Date: 20050714

Docket: T-2201-00

Citation: 2005 FC 1633

BETWEEN:

JANSSEN-ORTHO INC.

Applicant

and

THE MINISTER OF HEALTH

Respondent

REASONS FOR ORDER
(Public Version) *

*** [Deletion] - This indicates that words have been deleted to protect confidentiality.**

SIMPSON, J.

[1] This application is brought under section 44 of the *Access to Information Act*, R.S.C. 1985, c. A-1 (the "Act"). The Minister of Health (the "Respondent" or "Health Canada") has decided to disclose certain of the applicant's records in response to an access to information request under the Act. Janssen-Ortho Inc. (the "Applicant" or "JOI") resists disclosure of its records on the basis that they are exempt from disclosure under the provisions of paragraphs 20(1)(b) and 20(1)(c) of the Act (the "Exemptions").

THE BACKGROUND

[2] In response to the filing of thirteen adverse drug reaction reports, JOI and Health Canada held discussions in 1999 and 2000 about the safety of Prepulsid and about its withdrawal from the Canadian market. Many of the records at issue were created by JOI for those discussions.

[3] The request for access to information, dated June 26, 2000 (the "Access Request") related, in part, to those discussions and asked for:

> 1999, 2000 records, including briefing notes, media lines, testing, on the department's actions in assessing prepulsid, including their knowledge of its adverse effects, other countries' actions, their review of the drug's approval and use for a decade, and consumer, users' feedback and exchanges with Janssen-Ortho Inc., on its use, and withdrawal.

[4] On or about August 23, 2000, Ms. Bujaki of Health Canada identified several thousand pages of documents as the records which responded to the Access Request. She reviewed them and recommended disclosure of all information except that which, in her view, was covered by the Exemptions.

[5] On September 14, 2000, Ms. Parent of Health Canada accepted Ms. Bujakis' recommendation and sent JOI a notice indicating that the Access Request had been received and that Health Canada intended to disclose certain records. However, JOI objected to much of the proposed disclosure.

[6] On November 1, 2000, Ms. Parent again wrote to JOI and advised that further records would be withheld as a result of JOI's objections. However, she also said that Health Canada intended to disclose the balance of the records on the basis that they did not qualify for exemption under the Act. The records which Health Canada currently plans to disclose and which are at issue in this application consist of approximately 212 pages of material. This material will be described as the "Records".

[7] Because this proceeding concerns the confidentiality of the Records, the application was heard *in-camera* and the transcripts and Court files have been sealed pending this decision.

THE EVIDENCE

[8] The Applicant filed confidential affidavits which were sworn on April 1, 2001 and February 27, 2003 by Dr. Wendy Arnott. Dr. Arnott is JOI's Vice-president of Regulatory, Quality and Medical Services. She is a pharmacist and also has a clinical doctorate in pharmacy. **[Deletion]**

[9] Health Canada relies on four affidavits. The first two are the public and confidential affidavits of Mr. Durand sworn on May 11, 2001. The third affidavit is also confidential and was sworn by Ms. Parent on May 16, 2001. Finally, Mr. Durand swore a confidential reply affidavit on February 14, 2003.

[10] Ms. Parent has worked for Health Canada in various positions and departments for most of her career and is the administrator responsible for the Access Request.

[11] Mr. Durand is in charge of the Proprietary and Scientific Information assessment section of Health Canada's Therapeutic Products Directorate. He has held that position since 1996 and has been employed by Health Canada since 1988. Prior to that year, he worked as a pharmacist.

PREPULSID

[12] Prepulsid (or cisapride) was first marketed in Canada in 1990 for the treatment of gastrointestinal motility disorders. However, marketing in Canada ceased on May 29, 2000 in the wake of concerns about its safety. The only Prepulsid now available in Canada is a generic version manufactured by Apotex Inc. for Health Canada's special access program. Although JOI no longer markets Prepulsid **[Deletion]**.

BASIC PRINCIPLES

[13] Section 44 of the Act gives JOI the right to apply to the Federal Court for a review of Health Canada's decision on the Access Request. The section says:

Third party may apply for a review 44. (1) Any third party to whom the head of a government institution is required under paragraph 28(1)(b) or subsection 29(1) to give a notice of a decision to disclose a record or a part thereof under this	Recours en révision du tiers 44. (1) Le tiers que le responsable d'une institution fédérale est tenu, en vertu de l'alinéa 28(1)b) ou du paragraphe 29(1), d'aviser de la communication totale ou partielle d'un document peut, dans les vingt jours

Act may, within twenty days after the notice is given, apply to the Court for a review of the matter.

suivant la transmission de l'avis, exercer un recours en révision devant la Cour.

[14] On an application under section 44, the Court is required to conduct a *de novo* review of the Records Health Canada proposes to disclose (*Air Atonabee v. Minister of Transport* (1989) 27 C.P.R. (3d) 180 (FCTD)).

[15] In *H.J. Heinz Co. of Canada Ltd. v. Canada (Attorney General)*, [2003] F.C.J. No. 344, 2003 FCT 250 at paragraph 9, Justice Layden-Stevenson set out the applicable principles and I adopt them in this case. She said:

> I begin with a review of basic principles. Subsection 2(1) of the Act contains its purpose, which is to provide the public with a right of access to information in records under the control of the government. Exceptions to that right of access should be limited and specific: Canada Packers Inc. v. Canada (Minister of Agriculture), [1989] 1 F.C. 47 (C.A.) ...; *Dagg v. Canada (Minister of Finance)*, [1997] 2 S.C.R. 403 ... Public access ought not be frustrated by the courts except in the clearest of circumstances. It is a heavy burden of persuasion that rests upon the party resisting disclosure: *Maislin Industries Limited v. Minister of Industry, Trade and Commerce*, [1984] 1 F.C. 939 (T.D.) ...; *Rubin v. Canada (Mortgage and Housing Corp.)*, [1989] 1 F.C. 265 (C.A.) ...; *Canada (Information Commissioner) v. Canada (Prime Minister)*, [1993] 1 F.C. 427 (T.D.). The standard of proof to be applied in reviewing exemptions under subsection 20(1) of the Act is that of a balance of probabilities: *Northern Cruiser Co. v. Canada, [1995] F.C.J. No. 1168, (1995), 99 F.T.R. 320 n. (F.C.A.).*

THE EXEMPTIONS

[16] The Exemptions deal with confidentiality and harm. They are found in paragraphs 20(1)(b) (confidentiality) and 20(1)(c) (harm) of the Act and provide that:

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; (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 . . .	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; 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; . . .

Confidentiality

[17] In broad terms, JOI says that the Records contain confidential information about scientific, commercial and technical matters and that they were created in confidence and treated as confidential within JOI and its affiliates. It also says that they were transmitted to Health Canada in confidence and treated as confidential by Health Canada. Health Canada acknowledges the truth of these submissions but says that the fact that the Records were treated as confidential documents in 1999 and 2000 is not dispositive of the applicability of the confidentiality exemption. Health Canada submits, and I agree, that other matters, such as whether the information in the Records has been made public, must be considered.

[18] In this regard, I adopt the comments made by Justice MacKay in *Air Atonabee, supra* at pages 13 and 15. There he said:

> The second requirement under subsection 20(1)(b), that the information be confidential, has been dealt with in a number of decisions. These establish that the information must be confidential in its nature by some objective standard which takes account of the content of information, its purposes and the conditions under which it was prepared and communicated (per Jerome A.C.J. in Montana, supra at page 25). It is not sufficient that the third party state, without further evidence, that it is confidential (see, e.g., Merck Frosst Canada Inc. supra; Re Noel and Great Lakes Pilotage Authority Ltd. Et al. (1987) 45 D.L.R. (4th) 127 (F.C.T.D.)).

Information has not been held to be confidential, even if the third party considered it so, where it has been available to the public from some other source (Canada Packers Inc. V. Minister of Agriculture, [1988] 1 F.C. 483 (T.D.) and related cases, appeal dismissed with variation as to reasons on other grounds, [1989] 1 F.C. 47 (F.C.A.)), or where it has been available at an earlier time or in another form from government (Canada Packers Inc., supra; Merck Frosst Canada Inc., supra). Information is not confidential where it could be obtained by observation albeit with more effort by the requestor [sic] (Noel, supra). As outlined by Jerome A.C.J. in earlier cases dealing with subsection 20(1)(b):

> It is not sufficient that [the applicant] considered the information to be confidential. It must also have been kept confidential by both parties and must not have been otherwise disclosed, or available from sources to which the public has access.

(Maislin Industries Ltd. v. Minister for Industry, Trade and Commerce et al., [1984] 1 F.C. 939; 10 D.L.R. (4th) 417, 80 C.P.R. (2d) 253 (T.D.) at p. 257 C.P.R.); (D.M.R. Associates v. Minister of Supply & Services (1984), 11 C.P.R. (3d) 87 at 91 (F.C.T.D.)).

My review of the authorities, facilitated in part by submissions of counsel, is undertaken in order to construe the term “confidential information” as used in subsection 20(1)(b) in a manner consistent with the purposes of the Act in a case where the records in question under control of a government department consist of documents originating in the department and outside the department. This review leads me to consider the following as an elaboration of the formulation by Jerome A.C.J., in Montana, supra, that whether information is confidential will depend upon its content, its purposes and the circumstances in which it is compiled and communicated, namely:

a) that the content of the record be such that the information it contains is not available from sources otherwise accessible by the public or that could not be obtained by observation or independent study by a member of the public acting on his own,

b) that the information originate and be communicated in a reasonable expectation of confidence that it will not be disclosed, and

c) that the information be communicated, whether required by law or supplied gratuitously, in a relationship between government and the party supplying it that is either a fiduciary relationship or one that is not contrary to the public interest, and which relationship will be fostered for public benefit by confidential communication.

Harm

[19] JOI submits that the pharmaceutical industry is highly competitive and that other companies could obtain a competitive advantage from access to the Records. JOI says that, even though Prepulsid was withdrawn from the market in 2000, competitors working on similar or successor drugs might obtain information from the Records which would accelerate their work or help them improve the manner in which they interact with Health Canada on drug safety issues. Health Canada, on the other hand, says that JOI's submissions are speculative and, therefore, do not satisfy the requirements for an exemption from disclosure based on harm.

[20] The law on this topic is also set out by Justice MacKay in *Air Atonabee, supra*. There he said:

> In the case of subsection 20(1)(c) there are two circumstances under either of which, as alternatives to the criteria in other subsections and to each other, information is exempt from disclosure, that is:
>
> 1) where the disclosure of the information could reasonably be expected to result in material financial loss or gain to a third party, or
>
> 2) where the disclosure of the information could reasonably be expected to prejudice the competitive position of a third party

Both of these circumstances require a reasonable expectation of probable harm (*Canada Packers Inc. v. Canada (Minister of Agriculture*, [1989] 1 F.C. 47 at paragraph 22) and speculation or mere possibility of harm does not meet that standard (*Saint John Shipbuilding Limited v. The*

Minister of Supply and Services, (Unreported, Court File No. T-1682-87, October 3, 1988 (F.C.T.D.) at pp. 6-7). I have followed these cases in deciding this application.

THE RECORDS

[21] At Volume III of its Motion Record, JOI has included copies of the Records which remain in dispute. They have already undergone deletions as a result of earlier discussions between JOI and Health Canada and nothing in this decision is intended to reverse or in any way affect those deletions.

[22] What I must decide is whether further deletions are warranted.

[23] JOI has provided its submissions by marking the documents with highlighting and code letters to show the portions at issue and the applicable exemptions. The code is as follows:

The letter A marks references to JOI's **[Deletion]**

The letter B marks references to research data studies or reports

The letter C marks references to adverse event reports

The letter D marks references to draft materials

The letter E marks references to draft commercial and financial information

The letter F marks references to commercial, financial, scientific or technical matters which have consistently been treated by JOI as confidential or competitively sensitive information

[24] Health Canada has provided charts which offer detailed responses to JOI's requests for exemptions. This material is exhibited to Mr. Durand's affidavits.

THE CATEGORIES

[25] The parties have divided the Records into the following five categories:

(i) Personal Information

(ii) Two Research Reports

(iii) Suspect Adverse Reaction Reports

(iv) Miscellaneous items including (a) PowerPoint presentation slides,(b) correspondence (including a draft of a Dear Doctor letter) and (c) other documents

(v) The cover letter for the Applicant's National Library of Medicine search report

[26] I will deal with each category in turn.

Category (i) - Personal Information

[27] Section 19(1) of the Act deals with this topic in the following terms:

19. (1) Subject to subsection (2), the head of a government institution shall refuse to disclose any record requested under this Act that contains personal information as defined in section 3 of the Privacy Act.	19. (1) Sous réserve du paragraphe (2), le responsable d'une institution fédérale est tenu de refuser la communication de documents contenant les renseignements personnels visés à l'article 3 de la Loi sur la protection des renseignements personnels.

[28] There is a question about whether the names of JOI's employees fit within the definition of personal information in section 3 of the Privacy Act, R.S. 1985, c. P-21. Section 3(i) reads as follows:

(i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual,	i) son nom lorsque celui-ci est mentionné avec d'autres renseignements personnels le concernant ou lorsque la seule divulgation du nom révélerait des renseignements à son sujet;

[29] In this case, the personal information at issue is the names of JOI employees. None of the individuals have consented to the release of their names and it is not suggested that the disclosure is in accordance with section 8 of the *Privacy Act*. Further, JOI argues that the fact that the named employees were involved in JOI's dealings with Health Canada in the year 1999-2000 is not publically known.

[30] In my view, the disclosure of the employees' names would reveal information about them which is not in the public domain. This information includes the fact that they attended meetings, wrote letters and authored studies related to the interface between JOI and Health

Canada about whether Prepulsid should be withdrawn from the Canadian market. There is nothing in the Respondent's affidavit evidence which links the named employees to these negotiations. The public does not know of their involvement or about their opinions, suggestions and conclusions.

[31] Health Canada says that the public is aware that **[Deletion]** involvement with Health Canada dealing with the drug's safety can, therefore, not be considered confidential. It makes this submission because **[Deletion]** name was never publically associated with JOI's earlier work with Health Canada on the safety and withdrawal of Prepulsid.

[32] For these reasons, I have concluded that the names at issue are personal information which is exempt from disclosure. The following conclusions reflect this decision. The page references are to Volume III of JOI's Motion Record.

Page 731A	to be disclosed after the deletion of the name and position of the signatory at the top left, the two names in the first line of the third paragraph and all the words after "sincerely"
Page 732	to be disclosed after deletion of the name and phone number in the top section on the page
Page 733	not to be disclosed
Page 734	to be disclosed after deletion of the name after the word "From" and the fax and phone numbers at the top right hand side of the page
Page 735	to be disclosed after deletion of the last four lines in the fourth paragraph and all the words after "sincerely"

Page 741	to be disclosed after the deletion of the first four lines on the page and all the words after “yours sincerely”
Page 775	to be disclosed after the deletion of all the words after “sincerely” - see also paragraph 65
Page 814	see paragraph 41 herein (page 1 of 32)
Pages 841-845	see paragraph 41 herein (page 28 of 32 to page 32 of 32)
Page 898	to be disclosed after deletion of the name following the word “from” and the fax and phone numbers near the top right side of the page
Page 899A	not to be disclosed
Page 899F	not to be disclosed
Page 899G	to be disclosed after deletion of the name after the word “From” and the last two lines on the page and the fax and phone numbers near the top right side of the page
Page 899H	not to be disclosed
Page 899I	not to be disclosed
Page 899J	to be disclosed after the deletion of the name after the word “from” and the fax and telephone numbers in the top right hand corner of the page
Page 901	not to be disclosed
Page 902	not to be disclosed
Page 903	not to be disclosed
Page 904	to be disclosed after deletion of name in point 3
Page 924	to be disclosed after deletion of the name after the word “From” and the last five lines and the fax and phone numbers near the top right side of the page

Page 926	not to be disclosed
Page 928	to be disclosed after deletion of name after word “From” and the last five lines on the page and the fax and phone numbers near the top right side of the page
Pages 929-932	not to be disclosed
Page 934	to be disclosed after deletion of name following word “From” and the fax and phone numbers near the top right side of the page
Pages 935-936	not to be disclosed
Page 937	to be disclosed after deletion of name following the word “From” and all the words after the words “Dear Ms. Carès”
Page 939	not to be disclosed

Category (ii) - Two Research Reports

(a) The Appraisal

[33] The First Report is a thirty-two page document entitled “Cisapride - a benefit/risk appraisal in view of the CPMP Pharmacovigilance Working Party Recommendations” (the “Appraisal”).

[34] The Appraisal is dated April 6, 2000 and was prepared by the Janssen Research Foundation (“JRF”). It was originally submitted in confidence to the European Agency for the Evaluation of Medical Products. Health Canada asked JOI for a copy of the Appraisal during the confidential discussions with JOI in 1999-2000. Accordingly, JOI obtained a copy from JRF and provided it to Health Canada. The cover page displays a prominent notice which indicates that it

contains confidential information and there is no issue that it was provided to Health Canada in confidence.

[35] The Appraisal is a summary of other benefit/risk appraisal reports (the "Other Reports"). The Other Reports were also provided to Health Canada by JOI at Health Canada's request during the discussions relating to the safety of Prepulsid. Health Canada has agreed not to disclose the Other Reports. JOI says that, if the underlying reports are exempt, the Appraisal, which is the summary, should also be exempt. I have not been persuaded by this submission. In my view, the simple fact that a document is a summary of exempt documents does not automatically entitle it to an exemption.

[36] JOI further submits that, although the Appraisal does refer to some published studies and the conclusions they reached, the public does not know that JOI accepted the conclusions and relied on them in its discussions with Health Canada and in its evaluation of Prepulsid. JOI says that these facts remain confidential.

[37] Health Canada's position is that most of the information in the Appraisal is available in the public domain, albeit in a different format and that it should therefore be disclosed. In support of this position, Health Canada has provided the results of its internet searches. This material is referred in Mr. Durand's confidential affidavit. In this regard, Health Canada relies on *Cyanamid Canada v. Canada* (1992) 45 C.P.R. (3rd) 390 (FCA), in which the Court stated the following:

> An alternative argument is advanced under s. 20(1)(c). The Appellant submits that although the information may be publicly available, it is not available from a single source. However, if access were granted under the Act, it would confer an advantage upon the requester by saving him time and expense of collecting that information from several other public sources and enable him to construct the "larger picture" to the detriment of the Appellant. I am not persuaded by this argument.

[38] Health Canada has also taken the approach that, once reference is made to a published study, the inquiry about access is over because nothing said in relation to public information can be confidential. This means that, for example, the opinions expressed by JOI's scientists on published material would not be confidential.

[39] I have accepted JOI's submissions on this point. Although the information in dispute is largely a description of the findings in published studies which would therefore normally be disclosed, the fact that JOI considers the findings to be accurate and trustworthy has not been publicized and would only become known through disclosure. Accordingly, JOI's references to published studies will not be disclosed.

[40] My conclusions below delete personal information and commercial information including expert advice, opinions, conclusions and information about the studies the Applicant considered reliable. In my view, this material has never been published and remains confidential. It is, therefore, exempt from disclosure.

[41] I have worked with the version of the Appraisal found at pages 814 to 845 of Volume III of JOI'S Motion Record. Referring to the page numbers in the Appraisal, I have concluded that access should be provided as follows:

Page 1	disclose after deletion of information in the section entitled "Authors"
Pages 2, 3 and 4	disclose after deletion of bracketed references
Page 5	disclose after deletion of the four conclusions preceded by bullets
Page 6	not to be disclosed
Page 7	disclose only the last four lines on the page
Page 8	disclose after deletion of all bracketed references
Page 9	disclose after deletion of all bracketed references
Page 10	disclose only the text above the heading at section 2.3 after deleting the bracketed references
Page 11	disclose after deletion of all bracketed references
Page 12	disclose after deleting the last sentence in the 1st paragraph and all bracketed references
Page 13	disclose after deleting section 3.1 and bracketed references
Page 14	disclose after deleting the 1st paragraph on the page and the first sentence in section 4.1 together with all the bracketed references
Page 15	disclose after deleting the text of section 4.3 and all bracketed references
Page 16	disclose after deleting the text of section 5.1 and all bracketed references
Page 17	disclose after deleting (i) the paragraph beginning with the words "In patients", (ii) the last sentence in the paragraph which begins

	with the words “Several placebo controlled . . .” and (iii) all bracketed references
Page 18	disclose after deleting bracketed references and all the text in section 6.1 and the last sentence above the heading for section 6.1 which starts with the words - “different inclusion”
Page 19	disclose after deleting (i) bracketed references, (ii) the text under the heading in section 7, (iii) the text of the first three paragraphs under the heading in section 8.1, (iv) the first two sentences in the last paragraph on the page and (v) the text of the balance of the last paragraph on the page from the words “In approximately” to and including the word “prolongation”
Page 20	disclose only the first four lines on the page after deleting the bracketed references
Page 21	disclose after deleting the text in section 8.2 and the bracketed references
Page 22	not to be disclosed
Page 23	not to be disclosed
Pages 24-27	disclose in full
Pages 28-32	not to be disclosed

(b) The Summary

[42] The Second Report is entitled “JOI Comments on Issues Analysis Summary” (the “Summary”). It is found at pages 905 to 923 of Vol. III of JOI’s Motion Record.

[43] The Summary is JOI's response to a document prepared by Health Canada entitled *Issues Analysis Summary*. The confidential nature of the *Issues Analysis Summary* was established when Health Canada included the following passage in the document:

> Please be advised that this is a confidential document that may not be disclosed to any parties other than JOI. If the document is to be disclosed to anyone outside of the Department of Health or JOI, it is necessary to submit the document for a full review under the ATI Act so that the confidential information can be severed. You are furthermore advised that this is a DRAFT document in progress and further amendments may be made.

[44] The Summary reflected the work of four JRF scientists over a 2-3 week period and was based on the foundation's confidential data on Prepulsid. Each page of the report is clearly marked "Confidential".

[45] Although the Summary contains references to some published articles, it is uncontradicted that it is not publically known that JOI chose to rely on those articles in its discussions or correspondence with Health Canada or in its analysis of the risks and benefits of Prepulsid. JOI says that its analysis and interpretation of a particular reference or published information is confidential commercial information.

[46] As was the case with the Appraisal, I have accepted JOI's submission that its decision to refer to and rely on published studies is a confidential fact which is not disclosed by the publication of the study. However, in addition to study references, much of the Summary involves discussions about why, in the view of JOI's scientists, various study results can be challenged. It also includes their arguments in support of their positions.

[47] My conclusion is that the entire Summary is exempt from disclosure on the basis that it is confidential commercial information. In reaching this conclusion, I have rejected Health Canada's submission that, once reference is made to a published study, confidentiality is lost for all the related commentary and analysis provided by JOI's scientists.

Category (iii) - Adverse Reaction Reports For Year 2000

[48] At the relevant time, Health Canada's publication entitled "Guidelines for Reporting Adverse Reactions to Marketed Drugs (Summer 1996)" provided at page 11 that adverse drug reactions could be reported using either Health Canada's form or another form. The other form was used internationally and JOI chose to submit its reports on the international form. Both forms have a section for a description of the adverse drug reaction. However, only the international form asks for the manufacturer's opinion about causality. The information about causality is JOI's opinion about whether the patient's symptoms were attributable to Prepulsid. JOI takes the position that the reported information **[Deletion]**.

[49] Information about causality was not included in Health Canada's annual published summary of all suspect adverse reaction reports. However, it could, in theory, have been made public if one of JOI's reports had been chosen as the subject of an article in Health Canada's newsletter or if a member of the public had asked for a copy of one of JOI's adverse reaction

reports. However, because these events never occurred, JOI says that the reports were not, in fact, made public and that it therefore had a reasonable expectation of confidentiality.

[50] I do not agree. I have concluded that, although they were not made public, the reports were not treated as confidential documents by Health Canada. Further, they were not treated confidentially by JOI. They were not marked "confidential" and there is no evidence that they were submitted to Health Canada in confidence.

[51] Since the reports are not exempt from disclosure because of confidentiality, harm must be considered. The harm alleged is that information about JOI's assessment of the problems caused by Prepulsid would enable a competitor to accelerate its development and marketing of other cisapride-based drugs. **[Deletion]** JOI also says that the disclosed information could be used against it in litigation and that the public interest will be harmed because, if disclosure is ordered, it will no longer volunteer opinions about causality.

[52] Regarding JOI's submission about the public interest, it would be unfortunate if JOI decided not to report its views about causality. However, if Health Canada decides that such information is essential, it can amend its form and require its disclosure. Further, it is not clear that this submission is relevant. Paragraph 20(1)(c) of the Act does not speak of harm to the public. The only harm which triggers an exemption is harm to an applicant.

[53] The further difficulty is that JOI has not provided evidence about harm which would allow me to conclude that it faces a reasonable expectation of probable harm. Given the highly competitive nature of the pharmaceutical industry, it is conceivable that disclosure of JOI's views of causality might assist a competitor. However, speculation is not sufficient to justify an exemption, particularly when JOI acknowledges that **[Deletion]** and often based on heresay and anecdotal information about patients' experiences.

[54] It is also my view that the Act's exemption from disclosure for information which could reasonably be expected to result in material financial loss was not intended to cover litigation costs and damage awards. Further, even if such sums were included, I have no evidence on which to assess the likelihood of such losses.

[55] For all these reasons, the complete adverse event reports are to be disclosed

Category (iv) - Miscellaneous Items

(a) The Powerpoint Presentation Slides

[56] The meetings between Health Canada and JOI at which JOI used its powerpoint presentation slides (the "Slides") took place on February 4th, March 24th and April 13th, 2000 (the "Meetings"). It was during this period, on March 23, 2000 that JOI announced that it would be voluntarily withdrawing Prepulsid from the US market. As well, on that date, the US Food & Drug Administration issued a press release about JOI's decision. Health Canada agrees that the Meetings were held in confidence but says that the public would have been aware at that time that JOI would be meeting with Health Canada to discuss **[Deletion]**. However, in my view, this fact does not negate the confidentiality of the Slides.

[57] There are 47 Slides. JOI says that the deletions agreed to thus far are insufficient and says that the Slides are confidential in their entirety because they were presented in confidence at the Meetings and because the dates of the Meetings, the topics discussed and JOI's strategy for dealing with Health Canada on a drug safety issue is all commercial information which has never been made public. Lastly, JOI says that the names of the JOI personnel who attended the meetings are personal information which is protected from disclosure under section 19 of the Act.

[58] Health Canada acknowledges that the Slides were presented in confidence but also submits that confidentiality can be lost. It says that, because the Meetings took place in the year 2000 and because the drug Prepulsid has not been on the market for almost five years, the Slides

are no longer confidential and the information they contain can no longer be considered commercial.

[59] It is my view that confidential information remains confidential until the information becomes public or consent is given to its release. It is also possible that, after many years, confidentiality could be lost but that loss would depend on the circumstances of each case. In this case, although Prepulsid is not on the market, related litigation and drug development are ongoing. In my view, the passage of time is not relevant to the issue of confidentiality in the circumstances of this case. Further, with the one exception described in paragraphs 61 and 62, it is my view that the passage of time has not affected the commercial nature of the information in the Records.

[60] Against this background, I turn to the individual slides. I will refer to them using the page numbers in Volume III of JOI's Motion Record. The decisions which follow are based, in part, on my determination that the names of JOI personnel are exempt because they are personal information which discloses their opinions and, in part, on the confidential commercial nature of the information. It will be apparent that meeting dates and discussion topics have not been treated as commercial information.

Slides	Page 846	to be disclosed
	Pages 847 to 859	not to be disclosed
	Page 860	to be disclosed after deletion of the first two lines

Pages 861-866	not to be disclosed
Page 867	to be disclosed after deletion of the word Prepulsid
Pages 868-893	not to be disclosed

(b) Correspondence

[61] The final version of JOI's "Dear Doctor" letter was made public but the confidential draft which was sent to Health Canada for comment and discussion, includes two points which were not in the final version. **[Deletion]** The draft "Dear Doctor" at issue is found in Volume III of JOI's Motion Record at pages 940 and 941.

[62] Although the draft letter remains confidential, I am of the view that, due to the passage of time and the very specific and limited nature of the information, the letter can no longer be considered commercial. For this reason, the draft is to be disclosed.

[63] The other documents in this category are letters relating to Health Canada's Special Access Program (the "Program") and are found in Vol. III of JOI's Motion Record at pages 937-939. Health Canada submits that the Applicant wrote to healthcare professionals in August of 2000 advising that Prepulsid would not be available through the Program and that confidentiality has therefore been lost. JOI says that, although the public can be presumed to know that there were discussions about the Program, the substance of its proposals is not known and remains confidential. I agree with JOI's submission and conclude that this material is not to be disclosed.

(c) ***Other Documents***

[64] This material includes four letters and a four page chronology. The page references below are the page numbers on the top right side of the pages in Volume III of JOI's Motion Record.

Page 735	to be disclosed after deletion of the last four lines in the fourth paragraph and all the words after "sincerely") - see also paragraph 32 above
Page 739	not to be disclosed
Page 743	not to be disclosed
Page 894	to be disclosed after the deletion of the number in the second line of the second paragraph and the deletion of the first phrase in paragraph four beginning "on March 23 and ending "cisapride"
Page 895	to be disclosed after the deletion of the first two paragraphs; the last sentence of the third paragraph and the fourth paragraph
Page 896	to be disclosed
Page 897	to be disclosed
Page 899	not to be disclosed - confidential commercial information and personal information
Page 899A	not to be disclosed - see also paragraph 32 above
Page 899B	disclose after deletion of last sentence
Page 899C	not to be disclosed
Page 899D	not to be disclosed
Page 899E	not to be disclosed

Page 899F not to be disclosed - see also paragraph 32 above

Category (v) The Cover Letter for the Search Report

[65] This letter is found at page 775 of Volume III of JOI's motion record. It is to be disclosed after the deletion of all words after the word "sincerely".

SECTION 25 OF THE ACT

[66] Finally, I should note that sentences expressing courteous sentiments or conveying good wishes and gratitude appear in the Records from time to time. If severed for disclosure these passages would be meaningless scraps of narrative with no context. It is my view that severance of such material for disclosure under section 25 of the Act is not reasonable.

CONCLUSION

[67] The application will be allowed in accordance with these reasons.

"Sandra J. Simpson"
JUDGE

Ottawa, Ontario
July 14, 2005

FEDERAL COURT

Names of Counsel and Solicitors of Record

DOCKET:	T-2201-00
STYLE OF CAUSE:	JANSSEN-ORTHO INC. Applicant - and - THE MINISTER OF HEALTH Respondent
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MONDAY JANUARY 24, 2005
REASONS FOR ORDER AND ORDER BY:	SIMPSON, J.
DATED:	July 14, 2005

APPEARANCES BY:	Paul Schabas / Alice Tseng For the Applicant Suzanne Duncan For the Respondent
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