Federal Court  Cour fédérale

Date: 20230717

Docket: T-2627-22

Citation: 2023 FC 870

Ottawa, Ontario, July 17, 2023

PRESENT: The Honourable Madam Justice Aylen

BETWEEN:

JANSSEN INC.

Applicant

and

THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA

Respondents

PUBLIC JUDGMENT AND REASONS
(Confidential version issued on June 21, 2023)

[1] The Applicant, Janssen Inc [Janssen], seeks judicial review of a decision of the Office of Submissions and Intellectual Property [OSIP] on behalf of the Minister of Health dated November 15, 2022. OSIP determined that Canadian Patent No. 3,113,837 [837 Patent] was not eligible to be added to the Patent Register against STELARA® with respect to two supplementary new drug submissions.

[2] While Janssen has raised a number of issues on this application, of central importance are the following two issues: (i) whether OSIP's decision that a supplemental new drug submission approved for additional safety data that could provide a clinician more confidence in prescribing a drug long-term is not a "change in use of the medicinal ingredient" as prescribed by subsection 4(3) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PMNOC Regulations*] if the approved indication never included a temporal restriction on its use was reasonable; and (ii) whether the Canadian patent filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

[3] For the reasons that follow, I am not satisfied that Janssen has demonstrated that there is any basis for the Court's intervention. Accordingly, the application for judicial review shall be dismissed in its entirety, with costs.

I. Background

A. *Drug Approval under the Food and Drug Regulations*

[4] Drug manufacturers who wish to advertise or sell a new drug in Canada must first obtain a Notice of Compliance [NOC] pursuant to the *Food and Drug Regulations,* CRC, c 870, by filing a drug submission with the Minister.

[5] The *Food and Drug Regulations* refer to several types of drug submissions, including a new drug submission [NDS] and a supplemental new drug submission [SNDS]. An NDS is

typically filed by the innovator drug manufacturer in order to obtain an NOC. An NDS contains a variety of clinical, non-clinical, chemistry and manufacturing data relating to the safety, efficacy and quality of the drug. The Minister evaluates this information to determine whether the drug meets the regulatory requirements in order to initially approve the drug for sale on the Canadian market. After an NOC for an NDS is issued, a manufacturer will typically continue to file information about the drug. Significant changes made to the information or material contained in the NDS are made by filing an SNDS. An NOC is also issued by the Minister for each approved SNDS.

B. ***Product Monographs***

[6] As part of the drug review process for an NDS or SNDS, Health Canada reviews a Product Monograph which is a factual, scientific document that describes a drug product's properties, claims, indications, contra-indications, conditions, dosage, administration and any other relevant information that may be required for the optimal, safe and effective use of the drug. The "Indications and Clinical Use" section of a Product Monograph, among other things, lists the uses for which the drug has been approved through the issuance of an NOC.

C. ***The PMNOC Regulations***

[7] The *PMNOC Regulations*, which were enacted in 1993 and have subsequently been amended on a number of occasions, were promulgated pursuant to the authority granted to the Governor in Council by subsection 55.2(4) the *Patent Act*, RSC 1985, c P-4, which provides:

The Governor in Council may make regulations respecting the infringement of any patent that, directly or indirectly, could result or results from the making, construction, use or sale of a patented invention in accordance with subsection (1), including regulations

(a) respecting the conditions that must be fulfilled before a document — including a notice, certificate or permit — concerning any product to which a patent may relate may be issued to any person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

(b) respecting the earliest day on which such a document may be issued to a person and the earliest day on which it may take effect, and respecting the manner in which each day is to be determined;

(c) respecting the issuance, suspension or revocation of such a document in circumstances where, directly or indirectly, the document's issuance could result or results in the infringement of a patent;

(d) respecting the prevention and resolution of disputes with respect to the day on which such a document may be issued or take effect;

(e) respecting the prevention and resolution of disputes with respect to the infringement of a patent that could result directly or indirectly from the manufacture, construction, use or sale of a product referred to in paragraph (a);

Le gouverneur en conseil peut, par règlement, régir la contrefaçon de tout brevet qui résulte ou pourrait résulter, de façon directe ou autrement, de la fabrication, de la construction, de l'utilisation ou de la vente, au titre du paragraphe (1), d'une invention brevetée, et notamment :

a) régir les conditions complémentaires nécessaires à la délivrance à quiconque, relativement à un produit auquel peut se rapporter un brevet, de tout titre — avis, certificat, permis ou autre — en vertu de lois fédérales régissant la fabrication, la construction, l'utilisation ou la vente d'un tel produit;

b) régir la première date à laquelle un tel titre peut être délivré et celle à laquelle il peut prendre effet, ainsi que la manière de fixer chacune de ces dates;

c) régir la délivrance, la suspension ou la révocation d'un tel titre lorsque la délivrance de celui-ci entraîne ou pourrait entraîner, de façon directe ou autrement, la contrefaçon d'un brevet;

d) régir la prévention et le règlement de différends portant sur la date à laquelle un tel titre peut être délivré ou prendre effet;

e) régir la prévention et le règlement de différends portant sur la contrefaçon d'un brevet qui pourrait résulter, de façon directe ou autrement, de la fabrication, de la construction, de l'utilisation ou de la vente d'un produit visé à l'alinéa a);

f) régir le règlement de différends portant sur la contrefaçon d'un brevet qui résulte, de façon directe ou autrement, de la fabrication, de la

(f) respecting the resolution of disputes with respect to the infringement of a patent that results directly or indirectly from the manufacture, construction, use or sale of such a product;

(g) conferring rights of action with respect to disputes referred to in any of paragraphs (d) to (f);

(h) restricting or excluding the application of other rights of action under this Act or another Act of Parliament to disputes referred to in any of paragraphs (d) to (f);

(i) designating the court of competent jurisdiction in which a proceeding with respect to rights of action referred to in paragraph (g) is to be heard;

(j) respecting such proceedings, including the procedure of the court in the matter, the defences that may be pleaded, the remedies that may be sought, the joinder of parties and of rights of action and the consolidation of other proceedings, the decisions and orders the court may make and any appeals from those decisions and orders; and

(k) specifying who may be an interested person for the purposes of subsection 60(1) with respect to disputes referred to in paragraph (e).

construction, de l'utilisation ou de la vente d'un tel produit;

g) conférer des droits d'action concernant les différends visés à l'un ou l'autre des alinéas d) à f);

h) limiter ou interdire le recours à d'autres droits d'action prévus par toute loi fédérale concernant les différends visés à l'un ou l'autre des alinéas d) à f);

i) désigner le tribunal compétent à l'égard des procédures résultant de l'exercice des droits d'action visés à l'alinéa g);

j) régir ces procédures, notamment la procédure devant ce tribunal, les moyens de défense qui peuvent être invoqués, les conclusions qui peuvent être recherchées, la jonction de parties, la réunion de droits d'action ou d'autres procédures, les décisions et ordonnances qui peuvent être rendues ainsi que les appels de ces décisions et ordonnances;

k) préciser qui peut être un intéressé pour l'application du paragraphe 60(1) dans le cadre des différends visés à l'alinéa e).

[8] As confirmed by the Supreme Court of Canada in *AstraZeneca Canada Inc v Canada (Minister of Health)*, 2006 SCC 49 at paragraph 12, the *PMNOC Regulations* lie at the intersection of two regulatory systems with sometimes conflicting objectives – (i) the law governing the approval of new drugs (*Food and Drug Act*) with the objective of encouraging the bringing of safe

and effective medicines to market to advance the nation's health; and (ii) patent protection provided to innovators under the *Patent Act*.

[9] The Regulatory Impact Analysis Statement [RIAS] related to the 2006 amendments to the *PMNOC Regulations* describes the balancing function as follows:

> The Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors. The current manner in which that balance is realized was established in 1993, with the enactment of Bill C-91, the *Patent Act Amendment Act*, 1992, S.C. 1993, c. 2.
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> On the one end of the balance lies subsection 55.2(1) of the *Patent Act*, better known as the "early-working" exception. In the pharmaceutical industry, early-working allows second and subsequent entry drug manufacturers (typically generic drug companies) to use a patented innovative drug for the purpose of seeking approval to market a competing version of that drug. Normally, conduct of this kind would constitute patent infringement but an exception has been made so that generic drug companies can complete Health Canada's regulatory approval process while the equivalent innovative drug is still under patent, in order to be in a position to enter the market as soon as possible after patent expiry. The generic pharmaceutical industry estimates that early-working can accelerate the market entry of its products in Canada by some three to five years.
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> The PM(NOC) Regulations represent the other half of the balance. As explained in the original Regulatory Impact Analysis Statement (RIAS) which accompanied their passage in 1993, in creating the early-working exception, Bill C-91 removed an exclusive right otherwise available to patentees and the PM(NOC) Regulations are therefore required "…to ensure that this new exception to patent infringement is not abused by generic drug applicants seeking to sell their products during the term of the competitor's patent…" The PM(NOC) Regulations do this by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product the generic seeks to copy. Under the current scheme, a generic drug company which compares its product directly or indirectly with a patented, innovative drug in order to

> establish the former's safety and efficacy and secure marketing approval from Health Canada (which comes in the form of a "notice of compliance" or 'NOC") must make one of two choices. It can either agree to await patent expiry before obtaining its NOC or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.
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> Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic company's allegations. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

D. *The Patent Register*

[10] The Minister maintains a Patent Register, which is a list of patents and certifications of supplementary protection associated with each approved drug. Pursuant to subsections 3(2) to 3(8) of the *PMNOC Regulations*, the Minister has the discretion to maintain the Patent Register, including the ability to add or delete patents in various prescribed circumstances.

[11] A "first person" who files an NDS or SNDS may, pursuant to subsection 4(1) of the *PMNOC Regulations*, submit to the Minister a patent for listing on the Patent Register in respect of the drug for which approval is sought. A patent will only be added to the Patent Register if the Minister is satisfied that the relevant regulatory criteria are met.

[12] In the case of an SNDS, paragraph 4(3)(c) sets out the product specificity requirements that must be met for a patent to be listed on the Patent Register:

(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and […] (c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.	(3) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas : c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

[13] Subsection 4(4) of the *PMNOC Regulations* prescribe what must be included in a patent list:

A patent list shall contain the following: (a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates; (b) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the	La liste de brevets comprend : a) l'identification de la présentation de drogue nouvelle ou du supplément à la présentation de drogue nouvelle qui s'y rattachent; b) l'ingrédient médicinal, la marque nominative, la forme posologique, la concentration, la voie d'administration et l'utilisation prévus à la

supplement to a new drug submission to which the list relates;

(c) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the Patent Act;(d) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates

is the owner of the patent,

has an exclusive licence to the patent or to a certificate of supplementary protection in which that patent is set out, or

(iii) has obtained the consent of the owner of the patent to its inclusion on the list;

(e) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(a) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and

(f) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).

présentation ou au supplément qui s'y rattachent;

c) à l'égard de chaque brevet qui y est inscrit, le numéro de brevet, la date de dépôt de la demande de brevet au Canada, la date de délivrance de celui-ci et la date d'expiration du brevet aux termes des articles 44 ou 45 de la *Loi sur les brevets*;

d) à l'égard de chaque brevet qui y est inscrit, une déclaration portant que la première personne qui a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle qui s'y rattache :

(i) soit en est le propriétaire,

(ii) soit en détient la licence exclusive ou détient une telle licence à l'égard d'un certificat de protection supplémentaire qui mentionne ce brevet,

(iii) soit a obtenu le consentement du propriétaire pour l'inscrire sur la liste;

e) l'adresse au Canada de la première personne aux fins de signification de l'avis d'allégation visé à l'alinéa 5(3)a) ou les nom et adresse au Canada d'une autre personne qui peut en recevoir signification comme s'il s'agissait de la première personne elle-même;

f) une attestation de la première personne portant que les renseignements fournis aux termes du présent paragraphe

	sont exacts et que chaque brevet qui y est inscrit est conforme aux conditions d'admissibilité prévues aux paragraphes (2) ou (3).

[14] The *PMNOC Regulations* also prescribe timing requirements related to patent listing, which depend on when the patent is issued. Specifically, subsections 4(5) and (6) provide:

(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.	(5) Sous réserve du paragraphe (6), la première personne qui présente une liste de brevets doit le faire au moment du dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle qui s'y rattachent.
(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.	(6) La première personne peut, après la date de dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle et dans les trente jours suivant la délivrance d'un brevet faite au titre d'une demande de brevet dont la date de dépôt au Canada est antérieure à celle de la présentation ou du supplément, présenter une liste de brevets, à l'égard de cette présentation ou de ce supplément, qui contient les renseignements visés au paragraphe (4).

[15] As such, only patents that have a filing date in Canada before the filing date of an SNDS are eligible to be added to the Patent Register.

[16] For the purpose of the administration of the patent list, the Minister utilizes a form entitled "Form IV" that the Minister requires be completed by each first person. Form IV states in its header in bold to "COMPLETE ONE FORM PER PATENT PER SUBMISSION".

[17] Having a patent listed on the Patent Register in relation to a particular drug affords significant protections to an innovator. If a second person files a drug submission that directly or indirectly compares their drug with, or makes reference to, a first person's drug that is marketed in Canada under an NOC and which has one or more patents listed on the Patent Register, the second person must, pursuant to subsection 5(1) and (2.1) of the *PMNOC Regulations*, address each listed patent. One manner of addressing a listed patent is to serve on the first person a notice of allegation [NOA], pursuant to subsection 5(2.1)(c), alleging that the listed patent is invalid or would not be infringed by the second person making, constructing, using or selling their drug product. The first person then has the right, within 45 days of being served with a NOA, to bring an action against the second person pursuant to subsection 6(1) seeking a declaration that making, constructing, using or selling of the second person's drug product in accordance with the second person's drug submission would infringe the listed patent(s) addressed in the NOA. When such an action is brought, the Minister is prohibited from issuing a NOC to the second person for 24 months from the date of commencement of the action or such other periods of time prescribed by subsection 7(1) of the *PMNOC Regulations*.

[18] However, not all patents will receive the aforementioned protection afforded by the regulatory regime simply by relating to a drug for which an NOC has been issued. Only those

patents that meet the product specificity and timing requirements of the *PMNOC Regulations* will benefit from the regime's protections.

E. STELARA®

[19] STELARA® is a Schedule D biologic drug containing the medicinal ingredient ustekinumab [STELARA]. First approved in Canada in December of 2008 for the treatment of psoriasis, STELARA has since gained approvals for several other indications including its use to treat plaque psoriasis, active psoriatic arthritis and moderately to severely active Crohn's disease.

[20] There are currently no patents listed on the Patent Register in respect of STELARA. Canadian Patent No. 2,418,961 was previously listed on November 17, 2009, but expired on August 9, 2021.

[21] Health Canada's "Submissions Under Review" page shows at least one company has filed a submission for approval of a biosimilar of STELARA in January of 2023.

(1) SNDS 244739

[22] On February 15, 2019, the Applicant filed SNDS 224739 [SNDS 739] seeking approval for a new use of STELARA for the treatment of adult patients with moderately to severely active ulcerative colitis and updates to the Product Monograph. Supporting studies were submitted, including approximately one year of data (44 weeks) from a UNIFI-M maintenance study.

[23] On January 23, 2020, the Minister approved the use of STELARA for the treatment of ulcerative colitis, issuing an NOC for SNDS 739. The NOC stated, under the heading "Reasons for Supplement":

> New indication: The treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

[24] The "Dosage and Administration" section of the approved Product Monograph included a recommended induction treatment regimen for ulcerative colitis, as well as a recommended maintenance dose regimen. No temporal limitation on the duration of treatment was included in the Product Monograph. Put differently, the NOC for SNDS 739 did not approve the use of STELARA to treat ulcerative colitis for a limited period of time.

(2) SNDS 244670

[25] On October 1, 2020, Janssen filed SNDS 244670 [SNDS 670] seeking to update the Product Monograph of STELARA with updated two-year safety and efficacy data (96 weeks) from the same on-going UNIFI-M study on its use for ulcerative colitis (which use had been previously approved with SNDS 739).

[26] The Clinical Evaluation Executive Summary notes, under the heading "Subject", that SNDS 670 is to "update the product monograph to include results from the long-term extensions

of two Phase 3 studies for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis".

[27] Both the General Note to Reviewer and Regulatory Executive Summary notes the purpose of the submission was to provide data on safety and efficacy of STELARA through five years of treatment in subjects with Crohn's disease and two years of treatment in subjects with ulcerative colitis, including relevant data in regard to a post-marketing adverse drug reaction for hypersensitivity vasculitis.

[28] Janssen indicated in the Product Information Regulatory Process Form for SNDS 670 that "there [were] no changes to the indication/Use/Dosage (including the maximum daily dose)".

[29] On September 9, 2021, Health Canada issued an NOC for SNDS 670. Under the heading "Reason for Supplement", the NOC states "Updates to the Product Monograph". The approval resulted in two changes to the Product Monograph, as shown in bold and underlined below:

Product Monograph (SNDS 739)	**Product Monograph (SNDS 670)**
(1) In the "Clinical Trial Adverse Drug Reactions" section addressing adverse drug reactions reported in studies related to ulcerative colitis, on page 12:	
The safety of STELARA®/STELARA® I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients	The safety of STELARA®/STELARA® I.V. was evaluated in two randomized, double-blind, placebo-controlled studies (UNIFI-I and UNIFI-M) in 960 adult patients with moderately to severely active ulcerative colitis. The overall safety profile was similar for patients with psoriasis, psoriatic

with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.	arthritis, Crohn's disease and ulcerative colitis. **The safety profile remaining generally consistent throughout the Week 96 safety analysis.**
(2) In the "Study and Demographics and Trial Design" section on page 58:	
The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of STELARA® I.V. in UNIFI-I. These patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg of STELARA® every 8 weeks, 90 mg STELARA® every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment. The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction.	The maintenance study (UNIFI-M), evaluated 523 patients who achieved clinical response at Week 8 following the administration of STELARA® I.V. in UNIFI-I. These patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg of STELARA® every 8 weeks, 90 mg STELARA® every 12 weeks or placebo for 44 weeks. Randomization was stratified by clinical remission status at maintenance baseline (yes/no), oral corticosteroid use at maintenance baseline (yes/no), and induction treatment. The primary endpoint was the proportion of patients in clinical remission at Week 44. Secondary endpoints included the proportion of patients maintaining clinical response through Week 44, the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 44, the proportion of patients with corticosteroid-free clinical remission at Week 44, and the proportion of patients maintaining clinical remission through Week 44 in patients who achieved clinical remission 8 weeks after induction. **Patients who completed the maintenance study through Week 44 were eligible to continue treatment through Week 96.**

(3) The 837 Patent

[30] On September 24, 2019, Janssen filed in Canada a patent application for the 837 Patent. The 837 Patent, entitled "Safe and effective method of treating ulcerative colitis with anti-IL 12/IL23 antibody", claims priority from three U.S. provisional patents applications, the earliest one having been filed on September 24, 2018.

[31] The 837 Patent contains 68 claims generally directed toward the use of an anti-IL-12/IL-23p40 antibody (including ustekinumab) for the treatment of moderately to severely active ulcerative colitis, where the subject failed to respond to or was intolerant of at least one enumerated therapy or the subject demonstrated corticosteroid dependence and compositions for use in such treatment.

[32] The claims of the 837 Patent are directed to the treatment of ulcerative colitis, including numerous claims where the clinical response of the subject "continues at least 44 weeks after week 0".

[33] The 837 Patent was issued on July 12, 2022.

[34] On July 25, 2022, Janssen sought to list the 837 Patent in relation to SNDS 670 by submitting three Form IVs for the 837 Patent (one for each DIN).

[35] No Form IV was ever submitted for the 837 Patent in relation to SNDS 739. The deadline by which Janssen could have submitted a patent list for SNDS 739 (as prescribed by subsection 4(6) of the *PMNOC Regulations*) was August 11, 2022. There is no evidence in the record as to why this was not done.

F. OSIP's Preliminary Decision

[36] By letter dated July 29, 2022, OSIP acknowledged receipt of Janssen's patent lists for the 837 Patent in relation to SNDS 670. OSIP advised Janssen, in detail, of the basis for its preliminary view that SNDS 670 was not approved for a change in use of the medicinal ingredient and as such, SNDS 670 did not provide a basis to list the 837 Patent. Even if SNDS was considered to be approved for a change in use of a medicinal ingredient, OSIP advised that its preliminary view was that the 837 Patent did not contain a claim to the very change sought for approval in the submission.

[37] OSIP also noted the existence of SNDS 739 and that had a patent list been submitted in respect of the 837 Patent and SNDS 739, it would not meet the timing requirements of subsection 4(6), as the filing date for SNDS 739 was February 15, 2019 and the date of filing in Canada of the 837 Patent was subsequent to that date.

[38] OSIP requested that Janssen provide representations as to the eligibility of the 837 Patent for listing on the patent register in respect of SNDS 670.

G. Janssen's Response to the Preliminary Decision

[39] By letter dated September 14, 2022, Janssen provided detailed submissions in response to OSIP's request. With respect to SNDS 670, Janssen asserted that the 837 Patent claims [redacted] are a new method of use approved through SNDS 670, which is the submission against which Janssen originally sought listing on July 19, 2022. Janssen asserted that it was of the view that the 837 Patent is also listable as against SNDS 739 and that there are in fact no timing issues under subsection 4(6) as the only rational date to be used is the claim date and not the Canadian filing date. Janssen asserted that the use of the Canadian filing date in the *PMNOC Regulations* was illogical, arbitrary and *ultra vires* the scheme of the *Patent Act* and of the *PMNOC Regulations* themselves. Janssen asserted that OSIP ought to apply the intent of the *PMNOC Regulations* with respect to the timing of the patent and the submission under subsection 4(6) and when the claim date is properly applied, the 837 Patent is listable.

[40] In relation to Janssen's request that the 837 Patent also be listed in relation to SNDS 739, Janssen stated at footnote 2 of its submission:

> As a patent list was already submitted with respect to the '837 Patent within the requisite 30 days of its issuance we trust that the OPML will not consider this request to be out of time under subsection 4(6) of the *Regulations*. Further, we understand that the OPML has already considered the listing of the '837 Patent against SNDS 224739, as reflected in the Letter. If the OPML rejects this request, then we respectfully request that the OPML advise us of the reason and allow us an opportunity to respond.

[41] For reasons unknown to the Court, Janssen did not include a Form IV with its submission in relation to SNDS 739 and the 837 Patent.

[42] In support of its assertion that the 837 Patent claims [redacted] are a new method of use approved through SNDS 670, Janssen asserted that a clinician reviewing the new Product Monograph approved with SNDS 670 would change their prescribing practices, especially a clinician who may have been otherwise hesitant to prescribe STELARA beyond 44 weeks. Janssen supported this assertion regarding a clinician's understanding of the new additions to the Product Monograph with an expert statement from Dr. Brian Feagan and two publications.

[43] With respect to the publications, Janssen made the following submissions:

> A clinician's understanding of the additions to the Product Monograph is also reflected in publications reporting on the data collected for the treatment of patients with ustekinumab up to Week 96, including Panaccione R, et al. Ustekinumab is effective and safe for ulcerative colitis through 2 years of maintenance therapy. *Aliment Pharmacol Ther*. 2020; **52**: 1658-1675 ("Pannaccione (2020)"; enclosed). Panaccione (2020) concluded that the "efficacy of ustekinumab in patients with [ulcerative colitis] was sustained through 92 weeks" (abstract), that "[r]ates of symptomatic remission were maintained from Week 44 through Week 92" (page 1671), and that "[t]he results reported here in patients with moderately-to-severely active [ulcerative colitis], together with both clinical trial and registry data confirm the positive long-term efficacy and safety profile of ustekinumab-treated patients" (page 1672). With respect to safety, Panaccione (2020) concluded that "[n]o new safety signals were observed" (abstract) and that "[t]he safety profile observed for ustekinumab in the second year of maintenance treatment was consistent with that reported through the first year during the maintenance study and with the established ustekinumab safety profile" (page 1672). […]
>
> The importance of safety data for ustekinumab beyond one year was also stated in an integrated safety study, Sandborn WJ, et al. Safety

> of Ustekinumab in Inflammatory Bowel Disease: Pooled Safety Analysis Results from Phase 2/3 Studies. *Inflamm Bowel Dis*. 2021; **27(7)**: 994-1007 ("Sandborn (2021)", enclosed). Sandborn (2021) pooled data from six studies, including the UNIFI study for ulcerative colitis, through one year. The authors concluded (pages 1006-7):
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> > Though these and previously reported findings are reassuring, longer-term longitudinal data and larger (eg, real-world observational) studies are ongoing to confirm current findings of no increased malignancy risk with IL-12/23 inhibition.
> >
> > …
> >
> > There are several limitations to this study. In a lifetime disease, 1 year of treatment is relatively short; longer-term data will be needed to further support these findings. This may limit comparisons, especially for long latency events like malignancies or certain infections. Although the data contained in this article are only from clinical trials, limitations on interpretation may differ from outcomes observed in real-world.
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> The information added to the Stelara Product Monograph via SNDS 24470 thus provided clinicians with support of the safety findings made one year after that Sandborn (2021) indicated was required.
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> [Emphasis in original.]

[44] With respect to the expert statement of Dr. Feagan, Dr. Feagan is a gastroenterologist at London Health Sciences Centre and a Professor of Medicine at the Schulich School of Medicine and Dentistry at Western University, with a research focus on the design, conduct and execution of large-scale randomized controlled trials in Crohn's disease and ulcerative colitis. Dr. Feagan's mandate was to: (i) provide brief background information on ulcerative colitis and its treatment options (including STELARA); and (ii) to advise how, if at all, a clinician's prescribing practices would be influenced by the additions to the STELARA Product Monograph arising from the NOC

for SNDS 670. Dr. Feagan provided no evidence in relation to the aforementioned publications relied upon by Janssen.

[45] While Janssen did not make specific submissions related to Dr. Feagan's evidence (other than as detailed in paragraph 42 above), Dr. Feagan opined that community gastroenterologists (who are gastroenterologists not located in a teaching or research hospital) would "take comfort" in the additional information (as it would "alleviate fears relating to potential side effects") and would be more willing to prescribe or be more comfortable prescribing STELARA based on the additional information contained in the Product Monograph.

II. The Decision under Review

[46] On November 15, 2022, OSIP provided Janssen with its final decision. OSIP found that SNDS 670 was not approved for a change in formulation, change in dosage form or change in use of the medicinal ingredient and did not present an opportunity to list a patent on the Patent Register in accordance with subsection 4(3) of the *PMNOC Regulations*. OSIP noted that SNDS 670 amended STELARA's Product Monograph to include updated safety and efficacy data generated through an on-going study, which was the very same on-going study that had been previously included in the Product Monograph for SNDS 739. OSIP considered the text, context and purpose of subsection 4(3) of the *PMNOC Regulations*, the relevant jurisprudence and the submissions of Janssen, before concluding that updating the safety information in the product monograph did not result in a change in use in SNDS 670.

[47] OSIP went on to examine whether the 837 Patent would have been eligible for listing if one were to assume that SNDS 670 was in fact for a change in use. However, OSIP found that the 837 Patent did not contain a claim to the very change that Janssen alleged was approved by the NOC for SNDS 670 as required by subsection 4(3).

[48] In relation to SNDS 739, OSIP determined that Janssen had not filed a patent list to add the 837 Patent to the Patent Register against SNDS 739. The OSIP went on to find that, even if Janssen had submitted a patent list to add the 837 Patent against SNDS 739, Janssen would not have met the timing requirements in subsection 4(6) of the *PMNOC Regulations,* as the 837 Patent application was filed in Canada after the filing date of SNDS 739. OSIP held that to consider the claim date/priority date (as opposed to the Canadian filing date) as the appropriate date when assessing the application of subsection 4(6) as urged by Janssen would be to ignore the clear words of the *PMNOC Regulations*, circumvent the strict timing requirements and undo the balance struck by the *PMNOC Regulations* and subsection 55.2(1) of the *Patent Act*.

III. Issue and Standard of Review

[49] This application raises the following issues:

A. Whether OSIP's decision not to add the 837 Patent to the Patent Register in relation to SNDS 670 and SNDS 739 was unreasonable and in particular:

i. Whether OSIP's determination that SNDS 670 was not approved for a change in use of the medicinal ingredient was unreasonable;

ii. Whether OSIP's determination that the 837 Patent was not eligible to be added to the Patent Register as it did not meet the product specificity requirements of paragraph 4(3)(c) was unreasonable; and

iii. Whether OSIP's determination that Janssen failed to provide a patent list in relation to SNDS 739 was unreasonable.

B. Whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

[50] The parties agree and I concur that the first issue is reviewable on a standard of reasonableness. When reviewing for reasonableness, the Court must determine whether the decision under review, including both its rationale and outcome, is transparent, intelligible and justified. A reasonable decision is one that is based on an internally coherent and rational chain of analysis and that is justified in relation to the facts and law that constrain the decision-maker [see *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 15, 85]. The Court must be able to trace the decision maker's reasoning without encountering any fatal flaws in the overarching logic and the Court must be satisfied that there is a line of analysis within the given reasons that could reasonably lead the decision maker from the evidence before it to the conclusion at which it arrived [see *Vavilov, supra* at para 102].

[51] A number of elements will generally be relevant in evaluating whether a given decision is reasonable, including the governing statutory scheme, other relevant statutory or common law, the principles of statutory interpretation, the evidence before the decision maker and facts of which the decision maker may take notice, the submissions of the parties, the past practices and decisions of the decision maker and the potential impact of the decision on the individual to whom it applies [see *Vavilov, supra* at para 106].

[52] Where a decision involves a matter of statutory interpretation, the Court does not undertake a *de novo* analysis of the question. Rather, the Court still undertakes a reasonableness review, examining the administrative decision as a whole, including the reasons provided and the outcome reached. An administrative decision maker's task is to interpret the contested provision in a manner consistent with the text, context and purpose, applying its particular insight into the statutory scheme at issue. The modern principles of statutory interpretation apply equally when an administrative decision maker interprets a provision. Where the meaning of a statutory provision is disputed in administrative proceedings, the decision maker must demonstrate in its reasons that it was alive to these essential elements [see *Vavilov, supra* at para 115-116, 120, 121].

[53] The Court will intervene only if it is satisfied there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency [see *Adenjij-Adele v Canada (Minister of Citizenship and Immigration)*, 2020 FC 418 at para 11].

[54] With respect to the second issue, both parties agree that the issue of whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act* is reviewable on a reasonableness standard. However, they disagree as to whether, as the Respondent asserts, the pre-*Vavilov* case law (and in particular, *Katz Group Canada Inc v Ontario (Health and Long-Term Care)*, 2013 SCC 64) remains instructive and applicable to *vires* challenges to regulations.

[55] Prior to *Vavilov*, the Supreme Court of Canada outlined the method to determine if regulations were *ultra vires* in *Katz, supra* at paragraphs 24 to 28. The *Katz* approach requires the party challenging the *vires* of the regulations to show that the regulations (which benefit from a presumption of validity) are inconsistent with the purposes and objectives of the enabling statute or the scope of the statutory mandate when read as a whole. The three parts to the *Katz* rule are: (1) the challenging party bears the burden of proof; (2) the Court is directed to take a broad and purposive approach to interpreting the challenged regulation and the enabling statute, consistent with general guidance on statutory interpretation; and (3) the challenging party must overcome the presumption that the regulations are valid, which can only be done by establishing that the regulations are irrelevant, extraneous or completely unrelated to objectives of the governing statute. In particular, the Supreme Court directs that a *vires* challenge does not involve assessing the policy merits of the regulations as the motives or other considerations (political, economic, social or partisan) are irrelevant.

[56] After *Vavilov* established a general framework for review of administrative decisions, this prompted a debate regarding the extent to which the principles established in *Katz* were affected

by *Vavilov.* Some decisions of this Court continued to be guided by the *Katz* approach, mindful of this debate [see *Innovative Medicines Canada v Canada (Attorney General)*, 2020 FC 725 at paras 66-72; *Bertrand v Acho Dene Koe First Nation*, 2021 FC 287 at paras 73-76].

[57] The Federal Court of Appeal weighed into this debate in *Portnov v Canada (Attorney General)*, 2021 FCA 171. Justice Stratas, writing for the Court, explained how the approach outlined in *Katz* had been overtaken by *Vavilov* and thus, the Federal Court of Appeal did not follow the guidance of *Katz* but applied reasonableness review as per *Vavilov* [see *Portnov, supra* at paras 18-28].

[58] The Federal Court of Appeal weighed in again in *International Air Transport Association v Canadian Transportation Agency*, 2022 FCA 211, also considering the jurisprudence on whether courts reviewing the validity of regulations should apply a *Vavilov* standard of review analysis or the *ultra vires* doctrine from *Katz.* In *International Air Transport Association*, the appellant challenged numerous provisions of new regulations (in particular, challenging the Minister's Direction requiring the Agency to make regulations in respect of tarmac delays of three hours or less) on the basis that they exceeded the Agency's authority under the *Canada Transportation Act*. The Federal Court of Appeal discussed the analytical framework in the *Dunsmuir* era, wherein the reviewing court interpreted the statutory grant of authority to determine whether it fell within or outside its ambit. Justice de Montigny, writing for the Court, goes on to discuss the judicial review framework that was later applied in cases such as *Katz*, concluding that *Vavilov* did not bring clarity to the confusion around what framework to apply in the context of delegated legislation. Further, the *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11, wherein the

Supreme Court reviewed the validity of regulations at issue, made no mention of the *ultra vires* doctrine or *Vavilov* and reasonableness review. The Federal Court of Appeal noted that the issue is far from settled:

> [188] Unfortunately, *Vavilov* did not bring much clarity to that confusion. Because the Supreme Court purported to adopt the reasonableness standard as the default standard of review to all administrative actions, most intermediate appeal courts adopted the view that delegated legislation would henceforth be reviewed against that standard: see, for example, *1193652 B.C. Ltd. v. New Westminster (City)*, 2021 BCCA 176 at paras. 48-59; *Portnov v. Canada (Attorney General)*, 2021 FCA 171; *Canadian Association of Refugee Lawyers v. Canada (Citizenship and Immigration)*, 2020 FCA 196 [2021] 1 F.C.R. 271; Paul Daly, "Regulations and Reasonableness Review" (January 29, 2021), online (blog): *Administrative Law Matters* <https://www.administrativelawmatters.com/blog/2021/01/29/regulations-and-reasonableness-review/and the cases cited therein>.
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> [189] This approach, however, has not been followed unanimously: see, for example, *Hudson's Bay Company ULC v. Ontario (Attorney General)*, 2020 ONSC 8046, 154 O.R. (3d) 103; *Friends of Simcoe Forest Inc. v. Minister of Municipal Affairs and Housing*, 2021 ONSC 3813 at para. 25. Indeed, the reasonableness standard review is fraught with difficulties, not the least of which is that it assumes the body or person that has been granted the power to adopt delegated legislation has also been vested with the power to decide questions of law and to determine the proper interpretation of the habilitating statute; yet, this is obviously not always the case: see John M. Evans, "Reviewing Delegated Legislation After *Vavilov*: *Vires* or Reasonableness?" (2021) 34:1 Can. J. Admin. L.& P. 1.
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> [190] More recently, the Supreme Court has brought grist to the mill of those who support the view that the *Vavilov* judicial review framework does not apply to delegated legislation. In *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11, 455 D.L.R. (4th) 1 [*Ref re Greenhouse Gas*], the Court reviewed the validity of the regulations at issue on the basis of its own interpretation of the enabling statute, without expressing any deference to Cabinet on the interpretative issue. It is true that the majority (in contrast to the dissenting opinion of Rowe J.) made no mention of the *ultra*

> *vires* doctrine, but neither did it refer to *Vavilov* nor to reasonableness review. On the contrary, the majority took it upon itself to interpret the scope of the regulation-making powers found in the *Greenhouse Gas Pollution Pricing Act*, S.C. 2018, c. 12. While this is clearly not the last word on the subject, it signals at the very least that the issue is far from settled.
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> [191] That being said, and whether we assess the validity of the Direction and of section 8 of the Regulations through the lens of the reasonableness standard of review or through the more exacting prism of the ultra vires doctrine, the result would be the same. For the appellants to succeed with their argument that subsection 86.11(2) of the CTA does not encompass the power to issue the *Direction* (and section 8 of the Regulations) because it relates to matters covered at paragraph 86.11(1)(f), they would have to show either that the Direction: 1) is irrelevant, extraneous or completely unrelated to the statutory purpose (*Katz* at para. 28; *Shell Canada Products Ltd. v. Vancouver (City)*, [1994] 1 S.C.R. 231, 1994 CanLII 115 (SCC) at p. 280), or 2) rests on an unreasonable interpretation of subsection 86.11(2). If the *Direction* (and section 8 of the CTA) satisfies the more exacting *ultra vires* framework, it will obviously meet the less stringent reasonableness standard of review analysis.

[59] However, in its most recent decision in *Innovative Medicines Canada v Canada (Attorney General)*, 2022 FCA 210, Justice Stratas, writing on behalf of the Court, held that *Portnov*, a unanimous and binding decision of this Court, binds future panels of the Federal Court of Appeal (and thus this Court), such that the methodology to be used to assess a regulation is that set out in *Vavilov*, not *Katz* [see *Innovative Medicines, supra,* at paras 26-27].

[60] The Federal Court of Appeal offers specific guidance in *Innovative Medicines, supra,* to the review of regulations enacted by the Governor in Council:

> [39] …Under *Vavilov*, the broader the regulation-making power in a statute, particularly in matters of policy that are quintessentially the preserve of the executive, the less constrained the regulation-

> maker will be in enacting the regulation: *Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100, [2021] 1 F.C.R. 374 at para. 28 (applying *Vavilov* and earlier cases consistent with it), aff'd 2022 SCC 30.
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> [40] This is especially so for the Governor in Council. The Governor in Council is "at the apex of the executive", serves as "the grand co-ordinating body for the divergent provincial, sectional, religious, racial and other interests throughout the nation", and represents "different geographic, linguistic, religious, and ethnic groups": *Canada (Citizenship and Immigration) v. Canadian Council for Refugees*, 2021 FCA 72, 458 D.L.R. (4th) 125 at paras. 36-38. Thus, subject to limiting statutory language passed by our elected representatives, the Governor in Council's regulation-making power is often relatively unconstrained. The key is the limiting statutory language. *Vavilov* goes straight to that key, focusing on what meanings the language of the regulation-making power can reasonably bear. *Katz* doesn't. […]

[61] In conducting a reasonableness review, the Court is to assess the constraints on the administrative decision-maker (the primary constraint being the empowering legislation) and whether the decision maker has remained within them. The Court is entitled to look at the reasons offered by the decision maker, associated documents that shed light on the reasoning process, any submissions made to the decision maker and the record before the decision maker. In the case of decisions of the Governor in Council, reasoned explanations can often be found in the text of the legal instrument it is issuing, prior legal instruments related to it and any associated RIAS. Express explanations can be quite brief, yet still "pass muster" [see *Portnov*, *supra* at paras 33-34; *Innovative Medicines, supra* at para 44].

[62] I am satisfied that in this case, as no exception set out in *Vavilov* to reasonableness review applies, the standard of review is reasonableness and that the Court is to be guided by *Vavilov* (not

Katz) and the cases of the Federal Court of Appeal that apply *Vavilov* in conducting its reasonableness review.

IV. Analysis

A. OSIP's decision not to add the 837 Patent to the Patent Register for SNDS 670 and SNDS 739 was reasonable

[63] Paragraph 4(3)(c) of the *PMNOC Regulations* sets out the relevant product specificity requirement that must be met for a patent to be listed on the Patent Register in relation to an SNDS. A patent is eligible to be added to the Patent Register if: (i) the SNDS is for a "change in use of the medicinal ingredient"; and (ii) the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of an NOC in respect of the SNDS.

[64] In relation to SNDS 670, Janssen takes issue with OSIP's determination that: (a) SNDS 670 was not for a change of use of a medicinal ingredient; and (b) that the 837 Patent does not contain a claim for the alleged changed use of the medicinal ingredient. I will address those issues in turn.

[65] In relation to SNDS 739, Janssen takes issue with OSIP's determination that no patent list to add the 837 Patent was filed by Janssen in relation to SNDS 739. The *vires* of the filing date requirement in subsection 4(6) of the *PMNOC Regulations* and its impact on Janssen's ability to add the 837 Patent to the Patent Register in relation to SNDS 739 is addressed separately below.

(1) OSIP's determination that SNDS 670 was not approved for a change in use of the medicinal ingredient was reasonable

[66] Before turning to Janssen's submissions and a consideration of the decision under review, I want to begin by looking at any prior consideration (judicial or otherwise) of the phrase "a change in use of the medicinal ingredient".

[67] The phrase "change in the use of a medicinal ingredient" is not defined in the *Patent Act* or the *PMNOC Regulations*.

[68] One can have reference to subsection 2(1) of the *PMNOC Regulations* which defines a "claim for the use of the medicinal ingredient". Subsection 4(1) permits a first person to submit a patent list in relation to an NDS and paragraph 4(2)(d) provides that a patent on a patent list in relation to an NDS is eligible to be added to the register if the patent contains a "claim for the use of the medicinal ingredient" and the use has been approved through the issuance of an NOC in respect of the NDS. While the focus of paragraph 4(2)(d) is on whether the patent contains a claim for the changed use of a medicinal ingredient, it is focused on the "use of the medicinal ingredient" that is later sought to be "changed" in paragraph 4(3)(c). A "claim for the use of the medicinal ingredient" is defined in subsection 2(1) to mean "a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms".

[69] In *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 244, one of the issues before the Court was whether the patent at issue contained a claim for the very change in use that was approved by the issuance of an NOC with respect to an SNDS. In that case, it was not disputed that a new indication for a drug (to treat NSAID ulcers) constituted a change in use in the medicinal ingredient.

[70] In *Solvay Pharma Inc v Canada (Attorney General)*, 2009 FC 102, this Court dismissed an application for judicial review of a decision of the Minister refusing to add Solvay's patent to the Patent Register pursuant to paragraph 4(3)(c). The Minister had refused to add the patent as the SNDS against which listing was sought did not approve a change in use of the medicinal ingredient. The drug in question, AndroGel, had initially been approved on the basis of safety and efficacy information from a clinical trial following patients to whom the drug was administered for six months. Solvay filed an SNDS to provide additional safety and efficacy information following the extension of that clinical trial to 42 months, including making associated updates to the Product Monograph. An NOC issued in connection with the SNDS and indicated that the reason for the SNDS was to "Update PM with long term extension study results".

[71] Solvay asserted that the SNDS approved a change in use of the medicinal ingredient "as the safe and effective duration of use is extended and important changes to the implied use of the product, as authorized to be described in the Product Monograph, are clearly the essential subject of the SNDS". The Minister rejected this argument and also found that the patent did not contain a claim for the changed use introduced in the Product Monograph by way of the SNDS. Specifically, the Minister held that the patent did not contain "a claim for the changed use of the

medicinal ingredient, for the long term use and relative safety of AndroGel". Rather, the Minister held that the uses of AndroGel are the same uses that were previously approved by an earlier SNDS.

[72] The Court found that the evidence supported the Minister's conclusion that Solvay did not meet either requirement for the listing of its patent on the Patent Register. With respect to the first requirement – that the SNDS represent a change in use of the medicinal ingredient – the Court held:

> [79] The evidence in the record satisfies me that the SNDS, filed on March 11, 2005, did not represent a change in use of the medicinal ingredient of AndroGel testosterone in the form of topical gel. The jurisprudence supports the proposition that "change in use" as that term is used in subsection 4(3) of the NOC Regulations is measured by the approved use in AndroGel's product monograph, as approved by Health Canada, which is described in the Indications and Clinical Use section of that document. AndroGel is indicated for hormone replacement therapy in men suffering from conditions associated with a testosterone deficiency. No change of indication and use was made to Solvay's AndroGel product monograph as a result of the 2006 NOC.

[73] In discussing the amendments to the *PMNOC Regulations* in 2006, the 2006 RIAS also provides some insight into the intended meaning of the phrase "a change in use of the medicinal ingredient", where it states:

> The amendments to section 4 also formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right. Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for <u>a change in use of the medicinal</u>

> ingredient (i.e. a new method of use or new indication), a change in formulation or a change in dosage form and the patent contains a claim to the formulation, dosage form or use so changed…
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> [Emphasis added.]

(a) ***Janssen's submissions***

[74] Janssen asserts that OSIP's determination that SNDS 670 was not approved for a change in use is an improper fettering of OSIP's decision making power and is unreasonable. If a clinician's change in treatment duration or in prescribing practices would be changed by an SNDS, Janssen asserts that this should be sufficient to establish a change in use.

[75] Janssen asserts that OSIP's decision was unreasonable in light of the evidence before them – namely, the expert statement of Dr. Feagan and the two studies. In relation to Dr. Feagen, Janssen asserts that his evidence clearly demonstrated that the additional safety data would change prescribing practices of a community gastroenterologist. In the absence of any competing evidence procured by OSIP, Janssen asserts that there is no reasonable basis upon which OSIP could conclude that the approved health and safety data regarding the 96-week treatment and safety profile of STELARA in SNDS 670 is not a change in use.

[76] Janssen also points to the Sandborn and Panaccione studies, in which Janssen asserts the authors commented on the need for longer-term data to confirm findings of no increased malignancy risk with IL-12/23 inhibition. Janssen asserts that SNDS 670 provided that longer-term safety data that the authors called for and that Dr. Feagan stated would bring comfort or

confidence to Canadian clinicians to prescribe STELARA beyond 44 weeks. While OSIP held that a clinician who was "up to date" on ulcerative colitis research could have referred to either of the two studies before the approval of SNDS 670 to obtain information and "comfort" regarding prescribing STELARA for a longer period of time, Janssen says that this is irrelevant and does not change the fact that the addition of safety data to the approved Product Monograph is a change in use. Moreover, Janssen asserts that OSIP's finding is unsupported by any expert evidence and importantly, would not apply to clinicians who are not up to date on ulcerative colitis research, which is the sector of clinicians that Dr. Feagan was opining about. Janssen notes that there is no requirement in paragraph 4(3)(c) that all physicians change their prescribing practices, rather simply that there be a change in use and that Janssen has demonstrated such a change.

[77] Janssen further asserts that OSIP unreasonably applied *Solvay* to conclude that the addition of safety data can never be a change in use, whereas there is no express exclusion of safety data from the possible changes in use that can be covered by paragraph 4(3)(c) of the *PMNOC Regulations*. At the hearing, Janssen argued that OSIP was "blinded" by the *Solvay* decision and it tainted the entirety of OSIP's assessment of the meaning of "change in use".

[78] Moreover, Janssen asserts that the *Solvay* decision was guided by the evidentiary record before OSIP and in this case, the evidentiary record is distinguishable. Specifically:

A. In *Solvay*, there was no evidence before the Minister to support the conclusion that the SNDS contained a change in use, whereas in this case, the Minister had the evidence of Dr. Feagan and the two studies.

B. In *Solvay*, the Office of Patent Submissions and Liaison had sought the opinion of Health Canada experts, who concluded that there was no change in use, whereas in this case, the Minister did not adduce any of its own expert evidence or contradict Janssen's expert evidence.

C. In *Solvay*, the Court held that the patent claims contain no limitation on the duration of use and that the patent did not address the issue of the duration of testosterone therapy, whereas in this case, the nexus to the patent is present as the 837 Patent [redacted]

[79] Janssen asserts that OSIP failed to take into consideration these distinctions and that each of the aforementioned points of distinction alone undermines OSIP's "strong reliance" on *Solvay* and establish that OSIP's decision was based on a misapprehension of the law and evidence, thus rendering it unreasonable.

[80] Janssen further asserts that OSIP's interpretation of the product specificity requirement of a "change in use of the medicinal ingredient" is inconsistent with the context, language and purpose of the *Patent Act* and the *PMNOC Regulations*. Janssen asserts that the Governor in Council enacted paragraph 4(3)(c) with the broad terminology of change in use and the 2006 RIAS confirms an intention that a change in use was broad enough to include a new indication and a new method of use. Janssen asserts that the RIAS supports an understanding that change in use is not

to be restricted to changes to particular sections of the Product Monograph and that a change in use includes changes in the duration of treatment.

[81] Janssen asserts that the *PMNOC Regulations* must be read in line with the purpose of the *Patent Act* and should be considered in light of the societal imperative of encouraging new and better medical therapies and the difficulties associated with protecting pharmaceutical patent rights by way of conventional infringement litigation. Janssen asserts that the *PMNOC Regulations* are intended to protect that which the innovator has invested time and money to test and have approved for sale (or put different, to protect the patentee's contribution to the public through skill and ingenuity). The clinical trial data in SNDS 670 is the result of time and money invested by Janssen to obtain safety data for STELARA in patients with moderately or severely active ulcerative colitis, the exact type of substantive change intended to be protected by the *PMNOC Regulations*. By adopting an unduly restrictive meaning to change in use, Janssen asserts that it is being improperly denied the full benefit of the patent protection it should be provided as part of the balance of the early working exception. Such an unduly restrictive meaning also, according to Janssen, reduces incentives to research the safety and efficacy of existing medicinal ingredients because it stands in the way of listing patents tied to such research.

[82] Moreover, Janssen notes that the product specificity requirements were intended to prevent the listing of patents in respect of SNDSs for purely administrative changes (such as changes of manufacturer) and asserts that SNDS 670 is not akin to an administrative change.

(b) ***Consideration of Janssen's submissions***

[83] In interpreting a “change in use of the medicinal ingredient”, the 2006 RIAS provides guidance that a change in use can be a new indication or a new method of use, but cannot be an administrative change (such as a change in drug or company name). There is no dispute that SNDS 670 was not for a new indication, as the treatment of ulcerative colitis was added to the Product Monograph by SNDS 739.

[84] The question then becomes whether, on the record before OSIP and considering the text, context and purpose of section 4(3)(c) of the *PMNOC Regulations*, the guidance provided by the RIAS, this Court’s decision in *Solvay* and Janssen’s submissions, OSIP reasonably determined that SNDS 670 was not approved for a change in use.

[85] In reaching their decision, OSIP considered the following evidence that was before them:

A. The existing Product Monograph as approved in relation to SNDS 739 approved STELARA to be used to treat adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies. That approved use did not include a limitation on the duration of time STELARA could be used to treat ulcerative colitis (notwithstanding that the clinical trial data was limited to 44 weeks). Moreover, SNDS 670 did not seek to add a limitation on the duration of time STELARA could be used to treat ulcerative colitis.

B. The relevant NOC stated that SNDS 670 was approved for updates to the Product Monograph.

C. SNDS 670 did not result in any changes to the "Indications and Clinical Use" section of the product monograph, but rather only added safety and efficacy date to the "Clinical Trial Adverse Drug Reaction" and "Study Demographics and Trial Design" sections of the Product Monograph.

D. Dr. Feagan's evidence was that community gastroenterologists would "take comfort" in the additional information and would be more willing to prescribe or be more comfortable prescribing STELARA based on the additional information contained in the Product Monograph. However, he did not state that community gastroenterologists (or any other gastroenterologists) would not have prescribed STELARA for longer than 44 weeks based on the prior Product Monograph.

E. In Janssen's Product Information Regulatory Enrollment Process form, Janssen wrote (as opposed to checking a box) in relation to SNDS 670 that "there are no changes to the indication/Use/Dosage (including the maximum daily dose)".

[86] OSIP properly considered the aforementioned evidence, the text, context and purpose of the *PMNOC Regulations* (which I will address more fully below), considered the guidance provided in the 2006 RIAS, considered this Court's decision in *Solvay* (which I will also address in more detail below) and considered the submissions of Janssen before concluding as follows:

The OSIP recognizes that a change to the method of use of a medicinal ingredient can be reflected in sections of the product monograph other than the "Indications and Clinical Use" section. For example, the "Contraindications", "Warning and Precautions", and "Dosage and Administration" sections. However, the OSIP disagrees with Janssen's characterization that SNDS 244670 was approved for such a change. Rather, as detailed above, the OSIP is of the view that SNDS 244670 was approved for updates to the product monograph to include results from the long-term extensions of two Phase 3 studies for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis.

Following the approval of SNDS 224739, STELARA (I.V.) could be used in the treatment of ulcerative colitis for an indefinite period of time. Both Janssen and Dr. Feagan submit that a clinician would change their prescribing practices upon reading the two sentences added to the STELARA (I.V.) product monograph following the approval of SNDS 244670. It is the position of Janssen and Dr. Feagan that the clinician practice would have changed given their increased comfort in prescribing STELARA (I.V.) beyond 44 weeks. However a clinician's reluctance to prescribe a drug is not a limitation on the approved use of that drug.

Clinicians were not prevented from prescribing the drug for the long-term use in treating ulcerative colitis. Dr. Feagan states at paragraph 21 that a community gastroenterologist may not be up to date on ulcerative colitis research and would have concerns about the potential for issues to arise after one year's administration of STELARA (I.V.). Therefore, a clinician who was up to date on ulcerative colitis could have referred to either of the two studies enclosed in Janssen's representations before the approval of SNDS 244670 and could have obtained the comfort needed to change their prescribing practices in accordance with the use for which SNDS 224739 was approved. In any event, a submission approved for additional data that could provide a clinician more confidence in prescribing a drug long-term is not sufficient for the submission to be considered as having been approved for a change in use of the drug if the indication never included a temporal restriction on its use.

Implicit in Janssen's position is the idea that the use of STELARA (I.V.) was limited by the period of time during which ustekinumab was administered to patients in the clinical trials underlying the approval of SNDS 224739. Janssen had made this position explicit on page 7 of its representations, where it states that the use set out in SNDS 224739 is for the treatment of ulcerative colitis "for up to 44 weeks". The OSIP disagrees with Janssen's position that the

> length of time for which STELARA (I.V.) could be used was limited. No such limitation was provided in the STELARA (I.V.) product monograph. As STELARA (I.V.) was approved for the use in treating ulcerative colitis for an indefinite period of time, the inclusion of updates to the product monograph to include results from the long-term extension of two Phase 3 studies could not have changed the approved use of STELARA (I.V.), irrespective of any additional confidence the information may provide clinicians.
>
> As noted above, the Federal Court considered substantially similar facts in *Solvay* and held that the inclusion of safety and efficacy information into the product monograph following an extension of a clinical trial did not constitute a change to the use of the medicinal ingredient as required by paragraph 4(3)(c) of the *PM(NOC) Regulations*. Similarly, the inclusion of updates to the STELARA (I.V.) product monograph to include results from the long-term extensions of two Phase 3 studies does not meet the requirements of paragraph 4(3)(c) of the *PM(NOC) Regulations*.
>
> [Emphasis added.]

[87] I find that OSIP's decision is based on an internally coherent and rational chain of analysis and is justified in relation to the facts and law that constrain OSIP. I see nothing unreasonable about OSIP's focus, in its interpretation and application of paragraph 4(3)(c), on the actual approved use of STELARA (i.e. the use as approved by the Minister) and not the prescribing practices of clinicians, as that which is being "changed" in subsection 4(3) is the use as previously approved by the Minister.

[88] I will now turn to address the specific arguments raised by Janssen.

[89] Turning first to the evidence of Dr. Feagan, OSIP clearly considered Dr. Feagan's evidence and did not dispute his statements regarding the influence that the additional safety and efficacy data would have on certain gastroenterologists. However, OSIP's decision turned on their

determination that STELARA was approved for use to treat ulcerative colitis with no temporal limitation on its use and that a clinician's reluctance to prescribe a drug is not a limitation on the approved use of that drug. Similarly, OSIP considered the two studies and regardless of whether a clinician may or may not have read the studies, OSIP found that a submission approved for additional data that could provide a clinician more confidence in prescribing a drug long-term is not sufficient for the submission to be considered as having been approved for a change in use of the drug if the indication never included a temporal restriction on its use. I see no error on OSIP's part in reaching these conclusions.

[90] With respect to *Solvay*, I reject Janssen's characterization of OSIP's treatment of the decision. On a fair reading, OSIP's reasons do not state that the addition of safety data can never be a change in use. Rather, OSIP considered this Court's decision in *Solvay*, outlined the facts of that case and summarized the Court's findings. OSIP noted the factual similarities between this case and *Solvay* and noted that its finding was supported by the Court's reasoning in *Solvay*.

[91] Janssen's suggestion that OSIP was "blinded" by *Solvay* and that *Solvay* tainted the entirety of OSIP's decision is baseless. OSIP is obligated to follow applicable precedents originating from this Court [see *Bank of Montreal v Li*, 2020 FCA 22 at para 37] and given the factual similarities between the two cases, it was reasonable for OSIP to rely on *Solvay* as an influential precedent. Moreover, a fair reading of OSIP's 23-page decision reveals that OSIP considered all relevant factors in interpreting and applying paragraph 4(3)(c), not just *Solvay*.

[92] While Janssen has attempted to distinguish *Solvay* and faults OSIP for failing to take into account the factual differences between the two cases, I would note that Janssen did not raise *Solvay* with OSIP or put any of its purported distinguishing facts to OSIP to suggest that OSIP should not follow *Solvay*. In any event, I am not satisfied that the factual differences identified by Janssen render OSIP's reliance on *Solvay* unreasonable. OSIP did not state that the two cases were identical, but rather that they were similar and the presence or absence of expert evidence did not play a central role in OSIP's determination that there had not been a change in use in either case. As for Janssen's third argument, that argument relates to the next issue and thus I will address it there.

[93] Moreover, while Janssen made much of the fact that Dr. Feagan's evidence was uncontradicted and that OSIP had failed to secure its own expert evidence on the issue of change of use, this ignores the fact that the burden rested on Janssen to demonstrate that it meets the product specificity requirements of the *PMNOC Regulations*. OSIP was under no obligation to produce an expert statement in response to Dr. Feagan or that otherwise addressed the issue of change in issue. As noted by the Respondent, the only obligation on OSIP was to make a reasonable and procedurally fair determination of the issues before them and in doing so, OSIP was entitled to rely on OSIP's own expertise.

[94] I also reject Janssen's submissions that OSIP's interpretation of the product specificity requirement is inconsistent with the context, language and purpose of the *Patent Act* and *PMNOC Regulations*. I begin by noting that there is no express inconsistency between OSIP's interpretation

of subsection 4(3) and the *Patent Act*. Rather, what Janssen asserts is that there is a "conceptual" inconsistency between the two.

[95] It must be recalled that OSIP agreed with Janssen's interpretation of subsection 4(3) in part, expressly acknowledging that a change in use of a medicinal ingredient includes a change to the method of use (as recognized in the 2006 RIAS) and that a change to the method of use can be reflected in sections of the Product Monograph other than the "Indications and Clinical Use" section. Where OSIP and Janssen part ways is on the question of whether a change in use of the medicinal ingredient in subsection 4(3) includes the "change" asserted by Janssen.

[96] It is clear from a review of OSIP's reasons that OSIP was very much alive to the dispute between OSIP and Janssen as to the interpretation of subsection 4(3). In considering the reasonableness of OSIP's interpretation of subsection 4(3), the Court is guided by the following commentary of the Federal Court of Appeal in *Canada (Minister of Citizenship and Immigration) v Mason*, 2021 FCA 156:

> [16] *Hillier* begins by reminding reviewing courts of three basic things they should appreciate when conducting reasonableness review. First, in many cases, administrators may have a range of interpretations of legislation open to them based on the text, context and purpose of the legislation. Second, in particular cases, administrators may have a better appreciation of that range than courts because of their specialization and expertise. And, third, the legislation--the law on the books that reviewing courts must follow--gives administrators the responsibility to interpret the legislation, not reviewing courts.
>
> [17] For these reasons, *Hillier* tells reviewing courts to conduct themselves in a way that gives administrators the space the legislator intends them to have, yet still hold them accountable. Reviewing courts can do this by conducting a preliminary analysis of the text,

context and purpose of the legislation just to understand the lay of the land before they examine the administrators' reasons. But the lay of the land is as far as they should go. They should not make any definitive judgments and conclusions themselves. That would take them down the road of creating their own yardstick and measuring the administrator's interpretation to make sure it fits.

[18] Instead, *Hillier* recommends (at para. 16) that a reviewing court should "focus on the administrator's interpretation, noting what the administrator invokes in support of it and what the parties raise for or against it", trying to understand where the administrator was coming from and why it ruled the way it did: *Hillier* at paragraph 16.

[19] Under this approach, the reviewing court does not act in an "external" way, i.e., "arrive at a definitive conclusion about the best way to read the statutory provision under review before considering how the [administrator's] interpretation matched up with [the] preferred reading". Rather, as Professor Daly has observed, the reviewing court acts in an "internal" way, i.e., "a relatively cursory examination of the provision at issue, with a view to analyzing the robustness of the [administrator's] interpretation". See Paul Daly, "Waiting for Godot: Canadian Administrative Law in 2019" (online: https://canlii.ca/t/t23p at 11).

[20] By necessary implication, *Vavilov* supports the *Hillier* approach. *Vavilov* warns us that even though reviewing courts are accustomed in other contexts to interpret legislative provisions themselves, when conducting reasonableness review of administrative interpretations they should avoid that. Reviewing courts must not "ask how they themselves would have resolved [the] issue", "undertake a *de novo* analysis", "ask itself what the correct decision would have been" or "[decide] the issue themselves": *Vavilov,* at paragraphs 75, 83 and 116. In other words, reviewing courts must not "make [their] own yardstick and then use that yardstick to measure what the administrator did": *Vavilov,* at paragraph 83, citing *Delios,* at paragraph 28. Instead, reviewing courts must exercise "judicial restraint" and respect "the distinct role of administrative decision makers": *Vavilov,* at paragraph 75. They are to do this by examining the administrator's reasons with "respectful attention" and by "seeking to understand the reasoning process": *Vavilov,* at paragraph 84.

[97] Determining the meaning of “change in use of the medicinal ingredient” very much falls within OSIP’s area of expertise. In arriving at their interpretation of that phrase, OSIP considered the plain wording of subsection 4(3) and related provisions of the *PMNOC Regulations* and the intent of the 2006 amendments to subsection 4(3) as reflected in the 2006 RIAS (as cited above) and as acknowledged by the Court of Appeal in *GD Searle & Co v Canada (Health)*, 2009 FCA 35. I see nothing unreasonable with that approach and OSIP’s reasons allow the Court to understand how the text, context and purpose of the *PMNOC Regulations* factored into its reasoning process in arriving at its interpretation of subsection 4(3).

[98] There is no dispute between the parties as to the purpose of the *Patent Act* and the protections that it affords to innovators. However, I reject Janssen’s assertion that OSIP’s interpretation improperly denies Janssen the full benefit of the patent protection it should be provided as part of the balance of the early working exception. As stated above, the *PMNOC Regulations* seek to balance the patent rights associated with innovative drugs against the timely market entry of lower-priced competitor drugs [see *Fresenius Kabi Canada Ltd* v *Canada (Health)*, 2020 FC 1013]. In striking that balance, the product specificity requirements reflected in section 4 inherently acknowledge that not every patent is eligible for listing on the Patent Register, notwithstanding the time and money invested by the innovator. As noted by this Court in *Solvay*, supra at paragraph 69:

> …Under the heading Patent Listing Requirements, the RIAS states, at page 1511, that the NOC Regulations "are intended to operate as a very potent patent enforcement mechanism", citing the 24-month automatic stay when an innovator launches a prohibition application, adding that "it is this very potency which calls for moderation in the application" with the result that "[o]nly those

> patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to ... register and to the concurrent protection of the 24-month stay."
>
> [Emphasis added.]

[99] It must also be recalled that Janssen is not without the protections of the *Patent Act* under OSIP's interpretation, retaining the right to bring a patent infringement action outside of the PMNOC regime.

[100] Subsection 4(3) limits the subset of patents eligible for listing and I am not satisfied that Janssen has demonstrated how OSIP's interpretation unreasonably denies Janssen the patent protection intended by the balance struck by the *PMNOC Regulations*.

[101] Having determined that OSIP's decision that SNDS 670 did not meet the first product specificity requirement of paragraph 4(3)(c) was reasonable, Janssen's application in relation to the listing of the 837 patent in relation to SNDS 670 cannot succeed. While I need not do so, I will nonetheless go on to consider whether OSIP's determination in relation to the second product specificity requirement was reasonable.

(2) OSIP's determination that the 837 Patent was not eligible to be added to the Patent Register as it did not meet the product specificity requirements of paragraph 4(3)(c) was reasonable

[102] In considering whether the patent sought to be listed in relation to a particular SNDS meets the product specificity requirement of paragraph 4(3)(c) of the *PMNOC Regulations*, OSIP was

required to apply what is known as the *Abbott* test, as originally set out by Justice Hughes in *Abbott Laboratories Limited v Canada (Attorney General)*, 2008 FC 700 and later affirmed in *Canada (Attorney General) v Abbott Laboratories Limited*, 2008 FCA 354 and applied by the Federal Court of Appeal in a number of other cases, such as *Searle, supra*, *Purdue Pharma v Canada (Attorney General)*, 2011 FCA 132, *Gilead Sciences Canada Inc v Canada (Health),* 2012 FCA 254 and *Eli Lilly Canada Inc v Canada (Attorney General)*, 2015 FCA 166.

[103] Pursuant to the *Abbott* test, OSIP was required to consider the following three questions: (i) what does the 837 Patent claim? (ii) what is the change approved by SNDS 670? and (iii) does the 837 Patent claim the very change approved in SNDS 670?

[104] The current version of the *PMNOC Regulations* makes product specificity between the patent claims and the NOC for the approved drug a key requirement for a patent to be considered eligible for listing on the patent register [see *Gilead, supra* at para 33]. Under the prior version of the *PMNOC Regulations*, if the patent claims were shown merely to be "relevant to" the approved drug, the submitted patents were generally accepted for listing. The wording of the current *PMNOC Regulations*, as well as their object and purpose, suggest that the product specificity requirement sets a high threshold of consistency between the patent claims and the NOC [see *Gilead, supra* at para 40].

[105] In *Canada* (*Attorney General*) *v Abbott Laboratories Limited*, 2008 FCA 244, leave to appeal refused, [2008] SCCA No 408, [2008] 3 SCR v (*Abbott Prevacid*) [*Abbott 244*], Justice Pelletier commented on the level of specificity required under paragraph 4(3)(*c*). The debate there

concerned the eligibility for listing of a patent in relation to an NOC issued pursuant to an SNDS approving a new use. The Federal Court concluded that the patent was eligible for listing because the patent could be construed as including the new approved use notwithstanding that it was not explicitly claimed in the patent. The Federal Court of Appeal disagreed, stating at paragraphs 47 and 49:

> It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.
>
> […]
>
> I conclude that paragraph 4(3)(*c*) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.
>
> [Emphasis added.]

[106] Before turning to Janssen's submission on this application, I note that before OSIP, Janssen asserted:

> Further and contrary to the clear wording of the *Regulations*, which simply requires "a claim for the changed use … that has been approved", in its Letter, the OPML instead identified what it framed as the very change approved in SNDS 244670 and asked whether the '837 Patent claims the "very change" approved in SNDS 244670. In doing so, the OPML's approach was too narrow and required a nexus between the change approved in SNDS 244670 and

> the ‘837 Patent that is more stringent than what is in fact required by the *Regulations*.

[107] Janssen’s aforementioned description of the product specificity requirement for the 837 Patent as prescribed by subsection 4(3) is reflective of the approach prior to the 2006 amendments to the *PMNOC Regulations* and inconsistent with the clear enunciation of the applicable test as affirmed repeatedly by the Federal Court of Appeal.

[108] Before this Court, Janssen persists with this position in part, refusing in its written submissions to agree with OSIP’s interpretation of subsection 4(3) and its application of the *Abbott* test, yet taking no issue with the application of the *Abbott* test at the hearing. There is no merit to any suggestion that OSIP has misconstrued the applicable legal test and I find that OSIP properly formulated and applied the *Abbott* test by requiring that the 837 Patent claim the “very change in use” approved for SNDS 670.

[109] Without agreeing with OSIP’s interpretation of the requirements of subsection 4(3), Janssen asserts that OSIP’s decision is unreasonable as the 837 Patent meets the “very change in use” standard, as the 837 Patent contains claims covering the [redacted].

[110] [redacted] do not take issue with OSIP’s determination in relation to step one of the *Abbott* test and [redacted], in simple terms, the 837 Patent claims the use of the antibody to treat ulcerative colitis for at least 44 weeks after week zero or for 44 weeks and after.

[111] For step two of the *Abbott* test, one would have to presume that the change in use is as proposed by Janssen (albeit rejected by OSIP) – namely, the addition of longer term safety data up to 96 weeks that changes prescribing practise so as to prescribe STELARA beyond 44 weeks.

[112] It is at step three of the *Abbott* test that the parties' positions regarding the reasonableness of OSIP's determination greatly diverge. I will begin with OSIP's reasons for decision on step three, which provide as follows:

> The '837 Patent does not contain a claim to the very change for which SNDS 244670 was approved. In particular, the '837 patent does not contain a claim directed toward the use of ustekinumab for the treatment of moderately to severely active ulcerative colitis wherein ustekinumab is administered for 96 weeks as maintenance therapy.
>
> As explained above and as set out by the Federal Court of Appeal in *Abbott FCA* and *Searle FCA*, in order to meet the requirements of paragraph 4(3)(c) of the *PM(NOC) Regulations*, the patent must contain a claim to the very changed use. While the '837 patent contains claims directed towards the use of ustekinumab for the treatment of moderately to severely active ulcerative colitis, the duration of time within which the use of ustekinumab is claimed as a maintenance therapy is not limited to 96 weeks. The OSIP is of the view that reference at page 52 of the '837 patent description that the anti-IL-12/IL-23p40 antibody, which may be ustekinumab, could be administered for a total of two years does not restrict the duration of time within which the anti-IL-12/IL-23p40 antibody could be used in any of the 837 patent claims.

[113] Janssen asserts that OSIP unreasonably imposed a standard of "exact matching" between claim language. Janssen asserts that it was sufficient that the claims of the 837 Patent include [redacted]

[114] Janssen asserts that OSIP placed unreasonable reliance on *Abbott 244*, which Janssen asserts is distinguishable from this case. Janssen asserts that in *Abbott 244*, the issue was whether a patent with claims to the treatment of ulcers generally claimed the very change in an SNDS approved for a new use of a drug to treat ulcers caused by non-steroidal anti-inflammatory drugs. In that case, the Court held that the patent did not specifically claim the changed use even though the changed use may come within the claims of the patent. By contrast, Janssen asserts that at least some of the 837 Patent's claims provide the required specificity [redacted]

[115] Janssen further asserts that *Solvay* is distinguishable, as none of the claims of the patent at issue contained a claim directed to the duration of treatment. By contrast, Janssen asserts that the 837 Patent has "claims that include [redacted]

[116] Janssen urged the Court to find that the circumstances in *Eli Lilly Canada Inc v Canada (Attorney General)*, 2015 FCA 166, were more akin to those in this case and that OSIP should have followed *Eli Lilly* rather than *Abbott 244* (despite Janssen not raising either authority with OSIP). In *Eli Lilly*, one of the issues before the Federal Court of Appeal was whether this Court had erred in determining whether the formulation claimed in the relevant patent was the formulation found in the appellant's drug submission for Trifexis. Janssen asserts that *Eli Lilly* is instructive as the Federal Court of Appeal held that a claim to a broader class of compound includes a specific compound in that class.

[117] I am not satisfied that Janssen has established that OSIP's determination regarding step three of the *Abbott* test is unreasonable. Rather, what Janssen urges the Court to do is to reassess the issue and come to a different result, which is not the role of the Court on an application for judicial review.

[118] I find that there was nothing unreasonable in OSIP's reliance on *Abbott 244*, which was a paragraph 4(3)(c) case. While Janssen urges the Court to find that *Eli Lilly* has somehow "overtaken" *Abbott 244*, I am not satisfied that that is the case. *Eli Lilly* was a change in formulation case, not a change in use case and on that basis alone, I find that it is distinguishable. More specifically, I agree with the Respondent that in *Eli Lilly*, at the first step of the *Abbott* test, the Federal Court of Appeal found that the general class of compounds that the patent claimed actually included the very specific formulation that was approved in the NDS. The Federal Court of Appeal found that in such circumstances, this Court was unreasonable in requiring identical wording at step three of the *Abbott* test. The circumstances in this case are distinct.

[119] As confirmed in *Abbott 244*, the *PMNOC Regulations* require that a patent specifically claim the change in use, as opposed to broader claims that are wide enough to subsume the specific change in use. With that principle in mind, I see nothing unreasonable in OSIP's determination that a patent having broad "temporal features" (as described by Janssen) for the use of ustekinumab for an indefinite period of time (for 44 weeks or more) is not the very change in use approved in relation to SNDS 670 (even on Janssen's interpretation thereof) which specifically included safety data to only 96 weeks.

[120] With respect to *Solvay*, I note that OSIP did not refer to *Solvay* in its reasons for decision on this issue.

[121] Accordingly, even if Janssen had established that OSIP's decision in relation to a "change in use of the medicinal ingredient" was unreasonable, Janssen's application in relation to the listing of the 837 patent in relation to SNDS 670 could not succeed on this ground either.

(3) OSIP's determination that Janssen failed to provide a patent list in relation to SNDS 739 was reasonable

[122] Janssen asserts that OSIP's determination that Janssen failed to file a patent list for the 837 Patent in relation to SNDS 739 was unreasonable as a patent list was filed for the 837 Patent within 30 days of the issuance of the 837 Patent and Janssen sought, by way of its September 14, 2022 submission, to add SNDS 739 to an already submitted patent list, given that it had been raised by OSIP in its preliminary decision letter. Janssen asserts that subsection 4(7) of the *PMNOC Regulations* obligates a first person to keep their patent list up to date, so the Minister clearly contemplated amendments to a patent list.

[123] Moreover, Janssen asserts that the *PMNOC Regulations* do not contain a requirement to add to a patent list by using Form IV, but rather only that a first person must provide all of the information set out in subsection 4(4). Janssen submits that its September 14, 2022 submission provided all of the necessary information prescribed by subsection 4(4). As such, to refuse to add the 837 Patent to the Patent Register on the basis that Janssen did not provide the same information

by way of a Form IV would be an unreasonably harsh result and an extreme example of "form over substance".

[124] Turning to OSIP's reasons for decision, OSIP held:

> The *PM(NOC) Regulations* do not permit a patent list to be submitted in relation to multiple submissions. As noted above, subsection 4(1) of the *PM(NOC) Regulations* allows a first person to seek to add a patent to the Patent Register by submitting a patent list to the Minister. The content of a patent list is prescribed by subsection 4(4). Notably, paragraph 4(4)(a) of the *PM(NOC) Regulations* requires that the patent list identify the submissions to which the patent list relates. The patent list submitted in accordance with 4(6) provides a section dedicated for this purpose and allows the first person to identify the submission in relation to which it submits the patent list.
>
> The patent lists submitted by Janssen seeking to add the '837 patent to the Patent Register identified SNDS 244670. Janssen did not seek to add the '837 patent to the Patent Register against SNDS 224739. Janssen's suggestion that the submission in relation to which a patent list was filed can shift after its receipt would ignore the operation of paragraph 4(4)(a) of the *PM(NOC) Regulations*. The statements made on page 7 of Janssen's representations purporting to change the submission in relation to which its patent lists were submitted are not akin to filing a patent list in accordance with subsection 4(1). As such, the OSIP is of the view that no patent list was filed in relation to SNDS 224739 and that Janssen has not met the requirements to seek to add the '837 patent against SNDS 224739.
>
> In addition, the OSIP disagrees with Janssen's view that the '837 patent was considered for addition to the Patent Register against SNDS 224739 in its preliminary decision letter dated July 29, 2022. Rather, the OSIP is of the view that the use for which SNDS 224739 was approved was included in its preliminary decision letter to contextualize the change for which SNDS 244670 was approved.

[125] I see nothing unreasonable in OSIP's analysis and determination of this issue. OSIP properly considered the requirements of subsection 4(4) of the *PMNOC Regulations*, noting that the regulations prescribe one SNDS per patent list (as also set out in Form IV) and to permit Janssen to add a second SNDS to a pre-existing patent list would run afoul of the express mandatory language of paragraph 4(4)(a), which limits a patent list to one SNDS.

[126] Moreover, I find nothing unreasonable in OSIP's determination that Janssen's attempt to change/amend the SNDS in relation to which its patent lists for the 837 Patent were submitted was not akin to filing a patent list. Janssen was well aware of the requirement to file one patent list per SNDS, given that it had already filed multiple Form IVs in relation to STELARA and given the language of paragraph 4(4)(a). Why Janssen did not file a patent list for SNDS 739 in relation to the 837 Patent is unknown, but Janssen is bound by the consequences of that decision.

[127] While not expressly addressed by OSIP, I would note that, even if I were inclined to find that Janssen's September 14, 2022 submission could constitute a patent list for the 837 Patent, Janssen's September 14, 2022 submission did not, in fact, contain all of the information required by subsection 4(4) of the *PMNOC Regulations*. For example, the submission does not set out the Canadian patent filing date, the patent issue date, the patent expiry date or the address for service of the first person of a NOA. While that information might otherwise be available to OSIP in other documents, there is no obligation on the part of OSIP to search for missing information. Rather, the obligation rested on Janssen to clearly identify all of the information required by subsection 4(4) in its "patent list" [see *Hoffmann-La Roche Ltd v Canada (Health)*, 2005 FC 1415 at para 21].

[128] As acknowledged by Janssen in its written submissions, the Minister has the discretion to determine the manner in which a patent list is to be submitted and the Minister has done so by requiring the use of Form IV. Form IV requires that, in completing the form, a first person provide all of the mandatory information required by subsection 4(4) of the *PMNOC Regulations*. Janssen has pointed to nothing that is unreasonable about the Minister's adoption of Form IV or the Minister's requirement that it be completed by first persons. Rather, Janssen appears to be inviting the Court to find that it was open to the Minister to accept a deviation to the Minister's practices, but without pointing to any error made by the Minister or any lack of coherent and rational chain of analysis in the Minister's determination.

[129] Janssen further asserts that in footnote 2 of its September 14, 2022 submission, Janssen requested that if OSIP rejected their request to add SNDS 739 to the patent list for the 837 Patent, that Janssen be advised of the reason and given an opportunity to respond. Janssen asserts that their procedural fairness rights were breached as OSIP never gave them a chance to address the issue. I reject this assertion. I am not satisfied that OSIP was under any duty to alert Janssen as to its views on Janssen's failure to file a Form IV patent list for SNDS 739 and to provide Janssen an opportunity to make further submissions on the issue. The burden rested on Janssen to take the appropriate steps to submit a patent list for the 837 Patent in relation to each of its SNDSs within the time limits prescribed by the *PMNOC Regulations* and in any event, by September 14, 2022, the deadline for submission of a patent list for the 837 Patent for SNDS 739 had already passed.

[130] In its reply oral submissions, Janssen asserted that it also relied on section 32 of the *Interpretation Act*, RSC 1985, c I-21, which provides that "where a form is prescribed, deviations

from that form, not affecting the substance or calculated to mislead, do not invalidate the form used" and identified two decisions of the Federal Court addressing section 32. This argument, and the related statute and case law, were not raised by Janssen in its memorandum of fact and law filed in this proceeding (nor were they raised in Janssen's submissions before OSIP) and did not arise from something unexpectedly raised by the Respondent in their oral submissions. In the circumstances, it is not open to Janssen to raise the argument now and most certainly inappropriate to attempt to raise it only in reply. Accordingly, I will not consider this portion of Janssen's submission, as to do so would be unfair to the Respondent.

[131] For the reasons stated above, I am not satisfied that Janssen has demonstrated that OSIP's determination that Janssen did not file a patent list for the 837 Patent for SNDS 739 was unreasonable. While I appreciate that Janssen views the impact of OSIP's determination of this issue as unreasonably harsh, the *PMNOC Regulations* contain numerous mandatory requirements (such as the 30 day requirement in subsection 4(6)) that result in harsh consequences when not met. This is a function of the nature of the regulatory regime [see *Fournier Pharma Inc v Canada (Attorney General)*, [1999] 1 FC 327; *Immunex Corporation v Canada (Health)*, 2008 FC 1409; *Merck Canada Inc v Canada (Minister of Health)*, 2021 FC 345].

[132] My finding on this issue is sufficient to dispose of Janssen's application for judicial review in relation to OSIP's refusal to list the 837 Patent in relation to SNDS 739. Notwithstanding, I will nonetheless go on to consider whether the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires* the *Patent Act*.

B. The Canadian Filing Date Requirement in Subsection 4(6) of the *PMNOC Regulations* is *intra vires* the *Patent Act*

[133] Notwithstanding OSIP's determination that no patent list had been filed for the 837 Patent in relation to SNDS 739, OSIP went on to consider whether the 837 Patent could have been listed against SNDS 739 if such a patent list had been provided. OSIP determined that Janssen would not have met the timing requirement in subsection 4(6) as the 837 Patent was filed in Canada after SNDS 739 was filed. OSIP further determined that the consideration of the claim date or priority date of the 837 Patent when assessing the application of subsection 4(6) would be to ignore the clear wording of the *PMNOC Regulations* (which states "filing date in Canada"), circumvent the strict timing requirements and undo the balance struck by the *PMNOC Regulations* and subsection 55.2(1) of the *Act*.

[134] Janssen does not take issue with OSIP's interpretation of subsection 4(6) and acknowledges that the filing date requirement in subsection 4(6) refers to the date that the patent application was filed in Canada, rather than the claim date or priority date. Rather, Janssen asserted before OSIP and now before this Court that the filing date requirement in subsection 4(6) is *ultra vires*.

[135] In the alternative, Janssen asserts that the Canadian filing date is an illogical, irrational and/or arbitrary date to employ in subsection 4(6). However, Janssen did not, in its written submissions and at the hearing, develop these arguments and as such, I will not consider them separately. Rather, I will consider the arguments as they were advanced by Janssen.

[136] In conducting a reasonableness review of this issue, the Court is to determine the constraints on the Governor in Council and whether the Governor in Council remained within them, with the focus on any reasons given by the Governor in Council.

[137] In this case, the parties agree that the primary constraint on the Governor in Council is subsection 55.2(4) of the *Patent Act* (as set out above), which contains the Governor in Council's regulation making authority. Section 55.2(4) of the *Patent Act* provides for a broad grant of authority for the making of such regulations as the Governor in Council "considers necessary for preventing the infringement of a patent" by any person who makes use of the early working exception. The specific authority outlined in paragraphs (a) to (e) is said not to limit the generality of the initial grant. Rather, the only limitation lies in the limited purpose for which regulations may be made – the prevention of infringement by those who use the patented invention for the early working exception [see *Apotex Inc v Merck & Co Inc*, 2009 FCA 187 at para 40]. As such, in enacting the *PMNOC Regulations*, the Governor in Council had to interpret the scope of its regulation making power and enact a regulation (subsection 4(6)) that, in its reasonable view, was within that power [see *Innovative Medicines, supra* at para 44].

[138] In considering Janssen's submissions, I note that Janssen does not assert that including a reference to a filing date of the patent in subsection 4(6), in and of itself, exceeds the Governor in Council's regulation making authority. In that regard, I note that Janssen originally sought to quash the entirety of subsection 4(6) but, at the hearing, substantially modified the relief sought and now only seeks the quashing of the words "that has a filing date in Canada". This is an important point, as Janssen concedes that the Governor in Council has the authority to enact a regulation that

includes a filing date requirement. This is not necessarily surprising given this Court's determination in *Fournier*, *supra* at para 20, that the Governor in Council's authority and discretion in subsection 55.2(4) are sufficiently broad to embrace the enactment of subsections 4(3) and 4(4) of the *PMNOC Regulations,* which impose time limits on the registration of patent lists.

[139] On Janssen's wording, section 4(6) would read as follows:

> 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 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.

[140] Janssen's argument therefore boils down to an assertion that the specific choice of the Canadian filing date over the claim date or priority date is *ultra vires*. In that regard, Janssen asserts that the Canadian filing date requirement does not conform with the purpose of the *Patent Act* and the *PMNOC Regulations*.

[141] Turning to the purpose of the *Patent Act*, Justice Manson described its purpose as follows in *Innovative Medicines*:

> [76] The policy rationale underlying the *Patent Act* is the patent bargain, or *quid pro quo*. The patent bargain encourages innovation by offering an inventor exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge (*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 S.C.R.

> 625, at paragraph 32). Two central objectives of the *Patent Act* as a whole are to "advance research and development and to encourage broader economic activity" (*Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 S.C.R. 104 at paragraph 42; *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45 (Harvard College) at paragraph 185).
>
> [77] As acknowledged by both the applicants and the respondent, patent monopoly rights are not unlimited, and Parliament has at times balanced promotion of ingenuity against other considerations (*Harvard College*, above, at paragraph 185)…

[142] The purpose of the *PMNOC Regulations*, as noted previously, is to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors.

[143] Only limited information is known about the rationale for the Governor in Council's choice to use the Canadian patent filing date. The 2006 RIAS indicates that the Government was aware that "an increasing number of court decisions interpreting the PM(NOC) Regulations have given rise to the need to clarify the patent listing requirements" and that these decisions addressed issues of timing and relevance.

[144] Among those decisions was Justice Blanchard's decision in *Pfizer Canada Inc v Canada (Attorney General) (TD)*, 2002 FCT 706, in which the Court was considering an earlier version of subsection 4(4) of the *PMNOC Regulations* which provided:

> A first person may, after the filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or

> an amendment to an existing patent list, that includes information referred to in subsection (2).

[145] The issue before the Court was whether the "filing date" in subsection 4(4) should be interpreted to be the priority filing date (in that case, the date of filing in the United States) or the Canadian filing date. The Minister had determined that "filing date" meant the Canadian filing date. The Applicants advanced a number of arguments in support of their assertion that "filing date" meant the priority filing date, including that the Minister's interpretation would place patentees who file their patent applications first in a country other than Canada at a disadvantage compared to patentees who choose to file first in Canada and results in a loss of rights during the priority period. In rejecting the Applicant's submissions, Justice Blanchard stated:

> [50] At the risk of stating the obvious, the *Patent Act* is Canadian legislation and provides for the grant of a patent to an inventor, "if an application for the patent in Canada is filed" (see subsection 27(1) [as am. *idem*, s. 31] of the *Patent Act*). Moreover, the *Patent Act* specifically defines "filing date" to be the Canadian filing date. In my view, any reference to "filing date" in the Act, or in the Regulations thereunder, must be read with regard to this definition. Such an interpretation is consistent with other provisions of the *Patent Act* and the Regulations which, for the most part, explicitly set out, in the context of the specific section, when "filing date" is meant as a date other than the Canadian filing date.

[146] Given the *Pfizer* decision, the Government was accordingly well aware of the issue raised by stakeholders as to the use of the Canadian filing date and the consequences thereof and engaged in consultations with stakeholders prior to the enactment of the current version of subsection 4(6) during which submissions could be made by stakeholders on this issue. The Governor in Council ultimately decided, in enacting subsection 4(6), to expressly include the Canadian filing date.

[147] With respect to subsection 4(6), the only commentary thereon in the 2006 RIAS provides as follows:

> By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that product.

[148] No express rationale is given in the 2006 RIAS as to why the Canadian filing date was specifically chosen. In its reasons for decision, OSIP notes that the Governor in Council chose for subsection 4(6) to refer to the first date of a patent term, as opposed to a date relevant to considerations of novelty, inventiveness or prior use and that this was a deliberate choice.

[149] Janssen asserts that the choice of the Canadian filing date is inconsistent with the aforementioned purpose of the timing requirement (namely, to prevent patents for inventions discovered after the existence of a product from pre-empting generic competition on that product), as the date of the invention's discovery is actually the claim date and not the Canadian filing date. Janssen stresses that the claim date (which is defined in sections 2 and 28.1 of the *Patent Act*) is the relevant date in several sections of the *Patent Act*, including those directed at novelty, inventiveness and the prior use defence, which are concepts at the core of an invention, and demonstrate that within the overall scheme of the *Patent Act,* the invention sought to be protected is linked to the claim date.

[150] Further, Janssen asserts that the selection of the Canadian filing date fails to advance effective enforcement of patents that would be infringed by the use of the early-working exception, such that there is no rational connection between the early-working exception and the requirement that a Canadian patent application be filed before a drug submission to be listed.

[151] I am not convinced by Janssen's submissions. While the 2006 RIAS expresses a rationale for subsection 4(6), the expressed rationale is in regard to why the filing of the patent application must occur before the submission of the SNDS. It was about the sequencing of the patent application and the SNDS, not about the rationale for picking the Canadian filing date over the claim date.

[152] The Governor in Council was well aware that since 1998, the Minister has "sought to apply the amendments on timing and relevance in order to place reasonable limits on the ability of innovator drug companies to list new patents on the basis of SNDS filings" [see 2006 RIAS] and that:

> It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.
>
> [Emphasis added.]

[153] The Governor in Council made a choice that struck a particular balance between the PMNOC regime's competing objectives. The enactment of subsection 4(6) was within the Governor in Council's regulation making authority. As recognized by the Federal Court of Appeal in *Innovative Medicines*, having acted within the limits of the statutory language, the Governor in Council's regulation-making power is relatively unconstrained and it certainly falls within Governor in Council's purview to make policy-based choices such as this when deciding the balance to be struck. Could the Governor in Council have chosen to use the claim date in subsection 4(6)? Certainly. But the balance chosen by the date selected need not be perfect and it is not the role of the Court on this application to consider whether a different balance (as urged by Janssen) could have or ought to have been struck [see *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 551 at para 24]. The burden rested on Janssen to demonstrate that the inclusion of the Canadian filing date was not in pursuance of and connected with the prevention of patent infringement and I am not satisfied that they have done so. Rather, I am satisfied that requiring that a patent meet certain timing requirements based on its Canadian filing date, which ensures timely market entry of subsequent generic drugs, is reasonably in keeping with the balance of the competing policy interests at issue.

[154] In some circumstances, the operation of the regulatory regime may benefit a subsequent entry drug manufacturer and in others, the innovator, depending on when the innovator choses to file their patent application in Canada. However, I am not satisfied that this renders subsection 4(6) *ultra vires* or otherwise arbitrary, illogical or irrational. I agree with the Respondent that, in Janssen's view, the language chosen by the Governor in Council must be the most beneficial to innovators in order to be rationally connected to the purpose of the *Patent Act* and the *PMNOC*

Regulations. But such an approach ignores the balancing of interests that must be undertaken. Moreover, it also ignores that innovators (whose patents benefit from a priority application) who chose to file their Canadian patent after their SNDS retain their right to bring patent infringement actions under the *Patent Act* regime and are not deprived of the benefit of their priority date in such actions.

[155] Janssen bears the burden of demonstrating that the Governor in Council's inclusion of the Canadian filing date in subsection 4(6) was unreasonable. For the reasons stated above, I am not satisfied that they have done so.

V. Conclusion

[156] Having found that Janssen has failed to demonstrate that any aspect of OSIP's decision is unreasonable and that the Canadian filing date requirement in subsection 4(6) of the *PMNOC Regulations* is *ultra vires*, illogical, irrational or arbitrary, the application for judicial review shall be dismissed.

VI. Costs

[157] At the hearing of the application, the parties advised that they agreed that the successful party should be awarded their costs fixed in the amount of $7,500.00. As the Respondents were

successful on the application, they shall be awarded their costs in accordance with the parties' agreement.

JUDGMENT in T-2627-22

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. The Applicant shall pay to the Respondents their costs of this application fixed in the amount of $7,500.00, inclusive of disbursements and taxes.

"Mandy Aylen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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