PUBLIC

Court File No. T-1369-23

JD

FEDERAL COURT

BETWEEN:

EMD SERONO, A DIVSION OF EMD INC., CANADA and MERCK SERONO SA

Applicants

– and –

THE MINISTER OF HEALTH

Respondent

APPLICATION FOR JUDICIAL REVIEW UNDER Section 18.1 of the *Federal Courts Act* (Canada)

NOTICE OF APPLICATION

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED by the Applicants. The relief claimed by the Applicants appears on the following page.

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 Applicants. The Applicants request 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 Applicants' solicitor 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, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

July 4, 2023

Issued by: Jena Russell

Address of local office:
Federal Court
180 Queen Street West
Suite 200
Toronto, ON M5V 3L6

TO: The Honourable Jean-Yves Duclos
Minister of Health
Health Canada
Minister's Office
Address Locator 0900C2
Ottawa, Ontario
K1A 0K9

(service effected pursuant to Rules 133 and 304(1)(b)(i) of the *Federal Courts Rules*)

AND TO: The Honourable David Lametti
Minister of Justice and Attorney General of Canada
284 Wellington Street
Ottawa, Ontario K1A 0H8

(service effected pursuant to Rules 133 and 304(1)(b)(iii) of the *Federal Courts Rules*)

APPLICATION

THIS IS AN APPLICATION FOR JUDICIAL REVIEW IN RESPECT OF a decision of the Minister of Health, issued through the Office of Submissions and Intellectual Property ("**OSIP**" or the **"Minister"**) and communicated to the Applicants on June 15, 2023, in which the Minister purported to determine that: (1) Canadian Patent No. 3,087,419 ("**CA 419**") was reviewed in respect of drug submission numbers 200943, 236088, 238626, and 249245 and found eligible for listing on the Patent Register for MAVENCLAD™ as of the date of the Minister's decision, namely on March 23, 2023, and not on March 16, 2023, the date that the patent lists for CA 419 were submitted to OSIP in eligible form, and consequently (2) a second person did not have to address CA 419 because it filed its drug submission on [REDACTED], after March 16, 2023, but before March 23, 2023, and compared its drug to MAVENCLAD, in accordance with the requirements of the *Patented Medicines (Notice of Compliance) Regulations, SOR/93-133* ("*PM(NOC) Regulations*") (the "**Final Decision**").

THE APPLICANTS MAKE AN APPLICATION FOR:

a) An order quashing and setting aside the Final Decision;

b) A declaration that OSIP incorrectly added CA 419 to the Patent Register as of the date of OSIP's patent eligibility decision, namely as of March 23, 2023 (the "**Eligibility Decision**");

c) A declaration that the correct date for addition of CA 419 to the Patent Register in respect of submissions 200943, 236088, 238626, and 249245 is March 16, 2023, the date EMD Serono filed the patent lists for CA 419 in eligible form;

d) A declaration that OSIP incorrectly determined that a second person who filed its submission on [REDACTED], did not have to address CA 419 because it filed its drug submission before March 23, 2023, the date of the Eligibility Decision;

e) A declaration that the second person who filed its drug submission after March 16, 2023, and before March 23, 2023, is required to address CA 419 pursuant to the *PM(NOC) Regulations*;

f) An interim and permanent order enjoining and/or prohibiting the Minister from issuing a notice of compliance ("**NOC**") to any second person who filed its drug submission after March 16, 2023, and before March 23, 2023, until it has complied with the requirements of the *PM(NOC) Regulations*;

g) A declaration that the Minister is required to comply with subsection 3(2) of the *PM(NOC) Regulations* and "maintain a register of patents that have been submitted for addition to the register";

h) The costs of this application; and

i) Such further and other relief as counsel may request and/or this Honourable Court may permit.

THE GROUNDS FOR THE APPLICATION ARE:

A. The Parties

1. The Applicant, EMD Serono, a Division of EMD Inc., Canada ("**EMD Serono**"), is a corporation existing under the laws of Ontario, having a principal office or place of business at 2695 North Sheridan Way, Suite 200, Mississauga, ON, L5K 2N6, Canada.

2. The Applicant, Merck Serono SA ("**Merck Serono**"), is a Swiss corporation having a principal place of business at rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland.

3. EMD Serono and Merck Serono are research-based pharmaceutical companies active in the discovery and development of innovative medicines and the education of health care professionals as to the benefits of such medicines for patients.

4. The Minister, through the *Food and Drugs Act* and *Food and Drug Regulations*, is responsible for reviewing and administering drug submissions in Canada. The Minister is also responsible for administering and enforcing various provisions of the *PM(NOC) Regulations*, including subsections 3(2) and 5(1). The Minister's responsibilities with respect to the *PM(NOC) Regulations* are delegated to and exercised by Health Canada and, in particular, OSIP.

B. MAVENCLAD (Cladribine)

5. MAVENCLAD™ (cladribine) is a purine antimetabolite. It is approved by Health Canada for the treatment of adult patients with relapsing-remitting multiple sclerosis. Since its approval in Canada and around the world, MAVENCLAD has improved the lives of patients living with relapse-remitting multiple sclerosis by delaying disease progression. MAVENCLAD is dosed according to a patented weight-based dosing regimen. The discovery of a safe and effective weight-based dosing regimen was the result of an extensive research effort.

6. EMD Serono markets and sells MAVENCLAD in Canada in one presentation: orally administered tablets containing 10 mg of cladribine (DIN 02470179). Health Canada issued the first notice of compliance for MAVENCLAD on November 30, 2017. EMD Serono is the exclusive marketer and seller of MAVENCLAD in Canada.

7. Merck Serono is the owner of CA 419.

C. Factual Background

8. On Friday, March 7, 2023, CA 419 was issued by the Canadian Intellectual Property Office ("**CIPO**"). EMD Serono had 30 days after the issuance of CA 419 to submit its patent lists, pursuant to subsection 4(6) of the *PM(NOC) Regulations*.

9. On March 16, 2023, EMD Serono filed patent lists in respect of five drug submissions (200943, 236088, 238626, 249245 and 272844). All five of the patent lists were subsequently deemed by OSIP to be eligible for addition to the Patent Register.

10. On March 23, 2023, OSIP acknowledged receipt of the patent lists on March 16, 2023 and communicated its Eligibility Decision. Four of the five patent lists were "added to the Patent Register on the date of this letter" [March 23, 2023]. One of the five patent lists (for 272844) "will be added to the Patent Register after the NOC has issued."

11. Even though the patent lists were submitted in eligible form on March 16, 2023, OSIP communicated its decision a week later on March 23, 2023. In the Eligibility Decision, OSIP incorrectly determined that the patent lists should be added to the Patent Register as of the date of the letter, March 23, 2023. The Applicants maintain that the correct date as of which CA 419 should be added to the Patent Register is the date the patent lists were submitted in eligible form, namely, March 16, 2023.

D. Request for Correction of Patent Register

12. On April 20, 2023, EMD Serono wrote to the Minister requesting that OSIP correct the Patent Register to show March 16, 2023 as the date as of which the patent lists for CA 419 were added to the Patent Register. EMD Serono provided submissions explaining why the text, context and purpose of the *PM(NOC)Regulations* align with EMD Serono's position.

E. The Final Decision

13. On June 15, 2023, via a letter bearing the file name "2023-06-15 OPML Signed Final Decision", OSIP issued a final decision regarding CA 419. In its Final Decision, OSIP made two primary decisions:

(a) First, CA 419 was properly added to the Patent Register as of the date of OSIP's "patent eligibility decision", namely, March 23, 2023. In the Final Decision, OSIP takes the position that there is a distinction

between, on the one hand, the submission of a patent on a patent list for inclusion on the Patent Register and, on the other hand, the actual addition to the Patent Register of a patent on a patent list. The Final Decision states that this interpretation is in line with Canada's policy objective with respect to a balance between pharmaceutical innovation and generic entry as generics should not be required to address "retroactively added" patents. In addition, to support its Final Decision, OSIP relied incorrectly on Federal Court jurisprudence that was based on a long superseded version of the *PM(NOC)Regulations* and different facts.

(b) Second, a generic drug manufacturer who filed its drug submission for cladribine on [REDACTED] was not required to address CA 419 because on [REDACTED], "[the generic drug manufacturer] would have examined the Patent Register and determined that there was no CA 419 on the Patent Register in relation to MAVENCLAD". This is unfair and unreasonable. The generic would have seen the previously-submitted patent lists if the Minister had properly maintained the Patent Register pursuant to subsection 3(2) of the *PM(NOC) Regulations*.

F. The *PM(NOC) Regulations*

14. The Minister is responsible for maintaining the Patent Register. Subsection 3(2) requires the Minister to "maintain a register of patents that have been submitted for addition to the register". The Minister is not in compliance with this requirement as the Minister only maintains a register of patents that have been added to the register following administrative review and eligibility approval by OSIP.

15. Pursuant to subsections 4(2) and 3(2)(a), the Minister is required to add eligible patents to the Patent Register and does not have the discretion to refuse this duty:

> 3(2) The Minister shall maintain a register of patents that have been submitted for addition to the register …
>
> (a) by adding any patent on a patent list or certificate of supplementary protection that meets the requirements for addition to the register

> 4 (2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains …

16. A first person can submit a patent list for inclusion on the Patent Register immediately following its issuance, pursuant to subsection 4(6):

> 4 (6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.

17. In order to market a drug in Canada, a second person must file a submission for an NOC. Subsection 5(1) of the *PM(NOC) Regulations* requires a second person to address patent lists which have been *submitted* before the second person files its drug submission:

> If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the submission the required statements or allegations set out in subsection (2.1).

18. Subsection 5(2.1) must be read in conjunction with subsection 5(1), which is consistent with the fact that a second person must address patents that have been submitted and included on the Patent Register:

> (2.1) The statements or allegations required for the submission or the supplement, as the case may be, are — with respect to each patent included on the register in respect of the other drug and with respect to each certificate of supplementary protection in which the patent is set out and that is included on the register in respect of the other drug – the following

19. Notably, a second person's notice of allegation does not have to be filed with the drug submission, and can be filed after the drug submission.

20. Subsection 5(4), which must be read in conjunction with subsections 5(1) and (2.1), which clarifies a scenario where a first person's patent lists and second person's drug submission are filed with Health Canada on the same day:

> 5(4) A second person is not required to comply with
>
> (a) subsection (1) in respect of a patent, or a certificate of supplementary protection that sets out the patent, that is added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including one added under subsection 3(2.2) or (5); and

21. These provisions outline the overarching requirements of the Minister under the *PM(NOC) Regulations*. The Minister must maintain a register of patents that have been submitted for addition to the register. Such a list may indicate, for example, whether the submission is under review or whether a decision has been reached by OSIP with respect to patent listing eligibility. A second person seeking to come on the market must address any patents that have been submitted for addition to the Patent Register, whether or not OSIP has provided a decision on eligibility. Otherwise, the obligation established in subsection 5(1) would not properly be met.

A. The Minister Unreasonably and Incorrectly Interpreted and Applied Subsections 3(2), 4(2) and 5(1) of the *PM(NOC) Regulations* and Exceeded Their Statutory Authority

22. Contrary to the Final Decision, the text, context, and purpose of the *PM(NOC) Regulations* do not support the Minister's interpretation of subsections 3(2), 4(2) and 5(1) of the *PM(NOC) Regulations*

23. Administrative decision makers are required to make decisions that are consistent with the text, context and purpose of the provision they are interpreting. The Minister did not do so in this case.

a. Subsections 3(2) and 4(2)

24. Pursuant to subsection 4(2), the Minister is required to ("shall") add eligible patents to the Patent Register and does not have the discretion to refuse this duty.

Further, the Minister's duty to add an eligible patent arises on the date that the patent list submission is filed and received by the Minister. As of that date, the Minister has no discretion to refuse to add an eligible patent to the Patent Register. Since the Minister cannot refuse to list an eligible patent, it follows that the Minister has no discretion to delay the listing. As such, the date as of which an eligible patent list is added the Patent Register must necessarily be the date an eligible patent list was submitted.

25. The Applicants are entitled to, and should benefit from, the date on which the patent lists were submitted in eligible form, rather than a later, and necessarily arbitrary, date when OSIP communicated the Eligibility Decision. Given that the patent lists were found eligible for listing on the Patent Register, they were necessarily eligible for addition to the Patent Register as of their submission date, March 16, 2023.

26. The Final Decision states that OSIP "has the discretion to add (or refuse to add) a patent that has been submitted and meets (or does not meet) the requirements of section 4 of the *PM(NOC) Regulations*." This is inconsistent with the *PM(NOC) Regulations* and contrary to the *Regulatory Impact Analysis Statement* ("**RIAS**") accompanying the 2017 amendments to those regulations.

27. Adding a patent to the Patent Register is not discretionary. Pursuant to subsection 3(2), "*The Minister **shall** maintain a register of patents that have been **submitted for addition** to the register...(a) **by adding** any patent on a patent list...that meets the requirements for addition to the register*". There is no discretion provided to the Minister in the *PM(NOC) Regulations* in determining whether to add a patent list submitted in eligible form to the Patent Register.

28. The Final Decision relies on phrases such as "date of the decision" and "patent eligibility decision" in reference to the appropriate date and time for adding a patent to the Patent Register. Neither of these phrases appears in the *PM(NOC) Regulations*, nor are they supported by any reasonable interpretation of the provisions.

29. The Final Decision also refers to the RIAS in support of OSIP's assertion that a patent if "deemed eligible" should be added to the Patent Register as of the date of the "patent eligibility decision". The RIAS does not support OSIP's misinterpretation of the *PM(NOC) Regulations*.

30. OSIP's perception of a temporal difference between "submitted" and "addition" to the Patent Register is based on arbitrary ministerial administrative processes and not prescribed in the *PM(NOC) Regulations* or interpretive guides. The Minister does not have discretion to decide whether to add an eligible patent that is submitted for addition to the Patent Register any more than it has the discretion to arbitrarily decide the date as of which it is added. This is consistent with the mandatory rather than discretionary language employed in the *PM(NOC) Regulations*.

31. The Final Decision draws a distinction between the date a patent is submitted for addition to the Patent Register (section 4) and a second person's date of filing a submission for a notice of compliance (section 5), ascribing the benefit of the filing date to the second person while denying the benefit of such a date to the first person. This is both unfair and unreasonable, and is not supported by the *PM(NOC) Regulations* or the *RIAS*.

32. Indeed, the Applicants' interpretation is the only one consistent with paragraph 5(4)(a) of the *Regulations*. The only reasonable interpretation of "added" in paragraph 5(4)(a) is one that is in line with subsection 5(1): the date on which an eligible patent list was submitted, rather than a later arbitrary date on which OSIP had the administrative capacity to communicate its decision. To find otherwise would introduce impermissible uncertainty into Canada's patent-linkage system and would render the legislation inconsistent with itself. If paragraph 5(4)(a) is interpreted as the date of the Eligibility Decision and not the date of submission of the patent list in subsection 5(1), then the Minister's actions can never be fair because every single day of delay in adding a patent to the Patent Register represents an obvious preference in favour of generics. By simply delaying its decision on patent eligibility, the Minister favours the generics every time. Indeed, this is the effect in this instance. There can be

no fairness in this process, which effectively replaces the second person's obligation in subsection 5(1) with "at the whim of the Minister".

33. The Final Decision states that "[t]here is no language to direct retroactive effect of a decision to list a patent on a patent list on the Patent Register." This statement shows a profound misunderstanding and mischaracterization of the Applicants' position.

34. EMD Serono is not seeking to benefit from a retroactive date; rather, EMD Serono is seeking to benefit from the date it complied with the requirements of the *PM(NOC) Regulations* and submitted its patent lists in eligible form – the date as of which the Minister had no discretion to deny or arbitrarily delay adding the eligible patent to the Patent Register. Indeed, EMD Serono's interpretation is the only interpretation consistent with subsection 4(6) of the *PM(NOC) Regulations*, which allows patents lists to be submitted for inclusion on the Patent Register immediately following issuance. This is no different than the standard for which OSIP confers benefit to the second person in recognizing the date of filing a submission for NOC under section 5, rather than the acceptance date.

35. As such, March 16, 2023 must be the date as of which the patent lists for CA 419 should be added to the Patent Register. To hold otherwise would be to penalize the Applicants for the administrative capacity (or lack thereof) of OSIP. This is inconsistent with the balance struck by Canada's patent linkage system, and subjects first persons, such as EMD Serono, to an arbitrary and unfair system created by the Minister.

36. Lastly, OSIP relied unreasonably and incorrectly on Federal Court jurisprudence to support its Final Decision, including jurisprudence based on a long superseded version of the *PM(NOC) Regulations* and different facts.

b. Section 5

37. In addition, contrary to the Final Decision, the text, context, and purpose of the *PM(NOC) Regulations* do not support the Minister's interpretation of section 5.

38. Subsection 5(1) of the *PM(NOC) Regulations* requires a second person to address patent lists which "[have] been submitted" before it files its drug submission. Subsection 5(1) reads:

> 5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been *submitted*, the second person shall include in the submission the required statements or allegations set out in subsection (2.1). *[emphasis ours]*

39. This is consistent with the Minister's obligation to "maintain a register of patents that have been submitted for addition to the register" in subsection 3(2).

40. In its interpretation of subsection 5(1) of the *PM(NOC) Regulations*, OSIP unreasonably and incorrectly, re-wrote the provision to require a second person to only address patents that are listed on the Patent Register following review and addition to the Patent Register by OSIP:

> "The OSIP reviews each patent list it receives to determine eligibility for listing on the Patent Register. Patent lists can only be added to the Patent Register once the OSIP determines that the requirements in section 4 of the PM(NOC) Regulations are met, and once an NOC is issued for the drug submission to which the patent list relates.
>
> ...
>
> Subsection 5(1) of the PM(NOC) Regulations provides that if a second person (i.e., a subsequent entry drug manufacturer) files a submission for an NOC in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, a first person's drug marketed in Canada under an NOC and in respect of which there is a patent and/or certificate of supplementary protection *listed* on the Patent Register, the second person must address the listed patent and/or certificate of supplementary protection." *[emphasis added]*

41. A second person who files its submission after March 16, 2013, should be required to address CA 419. OSIP was unreasonable and incorrect in finding that a second person who filed its submission on [REDACTED], was not required to address CA 419 because, as of March 23, 2023, "[the generic drug manufacturer] would have examined the Patent Register and determined that there was no CA 419 on the Patent

Register in relation to MAVENCLAD". This rationale is both unfair and unreasonable, and is not supported by the *PM(NOC) Regulations.* The Minister went beyond their statutory authority by citing the above scenario as the reason why the second person does not have to address CA 419, a reason not contemplated in subsection 5(1) nor a scenario that subsection 5(4) is meant to address. The requirement in subsection 5(1) does not hinge on whether the second person actually examines the Patent Register, and is not the scenario subsection 5(4) is designed to protect.

B. The Minister Inconsistently Applied and/or Breached the *PM(NOC) Regulations* by Failing to Maintain the Patent Register

42. The Minister's current practice is in breach of the *PM(NOC) Regulations* for failing to keep a register of patents that have been submitted for addition. To the extent that the Minister draws a distinction between the date a patent is submitted for addition to the Patent Register and the date when a patent eligibility decision is made, the Minister's practice is inconsistent with the text and purpose of the *PM(NOC) Regulations.* The consequence of any inconsistency or breach should not be on the first person who submitted an eligible patent in time.

43. The Minister points to the "frozen" Patent Register in defending its current practice. Specifically,

> 5 (4) A second person is not required to comply with
>
> > (a) subsection (1) in respect of a patent, or a certificate of supplementary protection that sets out the patent, that is added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including one added under subsection 3(2.2) or (5);

44. Subsection 5(4) operates to prevent the mischief of patent owners seeking to add additional patents to the Patent Register once a second person has already filed its drug submission. Also, it clarifies a scenario where a first person's patent lists and second person's drug submission are filed with Health Canada on the same day. Those are not the circumstances of this case wherein EMD Serono submitted eligible patent lists *before* any submissions were filed by a second person.

45. If on [REDACTED] the second person had no notice that eligible patent lists were submitted in respect of MAVENCLAD and thus did not address CA 419 in its submission, the fault lies entirely with the Minister for failing to fulfil its obligations under the *PM(NOC) Regulations* to maintain a register of patents that have been submitted for addition to the register.

46. The Minister's interpretation of subsections 5(1) and 5(4) also contravenes Canada's international treaty obligations including, but not limited to, Article 20.50 of the Canada-United States-Mexico Agreement ("**CUSMA**"). Pursuant to Article 20.50 2(b) of CUSMA, the Minister has an obligation to promote transparency by providing information regarding applicable patents and relevant periods of exclusivity for pharmaceutical products that have been approved by Health Canada. The current system, whereby there is no notice to second persons of patent lists that have been submitted but a patent eligibility decision is still pending, contravenes CUSMA. Moreover, the interpretation of sections 3(2), 4, and 5 in the Final Decision effectively negates this obligation on the part of Canada.

47. While the Final Decision refers to the Minister's own administrative practices relating to the above provisions of the *PM(NOC) Regulations*, these are irrelevant to the correct interpretation of the *PM(NOC) Regulations* and assessing whether the Patent Register regime is compliant with both domestic and international obligations.

C. The Minister's Decision is Procedurally Unfair

48. The Final Decision is procedurally unfair in two ways. First, the Minister did not address EMD Serono's main argument regarding the arbitrariness of the Eligibility Decision and its unbalanced impact on first persons. Second, the Minister rendered a final decision without giving EMD Serono the opportunity to respond to the new arguments raised in OSIP's June 15, 2023 letter.

49. In its letter of April 20, 2023, EMD Serono argued that the only reasonable interpretation of "added" in paragraph 5(4)(a) is one that is in line with subsection 5(1): the date on which an eligible patent list was submitted, rather than a later arbitrary date

on which OSIP had the administrative capacity to communicate its decision on listing. EMD Serono asserted that to find otherwise would introduce impermissible uncertainty into Canada's patent-linkage system. Despite referencing this argument in the Final Decision, the Minister made no attempt to engage with it and it remains unclear whether this issue was considered at all. This is particularly important given the Final Decision's emphasis on fairness to the second person:

> [I]f the subsequent entry drug manufacturer intended to submit its ANDS for its version of cladribine on [REDACTED], on that day, it would have examined the Patent Register and determined that there was no '419 patent listed on the Patent Register in relation to MAVENCLAD. Accordingly, it was not required to address the '419 patent when it filed its ANDS on [REDACTED]. Following the addition of the '419 patent on the Patent Register in relation to MAVENCLAD on March 23, 2023, the subsequent entry drug manufacturer would have been in an impossible position as it could not possibly have met the requirements in subsections 5(1) and 5(2.1) of the *PM(NOC) Regulations* to include a statement or allegation with respect to the subsequently added '419 patent on the Patent Register in relation to MAVENCLAD.

50. What is clear from the Final Decision is that the Minister has considered how the second person could be impacted by the patent eligibility date. However, the Minister has not properly turned its mind to how the eligibility decision could (and, in this case, has) unfairly impacted the first person. Further, a second person's notice of allegation does not have to be filed with the drug submission, and can be filed after the drug submission. This demonstrates a lack of careful consideration on the part of the Minister.

51. Lastly, the Final Decision was presented as final when it was delivered to EMD Serono on June 15, 2023. This procedural unfairness has deprived EMD Serono of the opportunity to address the new issues and arguments raised by OSIP.

D. Grounds of Review

52. In making the Final Decision, the Minister:

(a) Acted without jurisdiction, acted beyond their jurisdiction, and/or refused to exercise their jurisdiction;

(b) Failed to observe a principle of natural justice or procedural fairness and other procedures that they were required by law to observe;

(c) Erred in law;

(d) Based the Final Decision on an erroneous finding of fact made in a perverse or capricious manner or without regard for the material before him; and

(e) Acted in other ways contrary to law.

E. Venue

53. The Applicants request that this application be heard at Toronto, Ontario.

F. Request for Material in the Possession of the Minister

54. Pursuant to Rule 317 of the *Federal Courts Rules*, the Applicants hereby request all of the material relevant to this application and to the Final Decision that is in the possession of the Minister and not in the possession of the Applicants (the "**Certified Tribunal Record**"), including:

(a) All relevant material, communications and evidence before the Minister leading up to the Eligibility Decision;

(b) All internal processes, guides, guidelines, policies and manuals that were, may have been or could have been consulted by the Minister in making the Eligibility Decision;

(c) All relevant material before the Minister at the time of the Final Decision;

(d) All materials forming any part of the Minister's analysis;

(e) All evidence in support of the Final Decision; and

(f) All materials forming part of the Minister's reasons for the Final Decision.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

a) The Final Decision;

b) The record and proceedings before the Minister relevant to the Final Decision, including the Certified Tribunal Record;

c) The affidavit(s) of at least one individual with knowledge of the facts in dispute, to be sworn or affirmed, served, and deemed filed pursuant to Rule 306;

d) *Food and Drugs Act*, R.S.C. 1985, c. F-27;

e) *Food and Drug Regulations*, C.R.C. c. 870;

f) *Patent Act*, R.S.C. 1985, c. P-4;

g) *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133;

h) *Federal Courts Act*, R.S.C. 1985, c. F-7;

i) *Federal Courts Rules*, SOR/98-106; and

j) Such further and other affidavits and material as the applicant may advise and this Honourable Court may permit.

July 4, 2023

McCarthy Tétrault LLP
Barristers & Solicitors
Box 48, Suite 5300
Toronto-Dominion Bank Tower
Toronto, ON M5K 1E6

Fiona Legere
Bohdana Tkachuk

Fax: 416-868-0673

Solicitors for the Applicants, EMD Serono and Merck Serono