C.J. No. 1054 (Fed. T.D.)

[Para 36.] The Commissioner also said that evidence of the following is required to prove significant harm or interference:

> (i) the connection between disclosure of the specific information and the harm which is alleged;
> (ii) how the harm constitutes "damage" or "detriment" to the matter; and
> (iii) whether there is a reasonable expectation that the harm will occur.

I have reviewed the submissions and the information at issue. I find that there is sufficient evidence that disclosure of the information could reasonably be expected to significantly harm the competitive position of Novartis under section 15(1)(c)(i) of the Act.

[Para 37.] I have decided that disclosure of the information could reasonably be expected to harm significantly the competitive position of Novartis pursuant to section 15(1)(c)(i). Therefore, I do not find it necessary to decide whether disclosure of the information could reasonably be expected to result in similar information no longer being supplied to the Public Body pursuant to section 15(1)(c)(ii) or to result in undue financial loss pursuant to section 15(1)(c)(iii).

E. Conclusion under section 15(1)

[Para 38.] Section 15(1) applies to the information at issue. Therefore, I uphold the head's decision to refuse to disclose this information to the Applicant.

V. ORDER

[Para 39.] I make the following order under section 68 of the Act. The only information at issue in this inquiry is a three-page letter, dated November 3, 1994, from Ciba to the

Public Body. I find that this information satisfies all of the criteria under section 15(1) of the Act. I uphold the Public Body's decision to refuse to disclose that information. I order the Public Body not to disclose that information to the Applicant.

Frank Work, Q.C.
Acting Information and Privacy Commissioner