Federal Court of Appeal | Cour d'appel fédérale

Date: 20211122

Docket: A-143-21

Citation: 2021 FCA 224

CORAM: **GAUTHIER J.A.**
LOCKE J.A.
LEBLANC J.A.

BETWEEN:

MERCK CANADA INC.

Appellant

and

THE MINISTER OF HEALTH

Respondent

Heard by online video conference hosted by the Registry on October 19, 2021.

Judgment delivered at Ottawa, Ontario, on November 22, 2021.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY: LOCKE J.A.
LEBLANC J.A.

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REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] This is an appeal from a decision of the Federal Court dismissing Merck Canada Inc.'s application for judicial review of the Minister of Health's refusal to list Canadian Patent 2830806 (the '806 Patent) on the patent register, pursuant to subsection 4(6) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (*PM (NOC) Regulations)* (*Merck Canada Inc. v. The Minister of Health*, 2021 FC 345).

[2] I agree with the parties that the Federal Court applied the appropriate standard of review, being that of reasonableness. Our Court's role in this appeal is thus to focus on the Minister's decision to determine whether the Federal Court correctly applied this standard (*Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 46). As this Court has observed, such a review "does not mean that the appellant can or should ignore the reasons given by the Federal Court in rejecting its application." Rather, "where, as is the case here, the Federal Court appears to have given a complete answer to all the arguments that it advances, an appellant bears a strong tactical burden to show on appeal that the Federal Court's reasoning is flawed" (*Bank of Montreal v. Canada (Attorney General)*, 2021 FCA 189 at para. 4).

[3] Before the Minister, Merck raised only one main issue. Based on its own reading of subsections 3(2) and 4(6) of the *PM (NOC) Regulations*, it argued that the Minister had the discretion to extend the 30-day time limit set out in subsection 4(6). Merck also submitted various reasons why the Minister should exercise its discretion in its favour, given the "exceptional" circumstances of this case. Particularly, it noted that an external patent agent's inadvertent error made in the context of COVID-19 resulted in a delay of only one day (according to their calculation, which does not accord with the electronic filing procedure). In any case, Merck argued, this error did not result in any prejudice to a third party.

[4] It was only in footnote 16 of the background section of its submissions to the Minister, which dealt with COVID-19, that Merck referred to Bill C-20, *An Act Respecting Further COVID-19 Measures* (Bill C-20), which became the *Time Limits and Other Periods Act*

(COVID-19), enacted by Section 11 of An Act Respecting further COVID-19 Measures, S.C. 2020, c. 11 *(*the *Time Limits Act)* on July 27, 2020. This, despite the fact that it made these submissions in a letter dated August 4, 2020 (that is, after the coming into force of the *Time Limits Act*). Though Merck did not base its arguments before the Minister on any provisions of the *Time Limits Act*, the Minister did consider this *Act*.

[5] Before us, Merck raises similar arguments to those made before the Federal Court to support its view that the Minister's conclusions with respect to subsections 3(2) and 4(6) of the *PM (NOC) Regulations* and the *Time Limits Act* were not reasonable. For the first time, however, it also submits that, even if this Court finds the Minister's interpretation of subsection 6(1) of the *Time Limits Act* to be reasonable, "equity should intervene to provide a remedy in this case" (Merck's Memorandum of Fact and Law at para. 48).

[6] Merck contends that this Court has the jurisdiction to grant an equitable remedy, and that the exercise of this jurisdiction is both necessary and appropriate in this case. In support of this submission, Merck argues that it acted reasonably and diligently to protect its right, and that factors outside of its control prevented it from doing so, namely its patent agent's error during COVID-19.

[7] This appeal is a valiant attempt by Merck to correct its patent agent's mistake, specifically, its patent agent's failure to advise Merck of the '806 Patent's issuance until June 15, 2020. However valiant and understandable, this appeal must fail. This is not the first time that a patent agent has missed a deadline. Unfortunately, it is unlikely to be the last. This appeal

constitutes one of several attempts since the late 1990s to circumvent the time limits set out in the *PM (NOC) Regulations*, particularly those in section 4.

I. Analysis

A. *The Minister's Discretion Pursuant to Subsections 3(2) and 4(6) of the PM (NOC) Regulations*

[8] I will first deal with the issue of the Minister's discretion pursuant to subsections 3(2) and 4(6) of the *PM (NOC) Regulations*. I acknowledge that Merck addressed the Minister's conclusion on the application of the *Time Limits Act* first; however, I address the arguments in this order because the alleged discretion to extend the time requirement under the *PM (NOC) Regulations* was the main issue before the Minister.

[9] It is not disputed that, before 2017, the stringent time limits set out in section 4 and subsection 6(1) of the *PM (NOC) Regulations* were an essential part of the balancing act made by the legislator since it adopted the somewhat draconian scheme set out in the *PM (NOC) Regulations*. Having reviewed the materials in this file, I find that the only novel aspect of this matter is that the mistake that Merck is understandably trying to correct was made soon after the onset of COVID-19, in June of 2020.

[10] For the reasons below, I have reached the conclusion that, although I have much sympathy for the appellant's plight, this Court's intervention would not be justified by applying the somewhat theoretical arguments before us. One should always be cautious when presented with so-called "exceptional circumstances" to interpret legislative provisions in a manner that

would apply in all of the circumstances where the provisions apply. This is key in this case, which stems from Merck's patent agent's error at a time when, despite the pandemic, thousands of patents continued to be issued.

[11] I note that Merck's representations before the Minister were brief and did not include the case law on which it heavily relies before us. Rather, it only included three references to Supreme Court of Canada decisions reiterating the application of the Driedger Modern Principle of Statutory Interpretation and the general purpose of the *Patent Act*, R.S.C., 1985, c. P-4 (the *Patent Act*).

[12] Merck simply argued that, since the 2017 amendments to the *PM (NOC) Regulations*, particularly subsection 3(2), the Minister has had the discretion to add patents to the patent register and that nothing in the wording of subsection 4(6) precluded her from extending the timeline set out therein. The most relevant statutory provisions are set out in Appendix A of these reasons. Merck proposed an interpretation of the word "may" in subsection 4(6) that was not mandatory, distinguishing it from the word "must" used in subsection 4(5). It then argued that, in the exceptional circumstances of this case (mostly COVID-related), the Minister should indeed exercise her discretion to list this patent because it would not, in this particular instance, result in any prejudice to a third party. Rather, Merck contended, doing so would align with the purpose of the scheme set out in the Patent Act and the PM *(NOC) Regulations* issued thereunder.

[13] Merck now challenges the reasonableness of the Minister's decision on the basis that the decision is not sufficiently justified. Allegedly, she did not conduct a full, purposive statutory interpretation as mandated by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 (*Vavilov*). According to Merck, the decision is nothing more than a series of statements. Merck also submits various other arguments as to why the Minister's interpretation itself was not reasonable.

[14] With respect to the sufficiency of the Minister's decision, I cannot agree with Merck's position. Although the decision is brief, as were Merck's representations, the Minister considered all of the concerns and arguments before her. First, she assessed Merck's argument that the filing was minimally late. She stated that, even if she could depart from the established electronic filing practice, the '806 Patent would still fail to meet the *PM (NOC) Regulations*' timing requirement because it would have been considered to have been filed at the end of the 31st day (at 10:35 p.m.) following the patent's issuance.

[15] Next, she summarized properly, in my view, the argument put forth by Merck. First, beginning at page 2 of her decision, she addressed the time requirement in subsection 4(6) based on Merck's submissions regarding the difference in the wording of subsections 4(5) and 4(6). In her view, the use of the word "may" in subsection 4(6) indicated the first person's option to file a patent list outside of the timeline prescribed by subsection 4(5). For this option to arise, however, the patent must be issued after the drug submission's filing and the patent list must be filed within 30 days of the patent's issuance.

[16] According to the Minister, Merck's interpretation of the word "may" would create an absurdity in the interpretation of the time requirements and defeat the very purpose of including a deadline in subsection 4(6). She further indicated that she did not share Merck's view that strictly enforcing the time requirement would run contrary to the object and purpose of the *PM (NOC) Regulations* and the *Patent Act*. She referred to the Regulatory Impact Analysis Statement (RIAS) accompanying the 2017 amendments, noting at page 5 of her decision that the purpose described in that RIAS is still that "the Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drug with the timely market entry of their lower-priced generic competitors." She found that the *PM (NOC) Regulations'* time requirements play an integral role in striking this balance. Because the Governor in Council chose to establish and maintain the 30-day deadline by administering the *PM (NOC) Regulations* in accordance with the prescribed deadline, she considered that the object and the purpose of the Regulations were upheld rather than circumvented.

[17] Upon reviewing the scheme contemplated in sections 3 and 4, she observed that the RIAS for the 2017 amendments (2017 RIAS) specifically states at page 3322 that the "eligibility requirements for listing a patent on the patent register remain unchanged." She further noted at page 4 of her decision that the 2017 RIAS mentioned under the heading "Maintaining the patent register" that the Minister's discretion to review the patent register (subsection 3(2.3)) "allows the Minister to reconsider earlier listing decisions in light of any subsequent judicial decision that interprets eligibility requirements differently than the Minister did at the time of listing."

[18] In the Minister's view, "the requirements for addition to the register" referred to in subsection 3(2) necessarily include the timing requirements under subsections 4(5) and 4(6). She sought guidance from the Federal Court's decision in *Hoffmann-La Roche Ltd. v. Canada (Health)*, 2005 FC 1415, aff'd 2006 FCA 335 (*Hoffmann*). In particular, she observed the passage in which the Federal Court could not agree that the Minister had the discretion to accept out-of-time filing under section 3 of the *PM (NOC) Regulations*. In *Hoffmann*, the Federal Court could not read an exception into the 30-day filing deadline on the basis of the wording of section 3 (as it then read), particularly when section 3 referred to section 4 and did not suggest any power to extend a deadline under section 4.

[19] Finally, the Minister noted that she did not have to consider the actual prejudice to a second person when applying the time requirement, given that she had no discretion to accept patent lists filed outside of the prescribed deadline under the *PM (NOC) Regulations*. She also dealt with the various arguments raised by Merck with respect to data protection and the particular impact of that regime in this case.

[20] I note here the Minister's observation that her refusal to include the '806 Patent list on the patent register did not deprive Merck of its right afforded under the *Patent Act*. As such, Merck could still assert its monopoly and exclusivity over the subject matter claimed in the '806 Patent, regardless of the '806 Patent's inclusion in the patent register.

[21] In *Vavilov*, the Supreme Court of Canada reminded us that administrative decision makers are not to be held to a standard of perfection, and that one could not expect their

decisions to read like a court decision conducting a statutory interpretation. Furthermore, "administrative decision makers may find it unnecessary to dwell on each and every signal of statutory intent in their reasons" (*Vavilov* at para. 122). In many cases, and in my view, in this one, "it may be necessary to touch upon only the most salient aspects of the text, context, and purpose" (*Vavilov* at para. 122).

[22] Although the merits of an administrative decision must be consistent with the text, context, and purpose of the legislative provision in question, the decision maker is not required to embark on an analysis that would cover any possible line of reasoning (*Vavilov* at paras. 120 and 127). Regard must be given to the submissions made to the Minister.

[23] As I will soon discuss, Merck now refers to certain passages of the 2017 RIAS to support new arguments that it did not make before the Minister. In these circumstances, I cannot fault the Minister for failing to specifically refer to these passages or avoiding speculation as to what they might mean in respect of an argument that was not before her.

[24] On a fair reading of the decision, although not organized exactly as presented by Merck, the Minister considered all of Merck's submissions. She simply did not agree with them. I am satisfied that the Minister's analysis was sufficient for this Court not to lose confidence in the outcome that she reached (*Vavilov* at para. 122). The decision is intelligible, transparent, and sufficiently justified.

[25] It is evident that the Minister could have said more, especially considering the long history of the time requirement in the *PM (NOC) Regulations*. For example, she could have referred to the RIAS accompanying the 2006 amendment to the *PM (NOC) Regulations* (Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Volume 140, No. 21 (2006)) (2006 RIAS) (see, in particular, "Purpose of Amendments" at p. 1515). This purported to clarify the "patent listing requirements" and put an end to various attempts by first persons to bypass the strict timelines under section 4. In fact, the Minister's position is perfectly in line with what one finds in this RIAS, which the Federal Court also described in *Immunex Corporation v. Canada (Health)*, 2008 FC 1409 at paras. 32-33. In this passage of the 2006 RIAS, one can also read:

> At page 1511
>
> …Embodied in each of these requirements are certain fundamental principles which must be respected if the *PM (NOC) Regulations* are to operate in balance with early-working. While the operation of some of these requirements is described in more detail below, a brief discussion of the principles they represent is warranted…
>
> […]
>
> At page 1513
>
> … Among the changes introduced by the 1998 amendments to "facilitate the market entry of generic drugs" were provisions designed to reinforce the patent listing requirements. In particular, the amended *PM (NOC) Regulations* reaffirm the application of strict time limitations for adding a patent to the register and contain an additional requirement that patents be relevant to the strength, dosage form and route of administration of the approved drug…
>
> [emphasis added]

[26] The 2006 RIAS mentions (as the Minister did in her decision) that, while some patents that do not qualify for protection under the *PM (NOC) Regulations* can ultimately be infringed by the fact of generic entry, the Government's view is that where the patent fails to meet the

listing requirement, policy considerations have tipped the balance in favour of immediate approval of the generic drug. In such cases, the matter is better left to the alternative judicial recourse of an infringement action (2006 RIAS at p. 1512).

[27] In my view, however, there was no need for the Minister to refer to this document, for Merck would have been familiar with it (as would its specialized counsel), given its use of this scheme since its inception and, I can safely assume, its awareness of all of the amendments and their purposes throughout the years. It was sufficient for the Minister to note, as she did, that the 2017 RIAS clearly states that the patent listing requirements have not changed.

[28] That said, in its Memorandum of Fact and Law and at the hearing, Merck's new counsel included somewhat surprising new arguments. Indeed, they are almost contradictory to the position that Merck took before the Minister and with other arguments that it raised in its Memorandum. I need only address them briefly as they are without merit.

[29] First, Merck suggests that the Minister's position was that she had no discretionary power under subsection 3(2), thereby contradicting this Court's statements in *Apotex Inc. v. Canada (Minister of National Health and Welfare)*, 2000 CanLII 14856, [1999] F.C.J. No. 1978 (F.C.A.) and *Astrazeneca Canada Inc. v. Canada (Minister of Health)*, 2004 FC 736, [2004] F.C.J. No. 883 (Q.L.), aff'd 2005 FCA 175, 335 N.R. 6. In these cases, this Court determined that the Minister's authority to refuse or add or delete patents from the register under subsection 3(1) is discretionary. Merck argued that, in *Hoffmann*, the Federal Court failed to refer to the above cases in concluding that the Minister lacked the discretion to accept patent lists outside the 30-

day time period. In asserting that *Hoffmann* should have not constrained the Minister's decision, Merck pleaded that the Minister's reliance on *Hoffmann* was unreasonable (Appellant's Memorandum at paras. 60-61).

[30] This was not at all what the Minister said. She recognized her power to maintain the register by adding or deleting patents in accordance with section 3 of the *PM (NOC) Regulations,* but she indicated that her discretion to add patents to the register was limited to those that met "the requirements for addition to the register."

[31] I thus see no inconsistency between this position, which is supported by the clear, and in my view, unequivocal, wording of subsection 3(2), the purpose of the *PM (NOC) Regulations* and their history, and the two cases relied upon by Merck in this respect (see para. 29 above). In fact, at the hearing before us, counsel for Merck even acknowledged that this argument was premised on a narrow interpretation of the Minister's decision, specifically, one in which she would have had no discretionary power at all under section 3.

[32] Second, contrary to Merck's view, the Minister's reference to *Hoffmann* did not render the Minister's decision unreasonable. The Federal Court's statements at paragraph 23 of that decision were relevant as they addressed the interplay between sections 3 and 4 (as they then read). When asked about this at the hearing, counsel for Merck adjusted their argument in response, saying that *Hoffmann*, like other cases dealing with time requirements in section 4 before the 2017 amendments, has become largely irrelevant.

[33] Merck proposed to us another surprising new interpretation. It submitted that the time requirements in subsections 4(5) and 4(6) are not conditions of eligibility for listing patents. Further, it contended that both are simply no longer relevant as a requirement for adding a patent within the meaning of the latest version of subsection 3(2), which, in its restructured form, does not expressly refer to section 4. Merck pointed to the fact that words like “eligible” and “eligibility” are used in subsections 4(2), 4(3), 4(3.1), and that no such words are found in subsections 4(5) or 4(6). Merck added that the 2017 RIAS supports this interpretation because, at page 3322, after stating that the patent requirements have not changed, it only refers to the substantive eligibility criteria. Thus, Merck concluded that, when one reads subsection 3(2) in conjunction with the RIAS and the wording of section 4 as a whole, there can only be one reasonable interpretation—that the Minister has the full discretion to extend the time requirements set out in the *PM (NOC) Regulations*.

[34] I do not agree.

[35] Merck’s interpretation runs contrary to how these regulations have been understood and applied for years. Therefore, and at the very least, one would have expected such a sweeping change pertaining to a key element of the requirements for adding patents to the register to have been clearly spelled out in the 2017 RIAS. As the Minister mentioned, the 2017 RIAS instead expressly states that the requirements for the addition of a patent have not changed.

[36] Furthermore, the sweeping change argued by Merck would not have gone unnoticed by the pharmaceutical industry or the intellectual property bar. Yet, Merck did not refer us to any commentary addressing such a change.

[37] As maintained in the 2017 RIAS, the main purpose of the 2017 amendments was to meet Canada's obligations and commitments under the *Canada-European Union Comprehensive Economic and Trade Agreement,* Canada and the European Union, 30 October 2016 (entered into force provisionally on 21 September 2017) (*CETA*). These were the sweeping changes made to the *PM (NOC) Regulations*.

[38] The reference to the specific substantive eligibility requirements at page 3322 of the 2017 RIAS can easily be understood when one considers that the last sentence of the first paragraph under the heading "Patent listing requirements" reiterates that the specific substantive requirements remain applicable, notwithstanding that all claims in a listed patent must now be litigated in an action brought under the *PM (NOC) Regulations.* The only other relevant passage of the 2017 RIAS starts at page 3322 under the heading "Maintaining the patent register", and explains that the changes there were made only to address concerns previously raised by the Standing Joint Committee for the Scrutiny of Regulations. It does not indicate any change of the well-known legislative policy underlying the listing of patents.

[39] This also runs contrary to the interpretation that Merck proposed to the Minister, specifically, making a clear distinction between the wording of subsections 4(5) and 4(6) of the *PM (NOC) Regulations*. Why focus on distinctions between the wording of subsections 4(5) and

4(6), if it is irrelevant to the alleged new discretion granted to the Minister under subsection 3(2)? How can Merck now say that its new proposed interpretation is the only reasonable one?

[40] This new argument is also inconsistent with the case on which Merck relies to support another of its attacks on the Minister's decision—that the Minister failed to follow or justify its departure from *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, [2003] 4 F.C. 445, 233 F.T.R. 189 (appeal dismissed on a separate ground in 2003 FCA 467, [2004] 2 F.C.R. 85) (*Procter & Gamble*).

[41] That case involved a motion to dismiss on the basis of the ineligibility of the patent for listing in paragraph 6(5)*(a)* (now section 6.07) because of the failure to meet the time requirement in what is now subsection 4(6) of the *PM (NOC) Regulations*. Here, it is important to note that the difference in the wording between the paragraphs dealing with time requirements and the substantive eligibility criteria was always there, despite the various versions used throughout time. Although Merck described *Procter & Gamble* as the only reported decision that directly considered a legal and factual situation comparable to the one before us, it is not the only case where the failure to meet the time requirement under section 4 was challenged by way of a motion contesting the eligibility of a patent for listing. The fact that the word "eligible" was not used in the various iterations of subsections 4(5) and 4(6) has never been viewed as meaning that the failure to meet those key timelines would not make a patent ineligible for listing.

[42] This brings me to Merck's last argument in relation to *Procter & Gamble*. I do not agree that the Minister could be said to have erred by not considering that case. Not only did Merck

fail to expressly cite it in its submissions to the Minister, but *Procter & Gamble* simply does not support Merck's proposition that, because "an exception was made" in that case, it was "thus incumbent upon the Minister to justify her departure from that authority in this case" (Appellant's Memorandum of Fact and Law at para. 75).

[43] As the author of *Procter & Gamble*, I am well acquainted with the issues raised in that case. I believe that this decision supports (rather than undermines) the Minister's conclusion that the time limit in subsection 4(6) is mandatory. There is no doubt in my mind that both the Federal Court and the Federal Court of Appeal in that case were of the view that the then-applicable version of subsection 4(6) provided for strict time limits that had to be met for the patent to be eligible for filing. In *Procter & Gamble*, the real issue before the Federal Court was when the 30-day period commenced. This was a factual issue that had to be determined according to the standard of review applicable to motions to dismiss.

[44] In *Procter & Gamble*, the Federal Court found that the date of the patent's issuance was in doubt because of the exceptional circumstances of that case (namely, the appointment of a new Commissioner of Patents and the ensuing delay in the actual issuance of the patent itself). The Federal Court of Appeal found that going beyond the date stipulated on the patent would create too much uncertainty. Thus, it held that courts should not look beyond this official statement. There was no suggestion whatsoever that the Minister had the discretion to extend the 30-day deadline set out in subsection 4(6) as it then read, or that the failure to meet this deadline was not fatal.

[45] In fact, it is only because of the mandatory nature of this deadline, and the public interest in the integrity of the patent register, that Justice Evans did not agree with the majority that the doctrine of issue estoppel could apply. The majority, led by Justice Rothstein (as he then was), did not disagree that the time requirements were key, but felt that this did not mean that the issue estoppel did not apply or that the Court should exercise its discretion not to apply such doctrine.

[46] As mentioned, the timelines under section 4 are key elements of the scheme set out in the *PM (NOC) Regulations*. They have always been regarded as such, and it was eminently reasonable for the Minister to conclude that they necessarily come within the words "meet the requirement for addition to the register" in subsection 3(2).

[47] I am therefore satisfied that the Federal Court correctly applied the standard of reasonableness when it concluded that the Minister's decision with respect to subsections 3(2) and 4(6) was reasonable.

B. *The Minister's Decision Regarding the Effects of the Time Limits Act*

[48] Before the Minister, Merck had an opportunity to present the views that it submitted to this Court and the Federal Court. Merck could have argued that section 6(1) of the *Time Limits Act* applied to the time requirement under subsection 4(6) of the *PM (NOC) Regulations* because the listing of a patent is the "gateway" to commence proceedings under subsection 6(1) of the *PM (NOC) Regulations*. It did not do so, even though this legislation was in force by the time it presented its written submissions. As mentioned, Merck merely noted the existence of Bill C-20

to support its view that COVID-19 constituted an exceptional circumstance that warranted the exercise of the Minister's discretion.

[49] Nevertheless, the Minister, having carefully reviewed Merck's submissions, including the footnotes in the background section, commented on this legislation. She did so because, contrary to Merck's submissions, she concluded that she did not have the discretion to extend time limits despite business interruptions.

[50] More specifically, at page 6, the Minister noted that the *Time Limits Act* "extends a number of legislated deadlines, including time limits for bringing proceedings before a court." She observed that the *Time Limits Act* does not extend the deadline within which first persons may submit patent lists in accordance with subsection 4(6) of the *PM (NOC) Regulations*.

[51] I agree with Merck that, because the Minister deals with this point, her views are judicially reviewable. But I do not agree that, in this case, this means that she should have conducted a full statutory analysis, as Merck suggests.

[52] I am satisfied that, in the circumstances of this matter, in which the wording of the *Time Limits Act* is clear and contains only three relevant sections, the Minister's views are intelligible and sufficiently transparent. Section 5 of the *Time Limits Act* clearly states that it only extends certain legislated timelines. Subsection 6(1) is limited to the suspension of limitation periods in respect of proceedings before a court. It is implicit that the Minister did not view the listing of a patent under section 4 of the *PM (NOC) Regulations* as a proceeding before a court. Indeed, the

only provision specifically setting out time limitation periods for proceedings before a court are those set out in section 6 of the *PM (NOC) Regulations*. More importantly, administrative timelines provided for in federal legislation are expressly contemplated in section 7 of the *Time Limits Act*. It gives authority to Ministers who are responsible for legislation listed in the schedule thereto to suspend or extend timelines in such legislation. Neither the *Patent Act*, nor the *PM (NOC) Regulations* were so listed, even though this is where one would normally expect time limits such as those set out in subsections 4(5) and 4(6) to be dealt with.

[53] Frankly, it is difficult to imagine how the Minister (or a court, for that matter) could have anticipated the argument that Merck now presents, namely that, because patent listing is a condition *sine qua non*, the time limits in subsection 4(6) and, presumably, those in subsection 4(5), in and of themselves, constitute limitation periods to commence proceedings before a court within the meaning of subsection 6(1) of the *Time Limits Act*.

[54] Turning to the outcome, namely that the *Time Limits Act* has no application to subsection 4(6), I am also satisfied that it is reasonable. Having carefully considered the submissions to the contrary and the case law presented by Merck, I find that this argument has no merit.

[55] I need not say much more in that respect, as I agree with the Federal Court's statements at paragraphs 18 to 31 of the reasons below. In fact, I agree with the respondent that Merck's position is akin to saying that any time limit for obtaining a patent under the *Patent Act* is also part of a limitation period for commencing a proceeding before a court because a patent is a condition *sine qua non* to the filing of an action for infringement under the *Patent Act*.

[56] Finally, Merck attacks the reasonableness of the Minister's finding on the basis of the following comment at page 6 of her decision:

> Further, on July 30, 2020, an Order in Council was made pursuant to subsection 6(4) of the *Time Limits Act* to clarify that no deadlines under the *PM (NOC) Regulations* are affected by the *Time Limits Act* by virtue of subsection 55.2(5) of the *Patent Act*.

[57] Merck challenges the validity of this comment, which is contrary to the Federal Court's conclusion in *Viiv Healthcare Company v. Sandoz Canada Inc.*, 2020 FC 1040 (*Viiv*), which was issued on the same day as the Minister's decision. The Minister appears to have focused on subsection 2(2) of the Order in Council, issued a few days after the legislation came into force, which was relevant to administrative time limits and not only to those relating to proceedings before a court. Conversely, the Federal Court in *Viiv* focused on subsection 2(1) of the Order in Council, which provides, in the Court's view, that any suspension under subsection 6(1) of the *PM (NOC) Regulations* for bringing an action before the Court was lifted, as this was the only issue before it. The Federal Court in *Viiv* also found that subsection 55.2(5) of the *Patent Act* did not have the impact ascribed to it by the Minister in the present matter, for there was no real inconsistency between subsection 6(1) of the *Time Limits Act* and subsection 6(1) of the *PM (NOC) Regulations*.

[58] The Federal Court's decision in *Viiv* is not on appeal before us. I therefore do not wish to comment further on it. It is sufficient, for our purposes, to say that, on its face, the above-quoted comment by the Minister appears to be flawed. However one characterizes this "error", I agree with the Federal Court that it does not render the Minister's finding that the *Time Limits Act* does

not apply to subsection 4(6) unreasonable as a whole. As indicated by the Minister's use of the word "further", this was only an additional argument supporting her view.

C. *Equitable Remedies*

[59] I now turn to the final issue before us, which Merck did not submit to the Federal Court.

[60] Merck acknowledges that this Court lacks the power to grant equitable relief where doing so would conflict with clear statutory rules. I would add that there is robust case law dealing with clear statutory time limitations.

[61] Yet, Merck asks us to distinguish this case law due to the exceptional circumstances of this case, specifically, the occurrence of COVID-19. It points to various steps taken by the legislator (the *Time Limits Act*) and administrative decision makers, such as the Commissioner of Patents (exercising her power under section 78 of the *Patent Act*). It claims that, in such exceptional circumstances, this Court should apply greater flexibility. Merck also argues that if the *Time Limits Act* does not apply to the deadlines under subsections 4(5) and 4(6), it is clearly a legislative oversight. I note in this respect, however, that both the *Time Limits Act* and the Order in Council issued on July 30th, 2020 reflect a deliberate consideration.

[62] Merck also argues that this Court has the discretion to grant it a remedy under the "expansive" equitable doctrine of relief from forfeiture.

[63] As mentioned at the hearing, this Court has sparingly used its power to address new arguments. It is paramount that the appellate court be satisfied that the evidentiary record bearing on the issue is complete. As the Supreme Court of Canada noted in *Alberta (Information and Privacy Commissioner) v. Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 S.C.R. 654 [*Alberta Teachers' Association*], raising issues for the first time (in a judicial review or on appeal from such a decision) "may unfairly prejudice the opposing party and may deny the court the adequate evidentiary record required to consider the issue" (*Alberta Teachers' Association* at para. 26).

[64] Even if this Court did have the power to grant the relief sought (which I doubt), I am not satisfied that the evidentiary record before us is adequate and that we could consider this new issue without causing prejudice to the respondent. As the respondent forcefully argued, it had no opportunity whatsoever, given the issues before the Federal Court, to challenge Merck's affidavit evidence or to produce additional evidence relating to the now relevant factual situation.

[65] Having carefully reviewed the record, there is very little evidence as to how the patent agent's mistake occurred. That evidence is not only scant, but it is also based on hearsay and, sometimes, double hearsay. Faultlessness may well not be a prerequisite to the application of the equitable doctrine of relief from forfeiture, as argued by Merck, but the reasonableness of the Appellant's conduct would still be a relevant factor to consider before exercising one's discretion (*Saskatchewan River Bungalows Ltd. v. Maritime Life Assurance Co.*, [1994] 2 S.C.R. 490, 115 D.L.R. (4th) 478 at p. 504).

[66] I would therefore decline to exercise any discretion this Court may have to deal with Merck's new request for an equitable remedy.

II. Conclusion

[67] In light of the foregoing, and seeing that neither party sought costs, I propose that the appeal be dismissed without costs.

"Johanne Gauthier"
J.A.

"I agree
George R. Locke J.A."

"I agree
René LeBlanc J.A."

Appendix A

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

[…]

Register and Patent List

3 (2) The Minister shall maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection in which any of those patents are set out

(a) by adding any patent on a patent list or certificate of supplementary protection that meets the requirements for addition to the register;

(b) by refusing to add any patent or certificate of supplementary protection that does not meet the requirements for addition to the register;

(c) by deleting any patent or certificate of supplementary protection

(i) that was added to the register due to an administrative error,

(ii) that has, under subsection 60(1) or 125(1) of the Patent Act, been declared to be invalid or void,

(iii) that has, under subsection 6.07(1), been declared to be ineligible for inclusion on the register, or

(iv) the deletion of which was requested by the first person in respect of the patent list that includes that patent;

[…]

Registre et liste de brevets

3 (2) Le ministre tient un registre des brevets qui ont été présentés pour adjonction au registre et des certificats de protection supplémentaire qui mentionnent ces brevets. À cette fin, le ministre :

a) ajoute au registre tout brevet inscrit sur une liste de brevets et tout certificat de protection supplémentaire qui sont conformes aux exigences pour adjonction au registre;

b) refuse d'ajouter au registre tout brevet et tout certificat de protection supplémentaire qui ne sont pas conformes aux exigences pour adjonction au registre;

c) supprime du registre tout brevet ou tout certificat de protection supplémentaire :

(i) qui y a été ajouté à la suite d'une erreur administrative,

(ii) qui a été déclaré invalide ou nul aux termes des paragraphes 60(1) ou 125(1) de la Loi sur les brevets,

(iii) qui a été déclaré inadmissible à l'inscription au registre au titre du paragraphe 6.07(1),

(iv) qui fait l'objet d'une demande de suppression par la première personne à l'égard de la liste de brevets qui comprend ce brevet;

(d) by deleting, in respect of a new drug submission or a supplement to a new drug submission, any patent that has expired, unless a certificate of supplementary protection in which the patent is set out is included on the register in respect of that submission or supplement; and

d) supprime, à l'égard d'une présentation de drogue nouvelle ou d'un supplément à une présentation de drogue nouvelle, tout brevet qui est expiré, sauf si un certificat de protection supplémentaire mentionnant ce brevet est inscrit au registre à l'égard de cette présentation ou de ce supplément;

(e) by deleting any certificate of supplementary protection that has expired.

e) supprime tout certificat de protection supplémentaire qui est expiré.

[…]

[…]

4 (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

4 (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

(1.1) The patent list may include a patent whose term under section 44 of the *Patent Act*, without taking into account section 46 of that Act, has expired and that is set out in a certificate of supplementary protection that has taken effect.

(1.1) La liste de brevets peut comprendre un brevet qui est périmé en application de l'article 44 de la Loi sur les brevets — compte non tenu de l'article 46 de cette loi — et qui est mentionné dans un certificat de protection supplémentaire ayant pris effet.

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

(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :

(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;

a) une revendication de l'ingrédient médicinal, l'ingrédient médicinal ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;

(b) a claim for the formulation that contains the medicinal

b) une revendication de la formulation contenant l'ingrédient

ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;

médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

(c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or

c) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

d) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

(2.1) The following rules apply when determining the eligibility of a patent to be added to the register under subsection (2):

(2.1) Les règles ci-après s'appliquent au moment de la détermination de l'admissibilité des brevets pour leur adjonction au registre aux termes du paragraphe (2) :

(a) for the purposes of paragraph (2)(a), a patent that contains a claim for the medicinal ingredient is eligible even if the submission includes, in addition to the medicinal ingredient claimed in the patent, other medicinal ingredients;

a) pour l'application de l'alinéa (2)a), un brevet qui contient la revendication de l'ingrédient médicinal est admissible même si la présentation comprend, en plus de l'ingrédient médicinal revendiqué dans le brevet, d'autres ingrédients médicinaux;

(b) for the purposes of paragraph (2)(b), a patent that contains a claim for the formulation is eligible if the submission includes the non-medicinal ingredients specified in the claim, if any are specified, even if the submission contains any additional non-medicinal ingredients; and

b) pour l'application de l'alinéa (2)b), un brevet qui contient la revendication de la formulation est admissible si la présentation comprend les ingrédients non médicinaux précisés dans la revendication — si des ingrédients non médicinaux y sont précisés — , même si la présentation contient des ingrédients non médicinaux additionnels;

(c) for the purposes of paragraph (2)(d), a patent that contains a claim for the use of the medicinal ingredient is eligible if the

c) pour l'application de l'alinéa (2)d), un brevet qui contient la revendication de l'utilisation de l'ingrédient médicinal est admissible si la présentation

submission includes the use claimed in the patent, even if

comprend l'utilisation revendiquée dans le brevet, même si :

(i) the submission includes additional medicinal ingredients,

(i) la présentation comprend l'utilisation d'ingrédients médicinaux additionnels,

(ii) the submission includes other additional uses of the medicinal ingredient, or

(ii) la présentation comprend d'autres utilisations,

(iii) the use that is included in the submission requires the use of the medicinal ingredient in combination with another drug.

(iii) l'utilisation comprise dans la présentation requiert l'utilisation de l'ingrédient médicinal en conjonction avec une autre drogue.

(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

(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 :

(a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;

a) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

(b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or

b) dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

(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

c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de

ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

(3.1) A certificate of supplementary protection is eligible to be added to the register in respect of a new drug submission or a supplement to a new drug submission if

(3.1) Est admissible à l'adjonction au registre, à l'égard d'une présentation de drogue nouvelle ou d'un supplément à une présentation de drogue nouvelle, tout certificat de protection supplémentaire si, à la fois :

(a) the patent that is set out in the certificate of supplementary protection is included on the register in respect of that submission or supplement; and

a) le brevet mentionné dans le certificat de protection supplémentaire est inscrit au registre à l'égard de cette présentation ou de ce supplément;

(b) the submission or supplement relates to a drug with respect to which the certificate of supplementary protection grants rights, privileges and liberties referred to in section 115 of the *Patent Act*.

b) cette présentation ou ce supplément vise une drogue à l'égard de laquelle le certificat de protection supplémentaire confère des droits, facultés et privilèges visés par l'article 115 de la *Loi sur les brevets*.

(4) A patent list shall contain the following:

(4) La liste de brevets comprend :

(a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;

a) l'identification de la présentation de drogue nouvelle ou du supplément à la présentation de drogue nouvelle qui s'y rattachent;

(b) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;

b) l'ingrédient médicinal, la marque nominative, la forme posologique, la concentration, la voie d'administration et l'utilisation prévus à la présentation ou au supplément qui s'y rattachent;

(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

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

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

(i) is the owner of the patent,

(ii) 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).

(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.

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).

4 (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).

(7) A first person who has submitted a patent list must keep the information on the list up to date but, in so doing, may not add a patent to the list.

(7) La première personne qui a présenté une liste de brevets doit tenir à jour les renseignements y figurant, mais ne peut toutefois y ajouter de brevets.

(8) The Minister shall insert on the patent list the date of filing and submission number of the new drug submission or the supplement to a new drug submission in relation to which the list was submitted.

(8) Le ministre inscrit sur la liste de brevets la date de dépôt et le numéro de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle qui se rattache à la liste présentée.

[…]

[…]

Right of 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 infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

Droits d'action

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 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.
[…]	[…]
6.07 (1) In an action brought under subsection 6(1), the Federal Court may, on the motion of the second person, declare that a patent or certificate of supplementary protection is ineligible for inclusion on the register.	**6.07 (1)** Lors de l'action intentée en vertu du paragraphe 6(1), la Cour fédérale peut, sur requête de la seconde personne, déclarer qu'un brevet ou un certificat de protection supplémentaire est inadmissible à l'inscription au registre.

Time Limits and Other Periods Act (COVID-19), enacted by section 11 of chapter 11 of the *Act respecting further COVID-19 measures*, S.C. 2020, c. 11

[…]	[…]
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.
[…]	[…]
Time Limits Related to Proceedings	**Délais concernant les instances**
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) any time limit in relation to something that is to be done in a proceeding before a court; and

(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.

b) tout délai relatif à l'accomplissement d'un acte dans le cadre d'une instance devant une cour;

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.

Other Time Limits and Periods

Ministerial orders — Acts and regulations

7 (1) The minister who is responsible for an Act of Parliament set out in column 1 of the schedule or a relevant portion of the Act may make an order

(a) suspending or extending a time limit that is established by or under any provision of the Act that is set out in column 2;

(b) extending any other period that is established by or under any provision of the Act that is set out in column 2;

(c) if a regulation is set out in column 2 in respect of the Act,

(i) suspending or extending a time limit that is established by or under that regulation, or

(ii) extending any other period that is established by or under that regulation; or

(d) extending a suspension or extension.

Ministerial orders — regulations

(2) The minister who is responsible for a regulation set out in column 1

Autres délais et périodes

Arrêtés – lois et règlements

7 (1) Le ministre chargé de l'application d'une loi fédérale figurant dans la colonne 1 de l'annexe — ou d'une partie pertinente de cette loi — peut, par arrêté :

a) suspendre ou prolonger tout délai prévu sous le régime d'une disposition de cette loi figurant dans la colonne 2;

b) prolonger toute autre période prévue sous le régime d'une disposition de cette loi figurant dans la colonne 2;

c) si un règlement figure dans la colonne 2 en regard de cette loi :

(i) suspendre ou prolonger tout délai prévu sous le régime de ce règlement,

(ii) prolonger toute autre période prévue sous le régime de ce règlement;

d) prolonger la suspension ou la prolongation.

Arrêtés – règlements

(2) Le ministre chargé de l'application d'un règlement figurant dans la colonne 1 de l'annexe — ou

of the schedule or a relevant portion of the regulation may make an order

(a) suspending or extending a time limit that is established by or under any provision of the regulation that is set out in column 2;

(b) extending any other period that is established by or under any provision of the regulation that is set out in column 2; or

(c) extending a suspension or extension.

[…]

Additional content

(6) An order under subsection (1) or (2) may provide that

(a) a suspension or extension does not apply in respect of any circumstance specified in the order without the consent of a person, court or body specified in the order;

(b) a suspension or extension applies in respect of any circumstance specified in the order unless a person, court or body specified in the order decides otherwise; or

(c) a person, court or body specified in the order may vary the effects of the order in relation to any circumstance specified in the order.

Regulations

(7) The Governor in Council may, on the recommendation of the Minister of Justice, make regulations restricting, or imposing conditions

d'une partie pertinente de ce règlement — peut, par arrêté :

a) suspendre ou prolonger tout délai prévu sous le régime d'une disposition de ce règlement figurant dans la colonne 2;

b) prolonger toute autre période prévue sous le régime d'une disposition de ce règlement figurant dans la colonne 2;

c) prolonger la suspension ou la prolongation.

[…]

Contenu supplémentaire

(6) L'arrêté pris en vertu des paragraphes (1) ou (2) peut prévoir :

a) que la suspension ou la prolongation ne s'applique à l'égard d'une situation précisée dans l'arrêté que si une personne, une cour ou un organe précisé dans l'arrêté y consent;

b) que la suspension ou la prolongation s'applique à l'égard d'une situation précisée dans l'arrêté à moins qu'une personne, une cour ou un organe précisé dans l'arrêté n'en décide autrement;

c) qu'une personne, une cour ou un organe précisé dans l'arrêté peut modifier l'effet de l'arrêté en vue de son application à une situation précisée dans l'arrêté.

Règlements

(7) Le gouverneur en conseil peut, par règlement pris sur recommandation du ministre de la Justice, limiter ou assujettir à des conditions le pouvoir de prendre des

on, a power to make an order under subsection (1) or (2).

arrêtés conféré par les paragraphes (1) ou (2).

Patent Act, R.S.C., 1985, c. P-4

[…]	[…]
Regulations	**Règlements**
Inconsistency or conflict	**Divergences**
55.2 (5) In the event of any inconsistency or conflict between (a) this section or any regulations made under this section, and (b) any Act of Parliament or any regulations made thereunder, this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.	**55.2 (5)** Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.
[…]	[…]
Time period extended	**Délai prorogé**
78 (1) If a time period fixed under this Act, in respect of any business before the Patent Office, for doing anything ends on a prescribed day or a day that is designated by the Commissioner, that time period is extended to the next day that is not a prescribed day or a designated day.	**78 (1)** Le délai fixé sous le régime de la présente loi, relativement à toute affaire devant le Bureau des brevets, pour l'accomplissement d'un acte qui expire un jour réglementaire ou un jour désigné par le commissaire est prorogé jusqu'au premier jour suivant qui n'est ni réglementaire ni désigné par le commissaire.
Power to designate day	**Pouvoir de désigner un jour**
(2) The Commissioner may, on account of unforeseen circumstances and if the Commissioner is satisfied that it is in the public interest to do so, designate any day for the purposes of subsection (1). If a day is designated, the Commissioner shall inform the public of that fact on the website of the Canadian Intellectual Property Office.	**(2)** Le commissaire peut, en raison de circonstances imprévues et s'il est convaincu qu'il est dans l'intérêt public de le faire, désigner un jour pour l'application du paragraphe (1) et, le cas échéant, il en informe le public sur le site Web de l'Office de la propriété intellectuelle du Canada.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE FOTHERGILL DATED APRIL 20, 2021, NO. T-l476-20

DOCKET:	A-143-21
STYLE OF CAUSE:	MERCK CANADA INC. v. THE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	OCTOBER 19, 2021
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	LOCKE J.A. LEBLANC J.A.
DATED:	NOVEMBER 22, 2021

APPEARANCES:

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