Federal Court Cour fédérale

Date: 20201222

Docket: T-670-20
T-673-20

Citation: 2020 FC 1180

Ottawa, Ontario, December 22, 2020

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

MERCK SHARP & DOHME CORP.
AND
MERCK CANADA INC.

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

Docket: T-673-20

AND BETWEEN:

MERCK SHARP & DOHME CORP.
AND
MERCK CANADA INC.

Plaintiffs

and

PHARMASCIENCE INC.

Defendant

JUDGMENT AND REASONS

I. **Overview**

[1] Each of Sandoz Canada Inc. and Pharmascience Inc. is a Defendant in a patent action brought by Merck Sharp & Dohme Corp. and Merck Canada Inc. (Court file numbers T-670-20 and T-673-20, respectively). Each Defendant has brought a motion in the action to which it is a party, seeking an order for summary judgment under Rule 215 of the *Federal Courts Rules*, SOR/98-106 [the Rules] or, in the alternative, an order striking out the Statement of Claim in that action under Rule 221.

[2] These motions are based on the Defendants' position that s 8.2 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the *PM(NOC) Regulations* or *Regulations*], made under the *Patent Act*, RSC, 1985, c P-4 [the *Act*], imposes a limitation period and that the within actions were commenced after expiry of this period.

[3] Merck Sharp & Dohme Corp. and Merck Canada Inc., the Plaintiffs in both actions, submit that these motions should be dismissed but also seek summary judgment, dismissing the Defendants' limitation period defence.

[4] The Defendants initiated the motions in both actions by filing Notices of Motion on July 17, 2020. The Defendants subsequently amended their Notices of Motion on September 4, 2020. The motions were heard together on November 23, 2020. As the parties' arguments in both matters are identical, these Reasons apply to the motions in both actions.

[5] For the reasons explained in more detail below, the Defendants' motions are dismissed, and the Plaintiffs' request for summary judgment is granted. This case presents circumstances where it is appropriate to grant summary judgment on the issue of statutory interpretation raised by the parties. I agree with the Plaintiffs' argument, that s 8.2 of the *Regulations* does not impose a limitation period applicable to actions commenced thereunder. My Judgment will therefore dismiss the Defendants' limitation period defence in each action.

A. *Legislative and Regulatory Background*

[6] The following is a general description of the regulatory regime that represents the context for the issue in these motions. The statutory and regulatory provisions relevant to this issue will be addressed in more detail in the Analysis portion of these Reasons.

[7] In order to sell a drug in Canada, pharmaceutical manufacturers must obtain authorization from Health Canada in the form of a notice of compliance [NOC] issued pursuant to regulations made under the *Food and Drugs Act,* RSC 1985, c F-27. A "first person" who files a submission for an NOC for a drug may submit to the Minister of Health a list of patents related to the drug and, if it receives an NOC, may have that list placed on the patent register under the *PM(NOC) Regulations* (ss 4(1) and 3(7)). When a "second person" subsequently files a submission for an NOC that references a drug in respect of which a patent is listed on the patent register, the *Regulations* require that second person to serve upon the first person a notice of allegation [NOA] in relation to the drug including any allegation that the listed patent is invalid (s 5 of the *Regulations*).

[8] Under s 6(1) of the *Regulations*, the first person or an owner of a patent who receives an NOA may, within 45 days of service of the NOA, bring an action in the Federal Court against the second person who served the NOA, seeking a declaration that the making, constructing, using, or selling of the drug in accordance with the second person's submission would infringe the patent. The s 6(1) right of action applies only to listed patent(s) that are referenced in the NOA. An action brought under s 6(1) triggers an automatic statutory stay preventing the Minister of Health from issuing an NOC to the second person for 24 months (s 7(1)(d) of the *Regulations*). The language of s 6(1) is as follows:

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.	**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.

[9] Section 8.2 of *Regulations*, the interpretation of which is at issue in these motions, provides a first person or patent owner the right, on receipt of an NOA, to commence an action for patent infringement that could result from the making, constructing, using, or selling of the

drug that is the subject of the second person's submission. The s 8.2 right of action applies to patents other than the listed patent(s) referenced in the NOA. The language of s 8.2 is as follows:

8.2 On receipt of a notice of allegation relating to a submission or supplement, a first person or owner of a patent may, under subsection 54(1) or 124(1) of the Patent Act, bring an action for infringement of a patent or certificate of supplementary protection — other than one that is the subject of an allegation set out in that notice — that could result from the making, constructing, using or selling of the drug in accordance with the submission or supplement.	**8.2** Sur réception d'un avis d'allégation à l'égard d'une présentation ou d'un supplément, la première personne ou le propriétaire d'un brevet peut, en vertu des paragraphes 54(1) ou 124(1) de la Loi sur les brevets, intenter une action en contrefaçon d'un brevet ou d'un certificat de protection supplémentaire — autre qu'un brevet ou un certificat de protection supplémentaire visé par une allégation faite dans cet avis — à l'égard de la contrefaçon qui pourrait résulter de la fabrication, de la construction, de l'exploitation ou de la vente de la drogue conformément à la présentation ou au supplément.

B. *Factual Background*

[10] The Plaintiff, Merck Canada Inc., is authorized by Health Canada to sell the drug sitagliptin (sold under the brand name JANUVIA) in Canada. The other Plaintiff, Merck Sharp & Dohme Corp., owns three patents listed in the patent register for sitagliptin. On February 13, 2020, each of the Defendants served Merck Canada Inc. with an NOA in respect of those three listed patents. Each NOA indicated that regulatory approval was being sought to market and sell a generic sitagliptin tablet in Canada.

[11] Less than 45 days later, the Plaintiffs issued Statements of Claim under s 6(1) of the *PM(NOC) Regulations* (in Court file numbers T-418-20 and T-419-20) against each of the Defendants related to the three patents that were the subject of the NOAs. As a result, pursuant to s 7(1)(d) of the *Regulations*, an automatic 24 month stay applies to the issuance of an NOC relating to the generic products that are the subject of the Defendants' submissions to Health Canada.

[12] In addition to the listed patents, Merck Sharp & Dohme Corp. owns Canadian Patent No. 2,518,435 [435 Patent], which is not listed on the patent register. On June 24, 2020, the Plaintiffs filed Statements of Claim commencing the actions underlying these motions (in Court file numbers T-670-02 and T-673-20), pursuant to s 8.2 of the *Regulations*, alleging that the making, constructing, using or selling of sitagliptin tablets by the Defendants will infringe certain claims in the 435 Patent.

[13] On July 17, 2020, the Defendants filed the original versions of the present motions to strike the s 8.2 actions under Rule 221. The basis of these motions was that s 8.2, properly interpreted, includes a 45 day limitation period, which began running upon service of the NOAs, and the Plaintiffs served their Statements of Claim for the s 8.2 actions 132 days after they received the NOAs.

[14] The hearing of the motions was originally scheduled for September 3, 2020. However, the Defendants advised the Court in late August 2020 that they intended to amend their motions to add a request for summary judgment. After hearing submissions from the parties,

Prothonotary Furlanetto issued an Order dated September 11, 2020, directing that the Defendants' amended motions for summary judgment and to strike would be heard on November 23, 2020, and that the Plaintiffs would maintain the right to raise the rescheduling and amendments relating to these motions as an argument relevant to costs.

II. **Issues**

[15] The Defendants submit that the issues to be decided in this motion are:

A. Whether the *PM(NOC) Regulations* impose any timing requirements for s 8.2 actions?

B. Whether the Plaintiffs' claim in each action should be dismissed or struck as time-barred?

[16] The Plaintiffs oppose the motions. They also submit that the Court should consider whether to grant summary judgment in favour of the Plaintiffs, dismissing the Defendants' limitation period defence as raising no genuine issue for trial.

III. **Analysis**

A. *Suitability of Limitation Period Issue for Summary Judgment*

[17] While this motion was originally framed as a motion to strike under Rule 221, the amended motion materials and the parties' arguments at the hearing focused upon the availability

of summary judgment to address the legal issue of whether a 45 day limitation period applies to actions commenced under s 8.2 of the *Regulations*.

[18] Rule 215(1) provides that, if on a motion for summary judgment the Court is satisfied that there is no genuine issue for trial with respect to a claim or defence, the Court shall grant summary judgment accordingly. In *Milano Pizza Ltd v 6034799 Canada Inc*, 2018 FC 1112 [*Milano Pizza*] at paras 24 to 41, Justice Mactavish summarized the law governing motions for summary judgment in the Federal Court, including explaining that the purpose of summary judgment is to allow the Court to summarily dispense with actions that ought not to proceed to trial because they do not raise a genuine issue to be tried, thereby conserving scarce judicial resources and improving access to justice (at para 25).

[19] As the Defendants note, Justice Norris observed in *Rodriguez v Canada*, 2018 FC 1125 that where there is no real dispute about the evidence, and the only dispute is about how to apply relevant legal principles, the case is something that can be readily and fairly determined in the context of a motion for summary judgment (at para 24). Addressing whether a limitation period has expired is the sort of circumstance in which summary judgment may be appropriate (see, e.g., *Lepage v. Canada*, 2017 FC 1136 at para 53).

[20] I need not canvass in any further detail the principles governing the availability of summary judgment, as the parties to these motions agree that the limitation period issue raised by the Defendants' motions is suitable for adjudication in this manner. The Plaintiffs oppose the motions, as they argue that there is no 45 day limitation period as the Defendants assert.

However, the Plaintiffs urge the Court to find in their favour through summary judgment on this issue. In other words, while the parties dispute whether there is an applicable limitation period, they agree the Court should decide that issue, one way or the other, on these motions and enter summary judgment on that issue accordingly.

[21] Of course, if the Plaintiffs prevail on this issue, summary judgment in their favour will serve only to remove one defence from the issues in these actions. However, as the Defendants note in their written submissions, Rule 215(2) and (3) permit the Court to grant motions for summary judgment in part. The Plaintiffs also rely on *Apotex Inc v Pfizer Canada Inc*, 2016 FC 136, at paras 33 to 36, in which Justice Diner held that, on a motion involving the interpretation of a law, the Court could grant summary judgment in favour of ether party, regardless of whether a cross-motion had been filed. (See also *Milano Pizza* at para 111.)

[22] The present motions raise an issue of statutory interpretation. There is little dispute between the parties as to the surrounding facts and, in any event, the determination of the statutory interpretation issue does not require any factual determinations. I concur with the parties that this issue is suitable for adjudication through summary judgment in the present motions.

B. *Principles of Statutory Interpretation*

[23] The parties also agree on the fundamental principles governing statutory interpretation although, as will be explained later in this Analysis, they do part ways on some of the nuances of

the interpretive principles identified in the authorities, and they disagree on the outcome resulting from application of these principles to the particular issue at hand.

[24] The parties agree that *Rizzo & Rizzo Shoes Ltd (Re)*, [1998] 1 SCR 27 [*Rizzo Shoes*] is the leading authority on the so-called "modern approach" to statutory interpretation, requiring that statutory language be read in its entire context and in its grammatical and ordinary sense, harmoniously with the scheme of the legislation, the object of the legislation, and the intention of Parliament (at para 21). The interpretation of a statutory provision involves a textual, contextual and purposive analysis to find a meaning that is harmonious with the statute as a whole (see, e.g., *Celegne Corp v Canada (Attorney General)*, 2011 SCC 1 at para 21).

[25] The Defendants also emphasize that the legislative purpose ought to be considered at every stage of a statutory analysis, including when conducting the textual analysis. To the extent the language of the text permits, interpretations that are consistent with or promote the legislative purpose should be adopted, while interpretations that defeat or undermine that purpose should be avoided (see Ruth Sullivan, *Construction of Statutes*, 6th ed (Toronto: Lexis Nexis, 2014) [Sullivan] at 260).

[26] The Defendants also rely substantially on the ability, in conducting the statutory interpretation exercise, to "read down" a provision when a contextual analysis indicates that a narrow scope was intended, so as to ensure the provision aligns with the statutory purpose. In *Merck Frosst Canada Ltd v Apotex Inc*, 2009 FCA 187, at paras 87-91, the Federal Court of Appeal endorsed this approach followed by the Federal Court, distinguishing "reading down"

from “reading in”. In the decision under appeal, *Apotex Inc v Merck & Co Inc*, 2008 FC 1185, at paras 98 to 102, Justice Hughes relied on Sullivan’s explanation of the difference between “reading down” and “reading in”. The former is described as a legitimate interpretative technique, involving adding restrictions or qualifications to give effect to the intended scope of legislation. The latter is described as expanding the reach of legislation and not a legitimate interpretative technique, other than perhaps as a constitutional remedy. Justice Hughes also explained that, while legislation is presumed to be well drafted (the so-called “presumption of perfection”), this presumption can be readily rebutted, because drafting mistakes inevitably occur.

[27] The Defendants also emphasize that, when the statutory language being interpreted appears in regulations, the interpretive process must be conducted in the context of the enabling legislation and its constraints (see *AstraZeneca Inc v Canada (Minister of Health)*, 2006 SCC 49 [*AstraZeneca*] at paras 15-16).

[28] Finally, the Defendants note that the history and evolution of a statute is an extrinsic aid that can be used to assist in determining legislative intent (see, e.g., *Rizzo Shoes* at para 31). Both parties rely on the Regulatory Impact Analysis Statement [RIAS], which accompanied the most recent amendments to the *Regulations* in 2017, as well as RIASs applicable to previous sets of amendments, as instructive in understanding the legislative intent.

[29] I have no difficulty accepting the principles described above as relevant to the process of statutory interpretation. I will apply these principles to the interpretation of the provision at issue in these motions.

C. *Sources of Legislative Purpose*

[30] Conscious of the Defendants' point that legislative purpose permeates all aspects of the legislative interpretation process, I begin by identifying their submissions as to the sources from which that purpose can be derived and, briefly, their respective positions on the legislative purpose.

[31] The Defendants' Amended Written Representations describe the *Regulations'* broad legislative purpose as follows:

> 29. The *Regulations* are intended to balance the interests in making safe and effective drugs available to the public while preventing abuse of the "early working" exception from patent infringement under s 55.2(1) of the *Patent Act*. The *Regulations* seek to achieve this balance by enabling legal proceedings to address patent concerns without unduly delaying access to generic medicines. This objective remained unchanged with the 2017 amendments to the *Regulations*.

[32] While the Defendants' description relies in part on *AstraZeneca* (at paras 15-16), which considered an earlier version of the Regulations, the Defendants also note that *Genentech, Inc v Celltrion Healthcare Co Ltd*, 2019 FC 293 [*Genentech*] described the legislative purpose of the current *Regulations* in similar terms. Specifically, *Genentech* (at para 23) relied on *AstraZeneca* in describing s 6(1) of the *Regulations* as enacted for the limited purpose of preventing

infringement by a person who takes advantage of the early working and stockpiling exemptions to patent infringement.

[33] Consistent with the Defendants' above characterization of the broad legislative purpose of the *Regulations*, they also reference the following paragraph from the "Background" section of the RIAS covering the 2017 amendments:

> 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 Regulations were intended to reflect this balance by enabling summary legal proceedings that would address patent concerns without unduly delaying access to generic medicines. Over time, the Regulations became less effective, in part because litigants commenced further litigation under the *Patent Act* (the Act) when unsatisfied with summary proceeding rulings.

[34] Against that background, the 2017 amendments incorporated into the *Regulations* a right of action for infringement of listed patents (see s 6(1)). However, the amendments also provided for rights of action related to non-listed patents (see ss 8.1 and 8.2). In relation thereto, the Defendants emphasize the following paragraphs of the RIAS:

> **Related rights of action**
>
> Not all patents are eligible for listing on the patent register (e.g. patents claiming chemical intermediates, patents claiming processes for making a drug) and not all eligible patents are necessarily listed on the register. **Such patents can create legal uncertainty if there is risk that they could be infringed by the generic product. To facilitate legal consideration of such patents without expanding the scope of proceedings under the proposed Regulations**, related rights of action are proposed.
>
> ….

> Innovator Right of Action
>
> The proposed Regulations would enable a first person or owner of a patent, upon receiving an NOA, to bring an action for infringement of a patent that is not the subject of an allegation in the NOA that could arise from making, constructing, using or selling a drug in accordance with the second person's submission or supplement. **This would not establish a standalone patent infringement process under the Regulations. The purpose is effectively to permit the first person or patent owner to bring an action prior to actual infringement occurring (essentially, an action *quia timet*).**
>
> [Defendants' emphasis]

[35] Noting the above reference to *quia timet* actions, it is useful to explain at this juncture that, prior to the 2017 regulatory amendments, the common law prohibited such actions (i.e., actions seeking to restrain an activity that was threatened but had not yet violated the plaintiff's rights) except in exceptional circumstances. *Connaught Laboratories Ltd v SmithKline Beecham Pharma Inc* (1998), [1998] FCJ No 1851 (FCTD), at para 20, explained that a statement of claim initiating a *quia timet* proceeding alleging patent infringement required: (a) allegations of a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement; (b) that the activity be alleged to be imminent and the resulting damage be alleged to be very substantial if not irreparable; and (c) that the facts pleaded be cogent, precise and material.

[36] As an aid to the interpretation of s 8.2 of the *Regulations*, the Defendants also point to the enabling legislation pursuant to which s 8.2 was enacted. The parties appear to agree that the relevant subsection of the *Act* is s 55.2(4)(e), which provides as follows:

55.2(4) 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	**55.2 (4)** 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 :
…	…
(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);	**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);

[37] I do not understand the Plaintiffs to take any particular issue with the Defendants' reliance on the above sources to inform an understanding of the legislative purpose. The Plaintiffs also rely on the following paragraph in the "Objectives" section of the RIAS for the 2017 amendments:

> … [T]he Government believes these amendments would achieve a number of objectives:
>
> ….
>
> - Fifthly, the proposed amendments remove barriers that may prevent innovators and generics from litigating certain patents outside the Regulations prior to generic market entry.

[38] Later in this Analysis, I will return in more detail to the parties' respective positions on the legislative purpose underlying s 8.2 of the Regulations, and their arguments in support of, and derived from, those positions. However, in brief, the Defendants' position is that the purpose is the pursuit of legal certainty, surrounding the risks associated with unlisted patents, before a generic product is launched. In contrast, the Plaintiffs' position is that the purpose is the removal of previously existing barriers to addressing the uncertainty arising from such risks, but not necessarily the elimination of such uncertainty or risks prior to generic product launch.

D. *Consideration of Text and Context*

[39] I now turn to the issue in dispute, whether s 8.2 imposes a limitation period as argued by the Defendants. Consistent with the applicable jurisprudence, the parties' submissions on the interpretation of s 8.2 focus on the text of that provision and the context of other sections in the *Regulations,* but with significant reliance on their respective positions surrounding the legislative purpose.

[40] For ease of reference, the text of s 8.2 is as follows:

8.2 On receipt of a notice of allegation relating to a submission or supplement, a first person or owner of a patent may, under subsection 54(1) or 124(1) of the Patent Act, bring an action for infringement of a patent or certificate of supplementary protection — other than one that is the subject of an allegation set out in that notice — that could result	**8.2** Sur réception d'un avis d'allégation à l'égard d'une présentation ou d'un supplément, la première personne ou le propriétaire d'un brevet peut, en vertu des paragraphes 54(1) ou 124(1) de la Loi sur les brevets, intenter une action en contrefaçon d'un brevet ou d'un certificat de protection supplémentaire — autre qu'un brevet ou un certificat de

from the making, constructing, using or selling of the drug in accordance with the submission or supplement.	protection supplémentaire visé par une allégation faite dans cet avis — à l'égard de la contrefaçon qui pourrait résulter de la fabrication, de la construction, de l'exploitation ou de la vente de la drogue conformément à la présentation ou au supplément.

[41] Focusing upon both text and context, the Plaintiffs' principal submissions emphasize that s 8.2 contains no express reference to a 45 day limitation period and stands in stark contrast to s 6(1), which does expressly set out such a limitation. The Plaintiffs argue s 6(1) demonstrates that those who drafted the *Regulations* clearly knew how to include a limitation period, and the fact they failed to do so in s 8.2 demonstrates that no limitation period was intended to apply to actions under that section. The Plaintiffs rely on similar reasoning in *65302 British Columbia Ltd v Canada*, [1999] 3 SCR 804 at paras 63 to 65. They also note the point expressed by the Supreme Court of Canada in *Syndicat de la fonction publique du Québec v Quebec (Attorney General)*, 2010 SCC 28 at para 37, that there is no reason to think that a legislature would choose to use two different drafting techniques to achieve the same result in the same statute.

[42] While these arguments are simple, they are compelling. However, I remain conscious of the Defendants' submission that the authorities caution against taking a purely literal approach to statutory interpretation. Even if the words of a legislative provision appear clear, it is necessary to go beyond the text and consider both the context and the legislative purpose (see *Apotex Inc v Pfizer Inc*, 2017 FCA 201 at paras 50-51). Before considering other arguments by the Plaintiffs, I

will explain those advanced by the Defendants to support their position that a limitation period applies to s 8.2, notwithstanding the absence of express words to that effect in the section.

[43] Focusing upon the text of s 8.2, the Defendants note that it affords the right of action "[o]n receipt of a notice of allegation …". They observe that the provision does not use the language, "[o]n or after receipt of a notice of allegation". Rather, the words chosen imply an immediacy, and they argue that meaning must be given to those words that achieves the intended legislative purpose of the section and the regime overall.

[44] Like the Plaintiffs, the Defendants also rely on s 6(1) as context, but they argue that the express 45 day limitation period in s 6(1) supports their interpretation, as they submit that consistency in the timing of commencement and therefore resolution of infringement actions, related to listed and unlisted patents, is necessary in order to achieve the legislative intent. As previously noted, the Defendants rely on the ability to "read down" a statutory provision, to limit or qualify express language in order to achieve that intent.

[45] The Defendants submit that, to achieve the legislative purpose of s 8.2 and address the legal uncertainty associated with the risk that unlisted patents could be infringed by the generic product that is the subject of an NOA, such uncertainly must be addressed in a timely manner. The Defendants argue that, to allow a first person to bring a s 8.2 action whenever it wishes after being served with an NOA would fail to address that uncertainty, as s 8.2 litigation (along with the possibility of the first person seeking injunctive relief) could continue beyond the period when s 6(1) litigation on listed patents is resolved.

[46] Indeed, the Defendants raise the spectre of a first person commencing multiple and serial s 8.2 actions. They argue this would frustrate the broad legislative purpose of facilitating timely entry of generic products to market and the specific legislative purpose underlying s 8.2 of addressing legal uncertainty surrounding the effect of unlisted patents upon such market entry. The Defendants note the issue of "evergreening," the concern about late-appearing patents frustrating generic market entry (see, e.g., *AstraZeneca* at para 39, for a discussion of the issue) that existed prior to 2006 amendments to the Regulations. Those amendments addressed that concern through a patent register that is "frozen" at the time a generic files a submission for an NOC. The Defendants argue that, without a limitation period applicable to s 8.2 actions, the potential for evergreening will reappear, as first persons can file serial lawsuits related to unlisted patents and thereby frustrate generic market entry.

[47] The Defendants therefore argue that the language "[o]n receipt of a notice of allegation …" in s 8.2 must be interpreted to mean that a s 8.2 action must be brought immediately upon receipt of an NOA and, at latest, within 45 days of such receipt. While s 8.2 does not include a reference to a 45 day limitation period, the Defendants contend that reading down the language to include such a limitation is necessary to facilitate the adjudication of unlisted patent infringement claims within the pendency of the 24 month statutory stay that results from s 6(1) infringement claims brought within the 45 day period.

[48] In response to these arguments, the Plaintiffs submit that the Court cannot disregard the actual words chosen by the legislator and rewrite the legislation (see *Canada (Information Commissioner) v Canada (Minister of National Defence)*, 2011 SCC 25 at para 40). They also

rely on *Friesen v Canada*, [1995] 3 SCR 103 [*Friesen*], for the proposition that the Court should not accept an interpretation which requires the insertion of extra wording when there is another acceptable interpretation that does not requires that extra wording (at para 41). Also, in *R v Zeolkowski*, [1989] 1 SCR 1378 [*Zeolkowski*] at p 1387, the Supreme Court referred to giving the same words the same meaning throughout a statute as a basic principle of statutory interpretation.

[49] The Defendants question the currency of the principles expressed in *Friesen* and *Zeolkowski*, noting that both pre-date *Rizzo Shoes*. I accept that there may be circumstances where a previous judicial expression of an interpretive principle may have to give way to the governing principles of the modern approach. However, in the absence of any compelling submissions identifying inconsistencies between the principles in those authorities and those explained in *Rizzo Shoes*, I see no reason to reject the guidance contained in the older authorities. Nor do I regard the application of the older authorities to guide the Court to a different result in the present matters than do the principles articulated in *Rizzo Shoes* and subsequent jurisprudence.

[50] The Plaintiffs point out that ss 6(1) and 8.2 employ similar language in referring to the effect of receipt of an NOA. Section 6(1) states that, “The first person or owner of a patent who receives a notice of allegation … may … bring an action …”. Section 8.2 states that “On receipt of a notice of allegation … a first person or owner of a patent may … bring an action …”. The Plaintiffs acknowledge that this language is not identical in the two provisions, but they argue it is sufficiently alike that the principle expressed in *Zeolkowski* applies.

[51] While accepting the value of the guidance in *Zeolkowski*, I am not convinced it assists the Plaintiffs in these particular matters. The Defendants rely on the use of the words "[o]n receipt" in s 8.2. These words are not reproduced identically in s 6(1). I therefore do not consider *Zeolkowski* to necessarily guide the Court to the result advocated by the Plaintiffs.

[52] Turning to *Friesen*, considering whether there is an acceptable interpretation of the provision at issue that does not require extra wording strikes me as similar to the interpretive exercise of considering whether or not respect for legislative purpose requires reading down through the insertion of qualifying wording. I therefore do not consider *Friesen* to conflict with the interpretive process that the Defendants argue must be conducted.

[53] In my view, the divergence in the parties' proposed interpretations of s 8.2 does not turn on reliance on different authorities or the interpretive principles found therein. Rather, it is the parties' different positions on the legislative purpose surrounding s 8.2 which drives different results through the application of those principles. I will now consider the parties' arguments in support of those positions.

E. *Consideration of Legislative Purpose*

[54] As previously explained, the Defendants submit that the language of s 8.2 must be read down to include a 45 day limitation period (or at least some limitation period), to facilitate the adjudication of unlisted patent infringement claims before expiry of the 24 month statutory stay applicable to s 6(1) infringement claims brought within the 45 day period. Otherwise, outstanding s 8.2 claims may frustrate the market entry of generics, even though all s 6(1) claims

have been resolved. The Defendants argue this interpretation of s 8.2 is necessary to achieve the legislative purpose of that section, the pursuit of legal certainty in respect of unlisted patents before a generic product is launched.

[55] In support of this articulation of the purpose of s 8.2, the Defendants rely on the statements in the 2017 RIAS cited earlier in these Reasons. In summary, the RIAS states that rights of action are proposed to facilitate legal consideration of unlisted patents that can create legal uncertainty, and (apparently in relation to s 8.2) it expressly refers to the "purpose" as permitting a first person to bring an action prior to actual infringement occurring.

[56] The Defendants also rely on the enabling s 55.2(4)(e) of the *Act*, noting in particular the reference in that section to the prevention of disputes with respect to the infringement of a patent. They argue that the prevention of infringement by a generic product for which an NOC is sought is possible only if the action under the enabled section of the Regulations is brought immediately upon service of the NOA, so that resulting litigation can be concluded prior to the product entering the market.

[57] The Defendants' arguments are not without merit, as I accept that the legal uncertainty associated with unlisted patents is reduced sooner if litigation surrounding those patents is commenced, and therefore resolved, promptly. I also accept the argument that the prevention of disputes with respect to the infringement of a patent is achieved by adjudication of potential infringement concerns before the potentially infringing product is launched. However, I am not convinced that the purpose of the *Regulations,* or s 8.2 in particular, should be understood

exactly as the Defendants advocate, or that the purpose drives the interpretation that the Defendants urge the Court to adopt.

[58] Examining first the interpretive influence of s 55.2(4)(e) of the Act, I note that it enables the enactment of regulations with respect to not only the prevention, but also the resolution, of disputes with respect to the infringement of a patent. This point detracts from the Defendants' argument that s 8.2 has a strictly preventative mandate that requires it be interpreted to permit only actions that are commenced quickly, and therefore capable of completion, prior to potential infringement. Even if one were to construe "prevention" as relating solely to litigation that concludes before generic product launch and "resolution" as relating to litigation that concludes after such launch, s 55.2(4)(e) enables the enactment of regulations with respect to both. Moreover, the Plaintiffs make the valid point that even litigation which does not conclude until after product launch serves to prevent infringement (if the first person is successful) following judgment.

[59] Turning to the 2017 RIAS, in addition to the paragraphs upon which the Defendants rely, the Plaintiffs note the paragraph that describes the 2017 amendments as removing barriers that may prevent innovators and generics from litigating certain patents outside the *Regulations* prior to generic market entry. The Plaintiffs argue that the legislative intention is that actions brought under s 8.2 not form part of the regulatory regime created by the *Regulations*. While the *Regulations* govern s 6(1) actions, s 8.2 actions are brought outside that regime, with the sole impact of *Regulations* on such actions being the elimination of the common law barriers to *quia timet* actions.

[60] I agree that such a purpose can be inferred from the language of the RIAS. I also agree with the Plaintiffs' submission that the intention that s 8.2 actions proceed independently of the regulatory regime applicable to s 6(1) actions can be inferred from other provisions of the *Regulations*. As previously noted, commencement of a s 6(1) action automatically triggers a 24 month stay of the grant of the NOC (s 7(1)(d)). The Plaintiffs refer to *Bayer AG v Canada (Minister of National Health and Welfare)*, [1993] FCJ No 1106 (FCA), at paras 12 to 14, as linking the 45 day limitation period to the statutory stay and the overall need to bring the litigation to conclusion expeditiously.

[61] I accept the Plaintiffs' submission that these features of the s 6(1) action are linked. The 45 day limitation period is a function of the intention that the stay, if it is to be invoked through commencing a s 6(1) action, be invoked promptly so that it will conclude promptly. This is part of the balance, intended to be achieved by the *Regulations*, between the protection of patent rights and the early availability of generic products. However, the regulatory stay applies only to s 6(1) actions, not to actions under s 8.2. This point favours the Plaintiffs' argument that the purpose for the 45 day period, applicable to the former, does not apply to the latter.

[62] Of course, a first person may seek a judicial stay in the context of a s 8.2 action. However, such a stay is discretionary, and whether it will be available will depend upon on assessment of the particular circumstances of the matter in which it is sought. It is the automatic nature of the 24 month stay triggered by s 6(1) actions that creates the need for the 45 day limitation period. In my view, the potential availability of the discretionary remedy of a judicial stay does not suggest a need for a similar limitation period applicable to claims under s 8.2.

[63] The Plaintiffs note that there are other provisions of the *Regulations*, which are also designed to achieve the expeditious advancement of s 6(1) actions. Such an action is automatically a specially managed proceeding under the Rules (s 6.1 of the *Regulations*), and there are provisions which require, or are designed to incentivize, diligence by the parties in conducting the proceeding (ss 6.09, 6.12, and 8(6)). These provisions do not apply to s 8.2 actions. Again, this difference favours the Plaintiffs' position that the 45 day limitation period, which is linked to the need for expeditious advancement of s 6(1) proceedings, is not intended to apply to s 8.2.

[64] The Plaintiffs emphasize in particular the effect of s 6.01 of the Regulations, which expressly prohibits any patent action against the second person for infringement of a patent that is the subject of an NOA, other than an action under s 6(1), unless the first person did not within the 45 day limitation period have a reasonable basis for bringing the action. The effect is to make s 6(1) actions brought within the limitation period an exclusive remedy, unless the "reasonable basis" exception applies. The potential availability of the exception militates against the Defendants' position. The Plaintiffs argue, and I agree, that it would be an odd result if, through the statutory interpretation advocated by the Defendants, s 8.2 actions were subject to an absolute 45 day limitation period when s 6(1) actions are not.

[65] In so concluding, I am conscious of the submission by the Defendants that its proposed interpretation would not mean that, if the 45 day limitation period was missed, a claim for infringement of an unlisted patent would be forever barred. The Defendants acknowledge that, while under their interpretation of s 8.2 the *quia timet* action permitted by s 8.2 would be barred

if out of time, the first person could still commence an action under the *Act* once the generic product is launched and infringement occurs. However, that point does not dissuade me from the conclusion that there would be no logic to subjecting s 8.2 claims to an absolute bar following the expiry of 45 days, when the same does not apply to claims under s 6(1).

[66] The Plaintiffs also rely on the purpose of the NOA, in the regulatory regime surrounding s 6(1) actions, to support their position on the interpretation issue in dispute. As explained in *AB Hassle v Canada (Minister of National Health & Welfare)*, [2000] FCJ No 855 (FCA) at para 19, that purpose is to enable the first person to confidently decide within the 45 day time limit whether to resist the issuance of the NOC by commencing a s 6(1) action. The Plaintiffs submit that the NOA and information provided therewith, much of which is focused upon the listed patents referenced in the NOA, provide the first person with sufficient information to be able to prepare its claim quickly enough to meet the 45 day deadline. However, as the NOA is not directed to unlisted patents, the first person would not be similarly equipped to commence a s 8.2 action within the same 45 days.

[67] Finally, the Plaintiffs note the s 6.02 prohibition against joinder of any other action to a s 6(1) action, while the 24 month stay is in place. In its recent decision in *Apotex Inc v Bayer Inc*, 2020 FCA 86 [*Bayer*], the Federal Court of Appeal explained that the purpose of this prohibition is to facilitate the expeditious resolution of s 6(1) actions within the 24 month stay period (at paras 96 and 122). In contrast, s 8.2 actions are not subject to such a prohibition. Indeed, the Plaintiffs argue that it would be inconsistent with the legislative purpose identified in *Bayer* to require s 8.2 actions to be commenced on the same timeline as s 6(1) actions, as this would

increase the litigation burden on the parties and the difficulty in concluding the s 6(1) litigation within the 24 months.

[68] I find that the above points advanced by the Plaintiffs, which focus on the specific features of the regulatory regime applicable to s 6(1) actions, and inapplicable to s 8.2 actions, to make a compelling case for their position. As the s 8.2 action proceeds outside the regulatory regime, the legislative purpose underlying the *Regulations* does not require, or indeed favour, reading down s 8.2 to include a limitation period, either the same as or comparable to that of s 6(1).

[69] The Plaintiffs also respond directly to the Defendants' argument that the legislative purpose of facilitating generic market entry following conclusion of s 6(1) litigation requires that s 8.2 actions be commenced and concluded on the same timeline, so as to avoid serial ligation. As the Plaintiffs observe, s 8.2 merely provides a first person with the option of commencing an action for infringement of an unlisted patent prior to generic market entry. The Plaintiffs note the Defendants' acknowledgement that, even if their interpretation of s 8.2 is accepted, a first person would still be free to sue on an unlisted patent following market entry, when the common law restrictions upon *quia timet* actions would no longer apply and the first person would no longer require recourse to s 8.2. As such, the Plaintiffs submit that it is not possible to conclude that the legislative purpose is to eliminate any further risk of patent litigation by the time the generic enters the market.

[70] In response to the Defendants' argument that, without a limitation period, s 8.2 will give rise to a resurrection of the pre-2006 evergreening concern, the Plaintiffs submit that the evergreening problem was a function of the automatic stay resulting from commencing an action for infringement of a listed patent. Under the pre-2006 regime, a series of such actions would trigger successive stays, continuing to delay generic market entry. However, commencing a s 8.2 action does not invoke an automatic stay. As previously noted, there is a possibility of a first person seeking a judicial stay in the context of a s 8.2 action. But this is discretionary relief and therefore does not raise the same concern as the potential for successive automatic stays of the pre-2006 era. Again, I agree with the Plaintiffs' submissions.

[71] I accept that the legislative purpose of s 8.2 is the removal of previously existing barriers to *quia timet* actions, so as to facilitate legal consideration of unlisted patents and thereby address uncertainty resulting from the risks associated with such patents. However, this purpose does not require the elimination of such uncertainty within any particular timeframe, as no interpretation of s 8.2 can eliminate the uncertainty that the potential for post-launch litigation of unlisted patents will continue to present. Rather, the elimination of the common law barrier achieved by s 8.2 permits earlier access to legal consideration, and therefore earlier resolution, of unlisted patent infringement claims. This result is in keeping with the overall objective of striking a balance between effective patent enforcement and timely generic market entry.

[72] As such, there is no basis to conclude that the relevant legislative purpose requires reading down s 8.2 to include a 45 day limitation period.

F. *Argument on Jurisdiction*

[73] Before concluding my analysis, I must address a jurisdictional point raised by the Defendants. They note that s 8.2 permits a first person to bring an action for infringement of an unlisted patent under s 54(1) (or, although irrelevant for present purposes, s 124(1)) of the *Act*. Section 54 of the *Act* provides as follows:

Jurisdiction of courts	**Juridiction des tribunaux**
54 (1) An action for the infringement of a patent may be brought in that court of record that, in the province in which the infringement is said to have occurred, has jurisdiction, pecuniarily, to the amount of the damages claimed and that, with relation to the other courts of the province, holds its sittings nearest to the place of residence or of business of the defendant, and that court shall decide the case and determine the costs, and assumption of jurisdiction by the court is of itself sufficient proof of jurisdiction.	**54 (1)** Une action en contrefaçon de brevet peut être portée devant la cour d'archives qui, dans la province où il est allégué que la contrefaçon s'est produite, a juridiction, pécuniairement, jusqu'à concurrence du montant des dommages-intérêts réclamés et qui, par rapport aux autres tribunaux de la province, tient ses audiences dans l'endroit le plus rapproché du lieu de résidence ou d'affaires du défendeur. Ce tribunal juge la cause et statue sur les frais, et l'appropriation de juridiction par le tribunal est en soi une preuve suffisante de juridiction.
Jurisdiction of Federal Court	**Juridiction de la Cour fédérale**
(2) Nothing in this section impairs the jurisdiction of the Federal Court under section 20 of the Federal Courts Act or otherwise.	**(2)** Le présent article n'a pas pour effet de restreindre la juridiction attribuée à la Cour fédérale par l'article 20 de la Loi sur les Cours fédérales ou autrement.

[74] On its face, s 54(1) invokes the jurisdiction of the provincial superior courts, not the Federal Court. Of course, s 54(2) provides that s 54(1) does not impair the Federal Court's jurisdiction under s 20 of the *Federal Courts Act*, RSC 1985, c P-4, which in turn states:

Industrial property, exclusive jurisdiction	**Propriété industrielle : compétence exclusive**
20 (1) The Federal Court has exclusive original jurisdiction, between subject and subject as well as otherwise,	**20 (1)** La Cour fédérale a compétence exclusive, en première instance, dans les cas suivants opposant notamment des administrés :
(a) in all cases of conflicting applications for any patent of invention or for any certificate of supplementary protection under the Patent Act, or for the registration of any copyright, trademark, industrial design or topography within the meaning of the Integrated Circuit Topography Act; and	**a)** conflit des demandes de brevet d'invention ou de certificat de protection supplémentaire sous le régime de la Loi sur les brevets, ou d'enregistrement d'un droit d'auteur, d'une marque de commerce, d'un dessin industriel ou d'une topographie au sens de la Loi sur les topographies de circuits intégrés;
(b) in all cases in which it is sought to impeach or annul any patent of invention or any certificate of supplementary protection issued under the Patent Act, or to have any entry in any register of copyrights, trademarks, industrial designs or topographies referred to in paragraph (a) made, expunged, varied or rectified.	**b)** tentative d'invalidation ou d'annulation d'un brevet d'invention ou d'un certificat de protection supplémentaire délivré sous le régime de la Loi sur les brevets, ou tentative d'inscription, de radiation ou de modification dans un registre de droits d'auteur, de marques de commerce, de dessins industriels ou de

	topographies visées à l'alinéa a).
Industrial property, concurrent jurisdiction	**Propriété industrielle : compétence concurrente**
(2) The Federal Court has concurrent jurisdiction in all cases, other than those mentioned in subsection (1), in which a remedy is sought under the authority of an Act of Parliament or at law or in equity respecting any patent of invention, certificate of supplementary protection issued under the Patent Act, copyright, trademark, industrial design or topography referred to in paragraph (1)(a).	(2) Elle a compétence concurrente dans tous les autres cas de recours sous le régime d'une loi fédérale ou de toute autre règle de droit non visés par le paragraphe (1) relativement à un brevet d'invention, à un certificat de protection supplémentaire délivré sous le régime de la Loi sur les brevets, à un droit d'auteur, à une marque de commerce, à un dessin industriel ou à une topographie au sens de la Loi sur les topographies de circuits intégrés.

[75] The Defendants' point is that the legislative language provides no express linkage between the s 8.2 right of action and the jurisdiction of the Federal Court. I do not understand the Defendants to be directly challenging the jurisdiction of this Court over the within actions, at least not on this motion. Rather, the Defendants submit that, if the legislative intent behind s 8.2 is to afford concurrent jurisdiction to the provincial superior courts and the Federal Court, the legislative drafting is less than elegant. The Defendants raise this point to illustrate the difficulty with taking a literal approach to statutory interpretation. They argue that, if the Court is inclined to find no limitation period applicable to s 8.2, because no express words to that effect appear in that section, the Court must then contend with a literal interpretation of the section's reference solely to s 54(1), raising concern that the Federal Court has no jurisdiction over s 8.2 actions. Put

otherwise, if the "presumption of perfection" has not been rebutted in relation to s 8.2, that presumption applies to the entirety of that section including its reference solely to s 54(1).

[76] I do not intend to engage in a detailed analysis of this jurisdictional point. I do not read the Defendants' Notice of Motion as seeking relief based on this Court having no jurisdiction over the within actions. Nor would I be prepared to reach a conclusion on this issue without it being raised more squarely, and argued more comprehensively, than was the case on the present motions.

[77] However, I have considered the Defendants' argument in the context of the statutory interpretation exercise in which it is raised. In my view, this argument does not assist the Defendants, as my conclusion that s 8.2 does not include a limitation period is not based on an analysis confined to a literal reading of that section. To be clear, the text of the section is an important component of the analysis and, as I have observed earlier in these Reasons, the absence of limitation period language in the section militates significantly against the Defendants' proposed interpretation. However, I have conducted the broader analysis advocated by the Defendants and supported by the authorities, taking into account not only the text but also the context and legislative purpose of s 8.2 and the *Regulations* overall and, with the benefit of that full analysis, have rejected the Defendants' proposed interpretation.

IV. **Conclusion**

[78] Based on the above exercise in statutory interpretation, I am satisfied that there is no genuine issue for trial with respect to the Defendants' limitation period defence. As there is no

such limitation period applicable to the within actions, that defence must fail. My Judgment will therefore dismiss the Defendants' motion but will grant summary judgment in favour of the Plaintiffs, dismissing the limitation period defence in both actions.

V. **Costs**

[79] Each of the parties seeks costs. The Plaintiffs seek costs of these motions, payable forthwith, in any event of the cause. They also argue that elevated costs are appropriate, to compensate them for the effect of the Defendants' decision to postpone their motions to strike, shortly before they were scheduled to be heard, to add the request for summary judgment.

[80] The Defendants suggest that costs should be in the cause and disagree that the adjournment of their motions should result in elevated costs.

[81] I agree with the Plaintiffs that costs should follow their success in these motions, payable forthwith, in any event of the cause. If the Defendants had prevailed, that result would have brought the actions to an end, and costs would necessarily have followed. The Plaintiffs should similarly receive their costs based on their success.

[82] However, I do not consider the circumstances leading to the hearing of these motions to warrant costs on an elevated scale. I can identify little additional effort on the Plaintiffs' part required to respond to the motions as a result of their adjournment or the addition of the Defendants' request for summary judgment. The statutory interpretation arguments associated with the summary judgment motions are the same as those related to the motions to strike.

Moreover, the Defendants' addition of the request for summary judgment opened the door for the Plaintiffs also to seek summary judgment in the event their position on the statutory interpretation question prevailed. To the Plaintiffs' benefit, this had resulted in the elimination of an issue that would otherwise have remained to be resolved at trial.

[83] Despite the Court's request that the parties attempt to agree on the quantification of a costs award, they have not been able to do so. I will therefore award costs based on Column III of Tariff B, plus reasonable provable disbursements. If, with the benefit of that direction, the parties remain unable to agree on quantification, costs will be assessed.

JUDGMENT IN T-670-20 AND T-673-20

THIS COURT'S JUDGMENT is that:

1. The Defendant's motion to strike and for summary judgment is dismissed.

2. Summary judgment is granted, on a partial basis, in favour of the Plaintiffs, dismissing the Defendant's defence that the Plaintiffs' action is time-barred.

3. The Plaintiffs are awarded costs of these motions, payable forthwith by the Defendant, in any event of the cause. Costs shall be calculated based on Column III of Tariff B, plus reasonable provable disbursements, to be assessed if the parties cannot agree on their quantification.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-670-20 T-673-20
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DATED:	DECEMBER 22, 2020

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