Federal Court  Cour fédérale

Date: 20210420

Docket: T-1476-20

Citation: 2021 FC 345

Ottawa, Ontario, April 20, 2021

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

MERCK CANADA INC.

Applicant

and

THE MINISTER OF HEALTH

Respondent

JUDGMENT AND REASONS

I. Overview

[1] Merck Canada Inc [Merck] seeks judicial review of the refusal by the Minister of Health [Minister] to add Canadian Patent No 2,830,806 [806 Patent] to the Patent Register pursuant to s 4(6) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM(NOC) Regulations*]. The Minister found that Merck's patent lists were not submitted within the specified 30 day time period.

[2] Merck says the Minister unreasonably held that the *Time Limits and Other Periods Act (COVID-19),* SC 2020, c 11, s 11 [*Time Limits Act*] did not have the effect of suspending the 30 day time period specified in s 4(6) of the *PM(NOC) Regulations*. In the alternative, Merck maintains that the Minister had a discretion to extend the 30 day time period, which she unreasonably refused to exercise given the extraordinary circumstances occasioned by the COVID-19 pandemic.

[3] The Minister's decision was justified, intelligible and transparent, and therefore reasonable. The application for judicial review is dismissed.

II. Background

[4] Merck markets KEYTRUDA®, a biologic drug containing the medicinal ingredient pembrolizumab. KEYTRUDA® was approved for use in Canada on May 19, 2015 for the treatment of certain advanced-stage cancers.

[5] KEYTRUDA® is a designated "innovative drug" listed pursuant to the data protection provisions of the *Food and Drug Regulations*, CRC, c 870 [F&DR]. KEYTRUDA® therefore benefits from an eight and a half year period of market exclusivity that expires on November 19, 2023. KEYTRUDA® also benefits from a six-year "no file" period under the F&DR, meaning that a subsequent market entrant cannot file a drug submission using KEYTRUDA® as its Canadian Reference Product until May 19, 2021.

[6] There is currently one patent listed on the Patent Register for KEYTRUDA®: Canadian Patent No 2,691,357 [357 Patent]. The 357 Patent was issued on September 23, 2014, and will expire on June 13, 2028.

[7] The 806 Patent was issued on May 12, 2020. The 806 Patent contains claims that are directed to a formulation of the drug KEYTRUDA®.

[8] The Canadian patent agent retained by Merck's United States parent company [Merck USA] did not report the issuance of the 806 Patent until June 15, 2020, more than a month after the patent was issued. However, on June 12, 2020, Merck USA independently discovered that the patent had been issued, and immediately instructed Merck to prepare and submit the necessary patent lists. The patent lists were submitted later that day, but after the close of business. Pursuant to Health Canada's electronic filing policies, the patent lists were considered by the Minister to have been filed on the next business day, Monday, June 15, 2020.

[9] Subsection 4(6) of the *PM(NOC) Regulations* provides as follows:

(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	**(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

relation to the submission or supplement.	présentation ou de ce supplément, qui contient les renseignements visés au paragraphe (4).

[10] On June 19, 2020, the Minister informed Merck of her preliminary determination that the patent lists relating to the 806 Patent were ineligible for listing on the Patent Register, because they had not been submitted within 30 days of the issuance of the 806 Patent. Merck responded with written representations and affidavit evidence.

[11] On November 6, 2020, the Minister confirmed that the patent lists relating to the 806 Patent were not eligible for inclusion on the Patent Register pursuant to s 4(6) of the *PM(NOC) Regulations*, holding as follows:

- the 30-day deadline provided in s 4(6) of the *PM(NOC) Regulations* is not discretionary;

- the 2017 amendments to s 3 of the *PM(NOC) Regulations* do not confer discretion on the Minister to extend the deadlines prescribed in s 4;

- prejudice to second persons is not a factor that is considered when applying the timing requirements;

- enforcing timing requirements does not contravene the purpose of the *PM(NOC) Regulations* or the *Patent Act*, and does not remove the rights afforded to Merck by the 806 Patent; and

- the *Time Limits Act* does not extend the deadline within which first persons may submit patent lists in accordance with s 4(6) of the *PM(NOC) Regulations*.

[12] Merck says the Minister's refusal to list the 806 Patent on the Patent Register deprives the patent holder of the substantial protections available under the *PM(NOC) Regulations*. Listing the 806 Patent would afford Merck four additional years of access to the summary litigation provisions of the *PM(NOC) Regulations*, beyond the expiry of the currently-listed 357 Patent. Any second person seeking approval to market a biosimilar version of KEYTRUDA® would have to either wait for both the 357 Patent and the 806 Patent to expire on March 29, 2032, or serve a notice of allegation [NOA] addressing both patents. Service of an NOA would enable Merck to commence litigation under the *PM(NOC) Regulations*.

[13] Merck asserts that listing the 806 Patent would not prejudice any subsequent market entrant, and is consistent with the overarching policy of the *PM(NOC) Regulations*: to balance effective patent enforcement for innovative drugs with the timely market entry of generic competitors. If the Minister's refusal to list the 806 Patent is confirmed, Merck says it will suffer prejudice because a subsequent entrant will be able to file a drug submission after the expiry of the six-year "no file" period for KEYTRUDA® on May 19, 2021. Due to s 5(4) of the *PM(NOC) Regulations*, also known as the "frozen register" provision, subsequent entrants are required to address only those patents listed on the Patent Register as of the date they file the submission.

III. Issues

[14] This application for judicial review raises the following issues:

A. Was the Minister's determination that the *Time Limits Act* did not have the effect of suspending the 30 day time period specified in s 4(6) of the *PM(NOC) Regulations* reasonable?

B. Was the Minister's determination that she had no discretion to extend the 30 day time period specified in s 4(6) of the *PM(NOC) Regulations* reasonable?

IV. Analysis

[15] The Minister's decision is subject to review against the standard of reasonableness. The Court will intervene only if "there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency" (*Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*] at para 100; *Elanco v Canada (Attorney General)*, 2019 FC 5 at para 50).

[16] An administrative decision maker's interpretation of a statutory provision must be consistent with the text, context and purpose of the provision. The usual principles of statutory interpretation apply equally when an administrative decision maker interprets a provision. Where the words used are "precise and unequivocal", their ordinary meaning will usually play a more

significant role in the interpretive exercise (*Vavilov* at para 120, citing *Canada Trustco Mortgage Co v Canada*, 2005 SCC 54 at para 10).

[17] An administrative decision maker cannot adopt an interpretation it knows to be inferior — albeit plausible — merely because the interpretation in question appears to be available and is expedient. The decision maker's responsibility is to discern meaning and legislative intent, not to "reverse-engineer" a desired outcome (*Vavilov* at para 121).

A. *Was the Minister's determination that the Time Limits Act did not have the effect of suspending the 30 day time period specified in s 4(6) of the PM(NOC) Regulations reasonable?*

[18] The *Time Limits Act* suspended a number of federally-legislated deadlines, including time limits related to proceedings before a court:

Suspensions	**Suspension**
6 (1) The following time limits are, if established by or under an Act of Parliament, suspended for the period that starts on March 13, 2020 and that ends on September 13, 2020 or on any earlier day fixed by order of the Governor in Council made on the recommendation of the Minister of Justice:	6 (1) Les délais ci-après prévus sous le régime d'une loi fédérale sont suspendus pour la période commençant le 13 mars 2020 et se terminant soit le 13 septembre 2020, soit à la date antérieure fixée par décret pris sur recommandation du ministre de la Justice:
(a) any limitation or prescription period for commencing a proceeding before a court;	(a) tout délai de prescription du droit d'introduire une instance devant une cour;
	(b) tout délai relatif à l'accomplissement d'un acte

(b) any time limit in relation to something that is to be done in a proceeding before a court; and	dans le cadre d'une instance devant une cour;
(c) any time limit within which an application for leave to commence a proceeding or to do something in relation to a proceeding is to be made to a court.	(c) tout délai dans lequel une demande visant à obtenir l'autorisation d'introduire une instance ou d'accomplir un acte dans le cadre d'une instance doit être présentée à une cour.

[19] It is clear from the language of the *Time Limits Act* that s 6(1) applies in only three circumstances: limitation or prescription periods for commencing a proceeding before a court; time limits for doing something in a proceeding before a court; and time limits where a party makes an application for leave of a court, either to commence a court proceeding or to do something in relation to a court proceeding.

[20] Merck says that s 4(6) of the *PM(NOC) Regulations* functions as a "gateway" to the summary litigation provisions that begin at s 6(1), which provides as follows:

Right of Action	**Droits d'action**
6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would	6 (1) La première personne ou le propriétaire d'un brevet qui reçoit un avis d'allégation en application de l'alinéa 5(3)a) peut, au plus tard quarante-cinq jours après la date à laquelle la première personne a reçu signification de l'avis, intenter une action contre la seconde personne devant la Cour fédérale afin d'obtenir une déclaration portant que la fabrication, la construction, l'exploitation ou la vente

infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.	d'une drogue, conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), contreferait tout brevet ou tout certificat de protection supplémentaire visé par une allégation faite dans cet avis.

[21] Merck therefore argues that the 30 day period specified in s 4(6) of the *PM(NOC) Regulations* is a "limitation period within a limitation period", comparable to the requirement of notifying a municipality within seven days of a possible civil action for personal injury. Merck relies on the Ontario Court of Appeal's decision in *Bannon v Thunder Bay (City)*, 2000 CarswellOnt 1307 (ONCA) [*Bannon*] (rev'd on other grounds, 2002 SCC 20).

[22] In *Bannon*, a plaintiff's failure to give timely notice to a municipality served as a bar to advancing a subsequent civil claim. The Ontario Court of Appeal held that the notice requirement was "akin" to a limitation period, and should be considered, together with the actual limitation period of three months, as the applicable limitation period (*Bannon* at paras 22-23).

[23] Merck says that the 30 day period in which to list a patent on the Patent Register is comparable to the notice requirement considered by the Ontario Court of Appeal in *Bannon*. Listing of the patent is "the first step" of the limitation period to commence litigation in accordance with the *PM(NOC) Regulations*. Absent a patent listing, the 45 day limitation period for commencing a court proceeding under s 6(1) of the *PM(NOC) Regulations* can never be triggered.

[24] In *Bannon*, the Ontario Court of Appeal found that the notice provision promoted the same interests served by limitation periods: it "prompts the plaintiff to pursue the claim diligently, affords the defendant an opportunity to make timely investigation of the incident giving rise to the action and allows the defendant to proceed with its affairs secure in the knowledge that it will not face claims for which notice was not given as required by the statute" (*Bannon* at para 22).

[25] The listing of a patent on the Patent Register performs a very different function from a limitation period. The listing of a patent is not inextricably connected to a prospective civil action, and it does not cause time to begin running. There is no precipitating event, and there is no defendant at the time of the listing. The listing of a patent on the Patent Register is not even the most proximate step to a possible court proceeding under s 6(1).

[26] While s 4(6) of the *PM(NOC) Regulations* has been described as the "gateway" to the advantages gained by a patent owner under the regulatory regime (*GD Searle & Co v Canada (Health)*, 2009 FCA 35 at para 13), these advantages are not limited to the commencement of an action under s 6(1). I therefore disagree with Merck's assertion that the *PM(NOC) Regulations* are "centred around" the initiation of a possible court proceeding.

[27] Pursuant to s 5(1) of the *PM(NOC) Regulations*, if a second person applies for an NOC and compares its drug to another drug in respect of which an NOC has been previously issued and a patent list has been submitted, the second person must comply with s 2.1. This is done by:

(a) confirming that the owner of the patent has consented to the making, constructing, using or selling the second person's drug in Canada;

(b) confirming the second person's acceptance that the NOC will not issue until the patent or certificate of supplementary protection expires; or

(c) serving an NOA on the first person that explains the legal and factual basis for the allegation that the issuance of an NOC to the second person will not improperly interfere with the first person's patent rights.

[28] It is only in the last of these circumstances that a first person in receipt of an NOA may, within 45 days, bring an action against the second person in respect of a listed patent. The dispute concerning the patent does not exist, nor are the parties known, until the second person files a drug submission and serves an NOA on the patent owner.

[29] I therefore conclude that the listing of a patent on the Patent Register pursuant to s 4(6) of the *PM(NOC) Regulations* is too remote from the commencement of a court proceeding under s 6(1) to constitute a "limitation period within a limitation period" for the purpose of s 6(1) of the *Time Limits Act*.

[30] Merck emphasizes the importance of flexibility in applying the *Time Limits Act*, as reflected in s 5:

Purpose	**Objet**
5 (1) The purpose of this Act is	**5 (1)** La présente loi a pour objet :
(a) to temporarily suspend certain time limits and to temporarily authorize, in a flexible manner, the suspension or extension of other time limits in order to prevent any exceptional circumstances that may be produced by coronavirus disease 2019 (COVID-19) from making it difficult or impossible to meet those time limits; and	**a)** de suspendre temporairement certains délais et de permettre, temporairement et d'une façon souple, la suspension et la prolongation d'autres délais afin d'éviter que des circonstances exceptionnelles découlant de la maladie à coronavirus 2019 (COVID-19) n'en rendent le respect difficile ou impossible;
(b) to temporarily authorize, in a flexible manner, the extension of other periods in order to prevent any unfair or undesirable effects that may result from the expiry of those periods due to those exceptional circumstances.	**b)** de permettre, temporairement et d'une façon souple, la prolongation d'autres périodes afin d'éviter que leur expiration n'entraîne des effets injustes ou indésirables en raison de ces circonstances exceptionnelles.

[31] However, the words "in a flexible manner" in s 5 relate to the ministerial discretion to order the temporary suspension or extension of time limits or other periods pursuant to s 7. This has nothing to do with the suspension of limitation and prescription periods relating to court proceedings mandated by s 6. The Minister of Industry has never suspended or extended the deadline in s 4(6) of the *PM(NOC) Regulations* pursuant to s 7 of the *Time Limits Act*, despite having the authority to do so.

[32] The recent decision of Justice Michael Manson in *ViiV Healthcare et al v Sandoz Canada Inc*, 2020 FC 1040 [*ViiV*] does not assist Merck. In *ViiV*, Justice Manson ruled that the

suspension of the time period in s 6(1) of the *PM(NOC) Regulations*, which is unquestionably in relation to "a proceeding before a court", was lifted as of the date of the applicable order-in-council (*i.e.*, July 30, 2020). This has no bearing on the 30 day period specified in s 4(6) of the *PM(NOC) Regulations*, which was never suspended by s 6(1) of the *Time Limits Act* or pursuant to s 7.

[33] *ViiV* contradicts the Minister's finding that the *Time Limits Act* did not affect any of the time limits prescribed by the *PM(NOC) Regulations*. However, the Minister's determination that the *Time Limits Act* did not suspend the 30 day time period specified in s 4(6) remains sound.

B. *Was the Minister's determination that she had no discretion to extend the 30 day time period specified in s 4(6) of the PM(NOC) Regulations reasonable?*

[34] Merck maintains that the Minister had a discretion to list the 806 Patent on the Patent Register, which she unreasonably declined to exercise. According to Merck, this discretion has been recognized in jurisprudence, and was enhanced by amendments to the *PM(NOC) Regulations* promulgated in 2017.

[35] Merck relies on this Court's decision in *Procter & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health)*, 2003 FCT 583 [*Procter & Gamble*] for the proposition that the Minister may add a "late" patent list to the Patent Register. In that case, Proctor & Gamble had submitted a patent list more than 30 days after the date of issue that appeared on the face of the patent. The Minister nevertheless added the patent to the Patent Register (*Procter & Gamble* at paras 43-45). In subsequent legal proceedings, Genpharm Inc [Genpharm], a generic

pharmaceutical company, sought to strike Proctor & Gamble's application on the ground that the patent was ineligible for listing on the Patent Register.

[36] Justice Johanne Gauthier, then a judge of this Court, dismissed the motion to strike. Due to a printing problem, the patent in question had not been issued until several days after the date of issuance that appeared on its face. The clerical error was admitted by the Patent Office. The patent was added to the Patent Register within 30 days of the date on which it had in fact been issued. Justice Gauthier therefore concluded that it was not plain and obvious that the patent was ineligible for listing on the Patent Register (*Proctor & Gamble* at paras 43-53).

[37] An appeal of Justice Gauthier's decision was dismissed, but on the separate ground that Genpharm was estopped from challenging the listing of the patent on the Patent Register due to its failure to challenge the listing at its first opportunity (*Procter & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health)*, 2003 FCA 467).

[38] Both the trial and appellate decisions in *Proctor & Gamble* provide very weak authority for the proposition that the Minister has a discretion to add a "late" patent to the Patent Register. The patent in that case was added within 30 days of its actual date of issuance. Even if one accepts that the Minister's decision in that case did involve an exercise of discretion, the litigation ultimately turned on whether the patent's ineligibility was plain and obvious, or whether the generic pharmaceutical company was estopped from raising the issue.

[39] It is well established that the timelines prescribed by the *PM(NOC) Regulations* are exact. In *Hoffman-La Roche Ltd v Canada (Health)*, 2005 FC 1415 at paragraphs 22 and 23, Justice Michael Phelan said the following with respect to the predecessor to s 4(6) of the *PM(NOC) Regulations*:

> Lastly, Hoffmann-La Roche argues that the Minister has the discretion to accept an out-of-time filing because the Minister has an obligation to maintain the accuracy and currency of the Patent Register.
>
> With respect, I cannot read ss. 4(4)'s 30-day time limit as admitting to an exception. If it was intended to give the Minister this type of discretion, there must be a clearer indication of its existence than the obligation of the Minister under s. 3 of the NOC Regulations to maintain the Register. This is particularly so where s. 3 refers to s. 4 information but gives no suggestion of a power to extend the deadlines in s. 4.

[40] In *Fournier Pharma Inc v Canada (Attorney General)*, [1999] 1 FC 327, Justice Max Teitelbaum observed at paragraph 35 that "strict" timelines "are necessary to give effect to the intention of the legislator to strengthen the position of patentees and to ensure the availability of reasonably priced medicine for Canadian consumers". In *Immunex Corporation v Canada (Health)*, 2008 FC 1409 at paragraph 15, Justice Judith Snider held that drug manufacturers are subject to strict timing deadlines for the listing of a patent, and amendments in 2006 did not change the timing requirement with respect to the submission of a patent for listing. Most recently, in *ViiV*, Justice Manson confirmed that the *PM(NOC) Regulations* "involve stringent timelines" (at para 74).

[41] Merck notes that, pursuant to amendments to the *PM(NOC) Regulations* that were promulgated in 2017 (Canada Gazette, Pt I, vol 151, No 28 at pp 3336-3337), s 3(2) was replaced with a more detailed scheme of ministerial powers in ss 3(2) to 3(2.3), including the ability to add and refuse patent lists in a greater range of circumstances. Merck argues that s 3(2.3) expressly grants authority to the Minister to perform discretionary reviews of the Patent Register.

[42] I am not persuaded that the 2017 amendments had the effect of altering the eligibility criteria for listing patents on the Patent Register, or conferred upon the Minister a new discretion to depart from those criteria. As the Minister noted in her decision, the Regulatory Impact Analysis Statement that accompanied the 2017 amendments specifically noted that the "eligibility requirements for listing a patent on the patent register remain unchanged."

V. Conclusion

[43] The Minister's decision was justified, intelligible and transparent, and therefore reasonable. The application for judicial review is dismissed.

[44] I commend counsel for both parties for the high quality of their written materials and oral submissions.

[45] By agreement of the parties, no costs are awarded.

JUDGMENT

THIS COURT'S JUDGMENT is that the application for judicial review is dismissed without costs.

"Simon Fothergill"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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