

Federal Court



Cour fédérale

Date: 20171122

Docket: T-1572-16

Citation: 2017 FC 1061

Ottawa, Ontario, November 22, 2017

PRESENT: The Honourable Mr. Justice Lafrenière

BETWEEN:

**BRISTOL-MYERS SQUIBB CANADA AND
OTSUKA PHARMACEUTICAL CO., LTD.**

Applicants

and

**APOTEX INC. AND THE MINISTER OF
HEALTH**

Respondents

JUDGMENT AND REASONS

[1] This is a motion by the Respondent, Apotex Inc. [Apotex], for an Order dismissing the underlying application in its entirety pursuant to paragraph 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the Regulations]. For the reasons that follow, the motion is granted.

I. Overview

[2] The underlying application is one of ten related prohibition proceedings commenced by the Applicants, Bristol-Myers Squibb Canada [BMS] and Otsuka Pharmaceutical Co., Ltd. [Otsuka], pursuant to subsection 6(1) of the Regulations seeking to prohibit the Respondent, the Minister of Health [the Minister], from issuing a Notice of Compliance [NOC] to Apotex for multiple dosage strengths of its Apo-Aripiprazole tablets until the expiry of Canadian Patent No. 2,429,496 [the '496 Patent] on January 29, 2022. BMS discontinued the nine other applications in March 2017.

[3] The '496 Patent is owned by Otsuka which, as the patentee, is made a party to the application as required by subsection 6(4) of the Regulations. The patent is listed on the Patent Register maintained by the Minister for 2, 5, 10, 15, 20 and 30 mg aripiprazole tablets marketed by BMS under the brand name ABILIFY.

[4] The '496 Patent relates to the use of aripiprazole for the treatment of people suffering from a number of brain disorders associated with the serotonin receptor subtype known as 5-HT1A. The only claims asserted by the Applicants relating to the use of aripiprazole (or a composition of same) in the treatment of bipolar I disorder are claim 16, which is dependent on claim 14, which is in turn dependent on claim 11 or 12, and claim 36, when dependent on claims 34 and 35.

[5] Claim 16 is for “[t]he use of aripiprazole in the treatment of, or for the production of a medicament effective in the treatment of, a disorder of the central nervous system associated with 5-HT1A subtype, wherein the disorder is bipolar I disorder with most recent episode of manic or mixed episodes.”

[6] Claim 36 is for “[a] pharmaceutical composition comprising aripiprazole, and an acceptable diluent or excipient, for use in the treatment of a disorder of the central nervous system associated with 5-HT1A subtype, wherein the disorder is bipolar I disorder with most recent episode of manic or mixed episodes.”

[7] On August 8, 2016, Apotex served a Notice of Allegation [NOA] on the Applicants advising that it was seeking to market 2, 5, 10, 15, 20, and 30mg Apo-Aripiprazole tablets for use as a monotherapy for the treatment of schizophrenia in adults and adolescents 15 to 17 years of age. Apotex alleges that no claim for the medicinal ingredient, the formulation, the dosage form, or the use of the medicinal ingredient in the '496 Patent would be infringed by Apotex's making, constructing, using, or selling of Apo-Aripiprazole. In particular, Apotex alleges that it would not infringe the claims of the '496 Patent because it will not make, use or sell, or induce others to make, use or sell:

- A. Apo-Aripiprazole for the treatment of the disorders of the central nervous system claimed in the '496 Patent, including bipolar I disorder with most recent episode of manic or mixed episodes; and

- B. Apo-Aripiprazole for the production of a medicament effective in the treatment of the disorders of the central nervous system claimed in the '496 Patent, including bipolar I disorder with most recent episode of manic or mixed episodes.

[8] The application was commenced on September 21, 2016, pursuant to subsection 6(1) of the Regulations seeking to prohibit the Minister from issuing an NOC to Apotex for its Apo-Aripiprazole tablets until the expiry of the '496 Patent. BMS disputed the allegation that no claim of the '496 Patent would be infringed by making, constructing, using, or selling the Apo-Aripiprazole tablets in Canada without further particularity.

[9] BMS also sought a declaration that Apotex's NOA is not a valid NOA as contemplated by the Regulations. However, on October 14, 2016, Apotex disclosed confidential portions of Apotex's regulatory submission for Apo-Aripiprazole that had been requested by BMS to allow BMS to assess Apotex's allegation of non-infringement, including the proposed draft product monograph. Updated draft product monographs were provided to the Applicants on October 26, 2016, and December 13, 2016, respectively. These documents were verified as accurate by the Minister. BMS made no submissions regarding the sufficiency of the disclosure at the hearing of this motion and appears to have abandoned its complaint.

[10] BMS disputes Apotex's allegations in respect of the four claims of the '496 Patent that relate to the use of compositions of aripiprazole for the treatment of manic or mixed episodes of bipolar I disorder.

[11] On February 17, 2017, BMS served its evidence in support of the application, which includes:

- a) four affidavits from psychiatrists across Canada that address, in part, Apotex's allegations of non-infringement:
 - i. affidavit of Dr. Vikram Dua, sworn February 17th, 2017 [Dua Affidavit];
 - ii. affidavit of Dr. Kevin Dwight Kjemisted, sworn February 16th, 2017 [Kjemisted Affidavit];
 - iii. affidavit of Dr. Ranjith D. Chandrasena, sworn February 17th, 2017 [Chandrasena Affidavit];
 - iv. affidavit of Dr. Atul Khullar, sworn February 17th, 2017 [Khullar Affidavit];and
- b) one affidavit from an expert pharmacologist that addresses, *inter alia*, the construction of the '496 Patent and Apotex's numerous allegations of invalidity: the affidavit of Philip Seeman sworn February 17, 2017 [Seeman Affidavit].

[12] By the present motion, Apotex seeks an order dismissing the application on the grounds that it is scandalous, frivolous, or vexatious or is otherwise an abuse of process. Apotex maintains that BMS's evidence cannot support a conclusion of direct or induced infringement of the '496 Patent by Apotex.

[13] Apotex has not filed any evidence on this motion, other than the affidavit of a law clerk attaching the affidavit evidence served by BMS in the underlying application. The Applicants have not filed any additional evidence on this motion.

[14] On May 1, 2017, this Court issued a protective order to provide for the protection and maintenance of confidentiality of portions of Apotex's Abbreviated New Drug Submission [ANDS] for its proposed Apo-Aripiprazole tablets as well as the affidavits served by the Applicants that include and/or reference the confidential portions of Apotex's ANDS.

[15] The Data Protection Period for ABILIFY ends on January 9, 2018, which is the earliest date that Apotex may receive a NOC absent the Regulations, assuming its submission is approvable. Data protection provisions in section C.08.004.1 of the *Food and Drug Regulations*, CRC, c 870, provide an eight-year period of market exclusivity for innovative drugs.

II. Issues to be Determined

[16] The issue on this motion is whether this Court should dismiss the within application on the ground that it is scandalous, frivolous or vexatious or is otherwise an abuse of process. The parties disagree about the proper test to be applied on a motion to dismiss pursuant to subsection 6(5) of the Regulations. They are also at odds over whether BMS has adduced any evidence to support a finding of infringement by Apotex or to support a finding that Apotex's NOC will induce infringement.

III. Test Applicable on Motions under paragraph 6(5)(b) of the Regulations

[17] Apotex has brought the present motion for an order dismissing the application in its entirety pursuant to paragraph 6(5)(b) of the Regulations, which reads as follows:

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|---|--|
| <p>6 (5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part</p> | <p>6 (5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :</p> |
| <p>(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.</p> | <p>b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.</p> |

[18] BMS submits that the proper question on this motion is whether there is any evidence on which the application judge could possibly base a finding that Apotex's allegations of non-infringement of claim 16, as it depends on claim 11, is not justified. BMS submits that a motion judge ought not to substantively consider the sufficiency of its evidence to determine whether it establishes that the allegations are not justified. It argues that Apotex must establish that it is "plain and obvious" that the Applicants cannot make out their case or that the application is "so clearly futile" that it does not have the slightest chance of success.

[19] BMS argues that claim 16 of the '496 Patent necessarily involves a claim construction analysis that would be inappropriate to be heard on a motion to dismiss the application under paragraph 6(5)(b) of the Regulations. It submits that any doubt as to whether there is an arguable

case on the merits of the application must be left for resolution by the application judge and any doubt as to whether Apotex has met its burden must be resolved in favour of the Applicants. Moreover, BMS submits that the Court must be satisfied that “no judge of the Court would ever not dismiss the application under paragraph 6(5)(b)”. I disagree.

[20] BMS is advocating for the application of a higher standard of proof that is not supported by the wording of paragraph 6(5)(b) or jurisprudence of this Court and the Federal Court of Appeal. The Court will find the requisite grounds to justify an order to dismiss an application under paragraph 6(5)(b) of the Regulations when an applicant fails to lead evidence that the second person’s allegations of non-infringement are not justified: *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167 (CanLII) at para 13 [Novopharm].

[21] A party moving for summary dismissal of an application certainly bears a heavy burden. The dismissal of an application pursuant to subsection 6(5)(b) is an extraordinary remedy and such relief will only be granted when the application is “clearly futile” or it is “plain and obvious” that the application has no chance of success: *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 (CanLII) at paras 28 and 36 [Sanofi-Aventis].

[22] The moving party bears the entire burden of proof in a paragraph 6(5)(b) motion: *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 (CanLII) at para 33. Further, a motion to dismiss will only be granted where it is apparent that there is no arguable case on the merits of the application.

[23] In order to make such a determination, the motion judge must be able to make the necessary findings of fact, viewed in the light most favourable to the first person, and apply the law to the facts. The Federal Court of Appeal has confirmed that a motion judge is entitled to assess whether the evidence offered in support of the application is relevant or could conceivably support the application: *Bayer Inc v Fresenius Kabi Canada Ltd*, 2016 FCA 13 (CanLII) at para 13. In the present case, I must determine whether there is any evidence capable of establishing that Apotex will infringe the '496 Patent, either directly or by inducing infringement by others.

IV. Analysis

A. *Evidence of direct infringement*

[24] BMS submits that the record is clear that:

- a. Apotex uses, or will use on issuance of the NOC, aripiprazole to manufacture a drug: Apo-Aripiprazole tablets;
- b. Apo-Aripiprazole tablets are bioequivalent with ABILIFY and ABILIFY is effective for the treatment of bipolar I disorder;
- c. Apo-Aripiprazole tablets are the same as Apotex's US Aripiprazole tablets;
- d. Apotex's US Aripiprazole tablets were approved for use in treatment of bipolar I disorder; and
- e. Apo-Aripiprazole tablets are thus effective for the treatment of bipolar I disorder.

[25] According to BMS, this evidence establishes that Apotex will use aripiprazole to manufacture or prepare a drug that is in fact effective for the treatment of bipolar I disorder as claimed in claim 16 as it depends on claim 11. This argument is not based any facts.

[26] When an NOA contains allegations of fact relating to non-infringement, these allegations are presumed to be true except to the extent the contrary is shown in the evidence. Apotex clearly states in its NOA that it is not making or intending to make the drug for the treatment of bipolar I disorder, but rather for the treatment of schizophrenia in adults and in adolescents 15 to 17 years of age. Moreover, the draft product monograph states that Apotex's Apo-Aripiprazole tablets will be "indicated as a monotherapy for the treatment of schizophrenia in adults" and "indicated as a monotherapy for the treatment of schizophrenia in adolescents ages 15 to 17". No reference is made to the treatment of bipolar I disorder with most recent episode of manic or mixed episodes.

[27] There is no evidence, other than speculation, that Apotex will use Apo-Aripiprazole to treat bipolar I disorder in Canada. Simply put, if Apotex does not manufacture Apo-Aripiprazole for the claimed uses, but rather, manufactures Apo-Aripiprazole solely for the unclaimed use, there can be no direct infringement of claim 16.

[28] I should also add this is not a matter of claim construction. A patentee's monopoly cannot be artificially extended to preclude the manufacture, use, and selling of a generic product simply because there is a possibility that someone somewhere will use the drug for the prohibited, patented purpose.

B. *Evidence of induced infringement*

[29] The tripartite test for establishing induced infringement is articulated in *Corlac Inc v Weatherford Canada Ltd*, 2011 FCA 228 (CanLII) at para 162 [*Weatherford*]:

- i. an act of infringement must have been completed by the direct infringer;
- ii. the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; and
- iii. the inducer knows that this influence will result in the completion of the act of infringement.

[30] It is important to bear in mind that the test from *Weatherford* is conjunctive and if BMS fails to establish all three of the prongs, their case must necessarily fail.

[31] BMS submits that its evidence establishes that Apotex is implicated in infringement of the '496 Patent by others via inducement. BMS argues that inducement can be established by inferences reasonably drawn from a number of factors, alone or in combination, beyond the content of the product monograph.

[32] Regarding the first prong of the test from *Weatherford*, BMS submits that there is evidence that once Apotex receives an NOC for Apo-Aripiprazole tablets, its product will be dispensed to patients who will use it for the treatment of bipolar I disorder, which is treated with

ABILIFY tablets. Once the generic product is available, patients will “likely” receive it because of cost differences and substitution laws and because physicians will not indicate “No Substitution” on the prescriptions for ABILIFY. BMS submits that this evidence was accepted in *Allergan Inc v Canada (Health)*, 2011 FC 1316 (CanLII) at paras 149-150 as sufficient to establish direct infringement.

[33] The Federal Court of Appeal has emphasized the importance of properly applying the test for induced infringement in the context of proceedings under the Regulations so as not to artificially extend the monopoly held by the patent holder by effectively transforming all pharmaceutical patents into compound patents, meaning that the patentee would monopolize the drug itself even where it is not protected by the patent.

[34] BMS argues that it is incorrect to suggest that in law, evidence is required from “a person who states that he or she will use Apo-Aripiprazole to treat bipolar I disorder” or that in fact, none of the Applicants’ evidence states that Apo-Aripiprazole will be used to treat bipolar I disorder. BMS states that the relevant question is whether Apotex’s tablets will in fact be used by patients for the treatment of bipolar I disorder. I disagree.

[35] To successfully prosecute a prohibition application under the Regulations in relation to a “use” patent where indirect infringement is alleged, the patentee would have to prove that third parties would, in fact, use the second person’s product for a claimed use in the first person’s patent, and that the second person had actively induced or encouraged such use: *AB Hassle Inc v*

Canada (Minister of National Health and Welfare), 2002 FCA 421 (CanLII) at paras 47-59 [*AB Hassle*].

[36] In *AB Hassle*, Mr. Justice Edgar Sexton stated as follows at paras 57 and 58:

[57] [...] a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holder would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost.

[58] Nor can Apotex be held liable in patent infringement proceedings under the Patent Act if, contrary to the evidence presented in the NOC proceeding, third party infringements do occur after the issue of a NOC, unless Apotex has implicated itself in the infringements by, for example, inducing or encouraging them [...].

[37] To induce or procure another to infringe a patent, something active must be done. Mere passivity is not sufficient: *Beloit Canada Ltd v Valmet Oy*, (1986) 8 CPR (3d) 289, [1986] FCJ No 87 (QL) at page 297 at paras 46-47.

[38] With respect to the second prong of the Weatherford test, according to BMS Apotex has taken actions that an application judge could ultimately consider to be the requisite influence leading to direct infringement by physicians and patients.

[39] BMS refers to paragraph 18 of the Kjernisted Affidavit and argues that the prescribing decisions (the act of infringement) of physicians would be influenced by Apotex's product information contained in the monograph, of which Apotex obviously has knowledge. BMS also references paragraphs 20-23 of the Kjernisted Affidavit to argue that information contained in the Canadian draft product monograph and the US prescribing information would influence Dr. Kjernisted to allow for substitution with the generic product. BMS maintains that this would represent an act of infringement with the knowledge of Apotex.

[40] BMS also relies on paragraph 21 of the Chandrasena Affidavit to show the influence of Apotex's US drug approvals for the bipolar I indication "informing" his teaching, practice, and prescribing of drug products in Canada.

[41] Referring to paragraphs 24-28 of Dr. Kjernisted's affidavit, BMS argues that the Apo-Aripiprazole draft product monograph presents information concerning comparative bioavailability, which "certainly emanates" from Apotex, would influence a doctor's decision to allow patients to receive Apo-Aripiprazole.

[42] Regarding Apotex's US promotional materials, BMS submits that Dr. Khullar attests to his and other physicians' understanding that Apotex is representing that its generic aripiprazole product may be substituted for ABILIFY with the same indications. Further, there is evidence that the approved indication as found in the US "would influence" such use and "would convince" physicians to approve and direct the use of Apo-Aripiprazole tablets by prescribing it for the treatment of bipolar I disorder.

[43] Dr. Kjernisted states at paragraph 28 of his affidavit that if the same Apotex aripiprazole tablet was specifically approved for bipolar I disorder in the US, which he was asked to assume, and was available in Canada, then it “would convince [him] and other physicians to approve and direct its use in Canada by prescribing it for the treatment of bipolar I disorder”.

[44] BMS submits that the specific comparative bioavailability generated by Apotex and presented in its draft product monograph would influence physicians’ decisions to prescribe Apo-Aripiprazole Tablets and not only ABILIFY with a “no substitution” warning. BMS argues that because the draft product monograph for Apo-Aripiprazole indicates that it has a formulation that does not present concerns about bioavailability, this information would influence physicians to allow substitution of ABILIFY with Apo-Aripiprazole.

[45] BMS submits that it is a logical and reasonable inference to assume the US and Canadian Apotex tablets are the same. BMS submits that physicians would naturally identify the name “Apotex” as the same generic company and would know that Apotex’s US product and Canadian products are manufactured in Canada by Apotex at the same location.

[46] The Applicant’s evidence falls well short of establishing any influence by Apotex in inducing infringement. In proceedings under the Regulations, an allegation of non-infringement of a claim for the use of a medicine is justified if the generic drug manufacturer is seeking an NOC only for a use that is not within the new use claim and the evidence fails to establish that the generic drug producer will infringe the new use claim by inducing others to prescribe or use the generic product for that new use. Such a proceeding is focused on the actions of the “second

person”, in this case Apotex. Absent evidence of inducement by Apotex, any potential infringement by patients, physicians or pharmacists cannot support the granting of a prohibition order.

[47] Even knowledge that one’s product will likely be used “off label” by another party in direct infringement of a patent is not sufficient to meet the second prong of the test, as held in *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461 (CanLII) at para 32; aff’d 2006 FCA 357:

[32] It strikes me as clear that Apotex's recognition that "off label" prescription by doctors, dispensation by pharmacists, and subsequent consumption by patients does not meet the "something more" requirement established by Sexton J.A. in *AB Hassle, supra*. Whether the "something more" consists of inducement, procurement, marketing or some other nexus will depend upon the facts of each particular case. However, there must be a nexus. Mere passive recognition that "off-label" prescription and/or consumption will occur does not amount to "something more". (See also *Pfizer Canada Inc. v. Apotex Inc.*, 2005 FC 1421 (F.C.) at paragraph 167.)

[48] The Chandrasena Affidavit is entirely irrelevant to a consideration of inducement of infringement of the '496 Patent for the following reasons:

- i. Dr. Chandrasena does not comment on Apotex’s draft product monograph for Apo-Aripiprazole.
- ii. He does not refer to Apotex at all in providing his brief opinion.
- iii. He does not suggest that Apo-Aripiprazole tablets would be prescribed in the treatment of bipolar I disorder with a most recent episode of manic or mixed

episodes in such a manner as to infringe the '496 Patent, let alone that such infringement would be directly influenced by Apotex's actions.

[49] The Dua Affidavit is similarly irrelevant to the consideration of inducement of infringement as Dr. Dua does not comment on Apotex's draft product monograph and only considered a US product monograph for aripiprazole tablets that were indicated to have been manufactured by Apotex. Dr. Dua was not informed or asked about how Apotex would market its Apo-Aripiprazole tablets in Canada. Further, he does not opine that he or any other psychiatrist would prescribe Apo-Aripiprazole tablets in the Canada for the treatment of bipolar I disorder because of Apotex's influence.

[50] The Khullar Affidavit is also insufficient to establish inducement by Apotex as Dr. Khullar does not comment on the draft Canadian product monograph and only looks to promotional material for US aripiprazole tablets. Dr. Khullar does not express any opinion about how Apotex would market its tablets in Canada. Nor does he opine on how he or any other psychiatrist would prescribe Apo-Aripiprazole in Canada for the treatment of bipolar I disorder.

[51] Finally, Dr. Kjernisted is only prepared to state at paragraph 25 that "[i]n most cases, I would be open to considering allowing substitution based on this specific bioavailability information, though there may be rare exceptions related to any patient specific consideration." None of the affiants were willing to assert that they would actually prescribe Apo-Aripiprazole based on bioavailability data.

[52] At paragraph 28 of his affidavit, Dr. Kjernisted opines that “[t]he same Apotex aripiprazole tablet having been specifically approved for bipolar I in the US would convince me and other physicians to approve and direct its use in Canada by prescribing it for the treatment of bipolar I”. However, Dr. Kjernisted does not indicate how a physician would be made aware that the tablet to be sold in Canada is the “same tablet” that is approved in the US. Indeed, Dr. Kjernisted states in the last sentence of paragraph 27 of his affidavit that “[t]his only assumes, as I have been asked to assume, that the Apotex tablet information is the same for the US and Canada.”

[53] Dr. Kjernisted’s evidence is that clinicians make prescribing decisions not on the “approved” indications of a generic drug, but on other bases, namely by scientific data that supports the use of the active ingredient (aripiprazole) for a particular disorder, and comparative bioavailability. Dr. Kjernisted does not suggest that the “scientific data that support the use of the active ingredient” emanates from Apotex.

[54] BMS’s reliance on the marketing of aripiprazole tablets in the US by Apotex in Canada is unfounded as the lawful promotion of a drug in another country, for an indication approved in that jurisdiction, cannot serve as the basis for inducement of infringement of a patent in another jurisdiction.

[55] In light of the above, it is plain and obvious that there is no evidence capable of meeting the second prong of the Weatherford test.

[56] As for the third prong of the test, none of the affiants were asked to opine on the question of whether the alleged inducer, Apotex, knows that its influence will result in the completion of the act of infringement. There is nothing in the record that shows that Apotex would be permitted to assert lawfully that Apo-Aripiprazole, approved in Canada, can be used to treat bipolar I disorder. In particular, there is no evidence that Apotex would violate, knowingly or otherwise, Canadian food and drug regulations by actively promoting the US product monograph or promoting information beyond that set out in the Canadian monograph to Canadians in or outside of Canada.

V. Conclusion

[57] For the above reasons and for the reasons set out in Apotex's submissions, which I adopt and make mine, I conclude that the motion pursuant to paragraph 6(5)(b) of the Regulations dismissing the application related to the '496 Patent should be granted.

[58] At the end of the hearing, it was agreed by the parties that costs of \$10,000.00, inclusive of disbursements and taxes, should be awarded in favour of the successful party.

JUDGMENT IN T-1572-16

THIS COURT'S JUDGMENT is that:

1. The motion is granted.
2. The application is dismissed in its entirety.
3. Costs of the motion, hereby fixed in the amount of \$10,000.00, inclusive of disbursements and taxes, shall be paid by the Applicants to the Respondent, Apotex Inc.

"Roger R. Lafrenière"

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1572-16

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THE MINISTER OF HEALTH

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