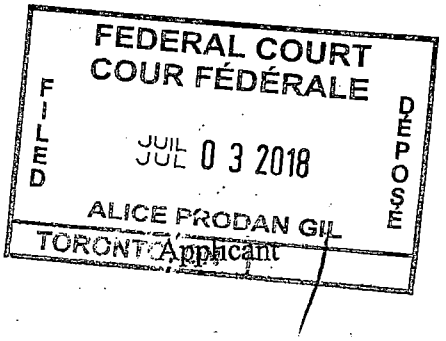
BETWEEN:

Court File No. T-1294-18

FEDERAL COURT



PRO DOC LTÉE

Applicant

- and -

THE MINISTER OF HEALTH

Respondent

NOTICE OF APPLICATION

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED by the Applicant. The relief claimed by the Applicant appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the applicant's solicitor, or if the applicant is self-represented, on the applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGEMENT MAY BE GIVEN IN YOUR ABSENCE WITHOUT FURTHER NOTICE TO YOU.

Date: JUL 0 3 2018 Issued by: ALICE PRODAN GIL
REGISTRY OFFICER
AGENT DU GREFFE

(*Registry Officer*)

Address of local office: 180 Queen Street West
Toronto, ON M5V 3L6

TO: **THE ADMINISTRATOR**
Federal Court
180 Queen Street West
Toronto, ON
M5V 3L6

AND TO: **THE MINISTER OF HEALTH**
Health Canada
c/o Access to Information and Privacy Division
7th Floor, Suite 700, Holland Cross – Tower B
1600 Scott Street, (Mail Stop: 3107A)
Ottawa, ON K1A 0K9

(service effected pursuant to rule 133 of the *Federal Courts Rules* and section 48 of the *Federal Courts Act*)

AND TO: **THE INFORMATION COMMISSIONER OF CANADA**
30 Victoria Street
Gatineau, QC K1A 1H3

AND TO: **THE ATTORNEY GENERAL OF CANADA**
Ontario Regional Office
Department of Justice Canada
120 Adelaide Street West, Suite 400
Toronto, ON M5H 1T1

(service effected pursuant to rule 133 of the *Federal Courts Rules* and section 48 of the *Federal Courts Act*)

APPLICATION

This is an application pursuant to section 44 of the *Access to Information Act,* RSC 1985, c A-1, as amended (“***Access to Information Act***”) in respect of the decision of the Minister of Health (the “**Minister**” or “**Health Canada**”) communicated to the Applicant by letter dated June 11, 2018 to disclose certain records pertaining to the Applicant in response to a request under the *Access to Information Act* (the “**Decision**”).

THE APPLICANT MAKES AN APPLICATION FOR:

(a) A review of the Decision;

(b) An order pursuant to section 51 of the *Access to Information Act* that the parts of the requested records which the Respondent intends to disclose be withheld from disclosure by the Respondent;

(c) An order restraining the Minister, by way of prohibition, injunction or otherwise, from disclosing confidential information of the Applicant from its drug submission for the Products at Issue;

(d) An order directing the Minister to issue a policy relating to the disclosure of confidential information from drug submissions filed with Health Canada;

(e) Costs of the within application; and

(f) Such further and other relief as counsel may advise and this honourable Court may deem appropriate.

THE GROUNDS FOR THE APPLICATION ARE:

A. The Parties

1. The Applicant, Pro Doc Ltée ("**Pro Doc**") is a generic pharmaceutical company having an office and place of business at 2925 boul. Industriel, Laval Québec, H7L 3W9. Pro Doc is a company incorporated under the laws of Québec.

2. Pro Doc markets and sells generic drug products in Canada, including the generic drug products at issue in this application for judicial review (the "**Products at Issue**").

3. The Respondent Minister is a Minister of the Crown with statutory authority to regulate the approval and sale of drugs in Canada. This power is conferred by the *Food and Drugs Act*, RSC 1985, c F-27 ("***Food and Drugs Act***"), as amended and by the *Food and Drug Regulations*, CRC, c 870 ("***Food and Drug Regulations***") adopted pursuant thereto.

4. The Minister administers access to information requests from Health Canada under the *Access to Information Act* on behalf of the Information Commissioner.

B. Drug Submissions in Canada

5. In order to market any drug in Canada, a manufacturer must obtain a Notice of Compliance ("**NOC**") and a Drug Identification Number ("**DIN**") from the Minister pursuant to section C.08.004 of the *Food and Drug Regulations*. Pursuant to C.01.014.2(1) of the *Food and Drug Regulations*, the DIN is issued to the manufacturer on a drug notification form. Either the assignment of a DIN or the issuance of a drug notification form indicates that Health Canada has completed to its satisfaction the review of a submission for approval of a drug product.

6. For a new drug product, a drug manufacturer may obtain a NOC and DIN by filing a new drug submission ("**NDS**") with the Minister. If the Minister approves the NDS, the manufacturer will receive a NOC, which permits the drug product to be marketed in Canada, and a DIN, which attests that the formulation, labelling and instructions for use of the drug product comply with the *Food and Drugs Act* and *Food and Drug Regulations*.

7. In conjunction with this process, the manufacturer of a drug product may cause Canadian patents relevant to the submission to be listed on a patent register maintained by the Minister under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("***Patented Medicines (Notice of Compliance) Regulations***").

8. A drug manufacturer may also obtain a NOC for a generic drug product by filing an abbreviated new drug submission ("**ANDS**") with the Minister pursuant to section C.08.002.1 of the *Food and Drug Regulations*, comparing the generic drug with a previously-approved drug product (the "**innovative drug**"). As part of this

process, the generic drug manufacturer must also address any patent listed on the patent register in connection with the innovative drug.

9. The Minister will not issue a NOC or a DIN for a generic drug until the relevant patents on the register have either expired or been successfully addressed under the *Patented Medicines (Notice of Compliance) Regulations*. The day on which a generic drug product would have received its NOC but for the operation of the *Patented Medicines (Notice of Compliance) Regulations* is known as the "patent hold date". This date is communicated to a generic drug manufacturer by letter.

10. The drug submissions, both NDS and ANDS, are reviewed by the Therapeutics Products Directorate of the Health Products and Food Branch within Health Canada.

11. Drug manufacturers file submissions with the Minister confidentially and in a manner in which they are expected to remain confidential. Drug manufacturers like Pro Doc have a legally-recognized expectation that confidential information filed with Health Canada will remain confidential.

C. The Request Under the *Access to Information Act*

12. The request for information under the *Access to Information Act* concerns records containing Pro Doc's information, including information for which the Minister initially refused disclosure.

13. By letter dated August 31, 2017, Health Canada notified Pro Doc that, due to the passage of time, it was reconsidering the release of information[1] and therefore Health Canada was undertaking a new consultation process under section 27 of the *Access to Information Act*.

14. The request related to information concerning Pro Doc's drug submission for the Products at Issue. Specifically, the request covered the following information:

> *1) Any documents reflecting the date(s) on which Health Canada's Therapeutic Products Directorate first assigned a Drug Identification Number (DIN), provisional or otherwise, to each of Pro Doc Limitee's ("Pro Doc") [Products at Issue]; and*
>
> *2) Any letters from Health Canada's Therapeutic Products Directorate to Pro Doc certifying that the examination of Pro Doc's [Products at Issue] was complete, that the product was approved and that a Notice of Compliance would not be issued until the requirements of the Patented Medicines (Notice of Compliance) Regulations were met*

15. In response to the notice, on or about October 6, 2017, Pro Doc made written representations to Health Canada objecting to the disclosure of certain information within the record pursuant to section 20(1) of the *Access to Information Act*. Specifically, Pro Doc objected to the disclosure of: (1) the date of the drug notification forms; (2) the DIN assignment date; and (3) the patent hold date (collectively, the "**Information at Issue**").

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[1] The record at issue also contains personal information pursuant to section 19(1) of the *Access to Information Act*, which the Minister has agreed will not be released.

16. In its representations, Pro Doc also cited and relied upon representations it had made to Health Canada prior to the reconsideration, including submissions dated April 10, 2015 and submissions dated March 31, 2017. These submissions also addressed the Information at Issue.

17. Health Canada and Pro Doc subsequently engaged in discussions by email and telephone regarding the request.

18. On or about May 10, 2018, Pro Doc made further written representations to Health Canada. In these representations, Pro Doc maintained its objection to the disclosure of the Information at Issue on the basis of paragraphs 20(1)(b), (c) and (d) of the *Access to Information Act*.

19. On or about June 5, 2018, Pro Doc received an email from Health Canada that the Information at Issue was going to be released because "the patent hold date has now expired".

D. The Decision

20. On or about June 11, 2018, Pro Doc received written notice from the Minister under section 28(1)(b) of the *Access to Information Act* of its decision to disclose the records, including the Information at Issue. In its decision, the Minister stated it had given careful consideration to the representations and concluded that the reasons provided in Pro Doc's representations were not sufficient to withhold all of the Information at Issue on the basis of paragraphs 20(1)(b), (c) and (d) of the *Access to*

Information Act. The Minister also concluded that its research determined that this information is available publicly at http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp and at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.

E. The Minister Erred in her Decision

21. Clear grounds exist to justify exempting the Information at Issue from disclosure under section 20(1) of the *Access to Information Act*. As set out below, the Information at Issue has been and remains subject to the mandatory exemptions from disclosure under paragraphs 20(1)(b), (c) and (d) of the *Access to Information Act*. The Minister erred in her Decision, including in relying on the passage of time. The passage of time, including the issuance of a NOC and/or DIN to Pro Doc for the Products at Issue, has not affected such grounds and does not justify disclosing the Information of Issue.

(a) Ground 1: The Information which the Respondent intends to disclose is required to be withheld from disclosure by paragraph 20(1)(b) of the *Access to Information Act*.

22. The Information at Issue constitutes valuable commercial, scientific or technical information that is confidential information supplied to Health Canada by Pro Doc and that is treated consistently in a confidential manner by Pro Doc.

23. The Information at Issue is confidential, not otherwise available to or observable by the public. The Information at Issue is not in the public domain and not available through another source.

24. The Information at Issue has never been disclosed publicly. Contrary to the Minister's assertion, the reasons for disclosure cited in the Decision are incorrect – the Information at Issue is not available publicly at http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp or at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.

25. Pro Doc has consistently kept the Information at Issue confidential, including by controlling access to its offices, restricting access to correspondence with regulatory authorities at Health Canada on drug submissions, and requiring employees to maintain confidentiality of information during and after their employment.

26. The Information at Issue originates or reveals information originating from Pro Doc. If the Information at Issue is disclosed, additional confidential commercial, scientific or technical information relating to and originating from Pro Doc will be inferred by knowledgeable third parties. This additional information includes information regarding Pro Doc's drug submission timing and strategy. This information is highly valuable to Pro Doc's competitors and may be used for their commercial benefit, to Pro Doc's detriment.

27. The Information at Issue was communicated by Pro Doc or reveals information communicated by Pro Doc with an expectation of confidentiality that it would not be disclosed.

(b) **<u>Ground 2</u>: The Information which the Respondent intends to disclose is required to be withheld from disclosure by paragraph 20(1)(c) of the *Access to Information Act*.**

28. There is a reasonable expectation of probable harm to Pro Doc if the Information at Issue is disclosed.

29. There is a reasonable expectation that disclosing the Information at Issue will result in material financial loss to Pro Doc and prejudice to its competitive position. Further, there is a reasonable expectation that Pro Doc's competitors will be able to take competitive advantage and materially gain from the disclosure, including to gain a competitive advantage in future transactions.

30. The Information at Issue, if disclosed, reveals strategic business decisions about Pro Doc and its drug products, including the Products at Issue.

(c) **<u>Ground 3</u>: The Information which the Respondent intends to disclose is required to be withheld from disclosure by paragraph 20(1)(d) of the *Access to Information Act*.**

31. There is a reasonable expectation of probable harm that contractual or other negotiations of Pro Doc will be obstructed by the disclosure of the Information at Issue.

32. Disclosing the Information at Issue would jeopardize ongoing relations and negotiations between Pro Doc and contractors, including ongoing negotiations or negotiations about to occur. Disclosing the Information at Issue would also prejudice Pro Doc's negotiating positions.

(d) The passage of time, including the issuance of a NOC and DIN to Pro Doc for the Products at Issue, has not affected the grounds under section 20(1) of the *Access to Information Act* and does not justify disclosing the Information of Issue.

33. The mere issuance of a NOC or DIN did not and could not reveal the Information at Issue. It is not possible to ascertain the patent hold date, DIN issuance date, or date of the drug notification form using either the NOC or DIN.

34. Further, the issuance of a NOC or DIN for Pro Doc's Products at Issue does not in any way affect the confidentiality; the financial, commercial, scientific or technical nature of the information; whether the information originated from Pro Doc and that it was treated consistently in a confidential manner.

35. The issuance of a NOC or DIN for Pro Doc's Products at Issue does not in any way reduce the expectation of probable harm to Pro Doc if the information is

disclosed; Pro Doc would still suffer material financial loss, prejudice to its competitive position and Pro Doc's competitors would materially gain from the disclosure.

36. The issuance of a NOC or DIN for Pro Doc's Products at Issue does not in any way reduce the expectation of probable harm to the interference with contractual or other negotiations that would result to Pro Doc is the Information at Issue is disclosed.

37. The Applicant relies on the *Access to Information Act,* RSC 1985, c A-1, section 20(1), 27, 28, 44 and 51; the *Federal Courts Act,* RSC 1985, c F-7, section 18.1; the *Federal Courts Rules*, SOR/98-106; the *Food and Drugs Act*, RSC 1985, c F-27 and the *Food and Drugs Regulations*, CRC, c 870; *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) The Minister's record of decision;

(b) The affidavits of one or more individuals to be filed; and

(c) Such further and other materials as counsel may advise and this Honourable Court may permit.

Dated at Toronto, Ontario this 3rd day of July, 2018.

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