Federal Court  Cour fédérale

**Date: 20190507**

**Docket: T-2182-18**

**Citation: 2019 FC 595**

**Ottawa, Ontario, May 7, 2019**

**PRESENT: Madam Prothonotary Mireille Tabib**

**BETWEEN:**

**TEVA CANADA INNOVATION AND TEVA CANADA LIMITED**

**Plaintiffs**

**and**

**PHARMASCIENCE INC.**

**Defendant**

**and**

**YEDA RESEARCH AND DEVELOPMENT CO., LTD.**

**Patentee added pursuant to ss 6(2) of the *PM (NOC) Regulations* and ss 55(3) of the *Patent Act***

## ORDER AND REASONS

[1] In the context of this action, filed pursuant to section 6(1) of the recently amended *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 ("the *Regulations*"), the Defendant Pharmascience Inc. seeks to strike out portions of the Statement of Claim of the Plaintiffs Teva Canada Innovation and Teva Canada Limited (collectively referred to as "Teva" in these reasons) on the basis that they improperly plead or join a cause of action in infringement in respect of a drug product for which Pharmascience already holds a Notice of Compliance and which has not been addressed in a Notice of Allegation.

[2] For the reasons that follow, Pharmascience's motion will be granted in part, but only in respect of striking those parts of Teva's Statement of Claim that assert a cause of action for current and past infringement.

## I. FACTUAL AND PROCEDURAL CONTEXT

[3] Yeda Research and Development Co. Ltd. is the owner of Canadian Patent 2,702,437, relating to the use of glatiramer acetate in treating patients with or at risk of developing multiple sclerosis. With Yeda's consent, Teva has obtained Notices of Compliance (NOCs) to sell a glatiramer acetate product in Canada under the brand name Copaxone, in strengths of 20 mg/1 mL and 40 mg/1 mL. Teva has also, with Yeda's consent, listed the '437 Patent on the Patent Register maintained by the Minister of Health pursuant to the *Regulations*, but only in respect of

the 40 mg/1 mL dosage strength. There are no patents listed on the Register in respect of the 20 mg/1 mL strength.

[4] Pharmascience obtained a NOC and has been selling in Canada since August 2017 its own 20 mg/1 mL glatiramer acetate product, under the brand name Glatect 20 mg.

[5] In November 2018, Pharmascience filed a Submission for a NOC for Glatect 40 mg, a 40 mg/1 mL dosage form of glatiramer acetate. Pharmascience's drug submission directly or indirectly compares Glatect 40 mg to Copaxone and was filed in the form of a Supplemental New Drug Submission (SNDS) to the New Drug Submission (NDS) pursuant to which it had previously obtained its NOC for Glatect 20 mg.

[6] Because the '437 Patent is not listed against the 20 mg/1 mL dosage but is listed against the 40 mg/1 mL dosage, Pharmascience did not have to address that Patent to obtain its initial NOC for Glatect 20 mg, but it did need to address it in respect of Glatect 40 mg. Pharmascience did so by serving on Teva a Notice of Allegation (NOA) dated November 13, 2018, in which it alleges that the making, constructing, using or selling of Glatect 40 mg will not infringe the '437 Patent and that the '437 Patent is invalid.

[7] By Statement of Claim filed in the present action, Teva invokes section 6(1) of the *Regulations* and seeks a declaration that the making, constructing, using or selling of both Glatect 20 mg and Glatect 40 mg in accordance with the SNDS filed November 2018 would infringe the '437 Patent. The Statement of Claim also asserts and seeks relief for

Pharmascience's past and current infringement in respect of the sale of Glatect 20 mg under Pharmascience's previously issued NOC, since August 2017.

[8] Pharmascience brings this motion, seeking to strike all parts of the Statement of Claim that relate to its Glatect 20 mg product, on the basis that Teva's attempt to frame a cause of action pursuant to section 6(1) of the *Regulations* in respect of the 20 mg/1 mL product discloses no reasonable cause of action, is frivolous, vexatious or otherwise an abuse of process, and that Teva's inclusion of a patent infringement action in respect of Glatect 20 mg is prohibited by section 6.02 of the *Regulations*.

## II. FRAMEWORK FOR ANALYSIS

[9] Causes of action for the infringement of patents are purely statutory in nature. Section 55 of the *Patent Act* RSC 1985 c P-4 provides for a right of action for patent infringement. However, section 55.2 (1) of that Act, known as the "early working exemption", provides an exemption for uses of a patented invention solely for the purpose of developing and submitting information required by regulations. A pharmaceutical manufacturer who intends to sell a generic version of a patented medication is therefore not amenable to being sued for patent infringement solely for having made or tested an allegedly infringing product for the purpose of applying for a NOC before the expiration of the patent. Absent an actionable act of infringement, a patentee would have no means under the *Patent Act* to pre-emptively sue or seek an injunction to prevent a generic from coming to market with an infringing product, unless it can plead facts showing that the generic is using the invention for purposes other than seeking regulatory approval or unless it can meet the very stringent test for bringing a *quia timet* action.

[10] In order to create an appropriate balance between generics' early working rights and innovators' patent rights in the pharmaceutical industry, the Government has used the regulatory powers conferred by section 55.2(4) of the *Patent Act* to create the rights of action found in section 6(1) of the *Regulations*. Broadly speaking, section 6(1) allows a patentee, in certain specific circumstances, to seek a determination from the Court that the making, constructing, using or selling of a proposed drug product for which a generic is seeking a NOC would infringe its patents.

[11] Any rights of action for patent infringement in Canadian law are therefore confined to the rights of action created by section 55 of the *Patent Act*, and those created by section 6(1) of the *Regulations*. The *Regulations*, however, contemplate that the rights of action conferred by section 6(1) be exercised within a strict procedural framework and section 6.02 provides that, during the period of time defined in section 7(1) of the *Regulations*, these rights should not be combined with any other rights arising from the *Patent Act*.

[12] Bearing in mind the legislative context described above, it is helpful for the purposes of this motion to consider Teva's Statement of Claim as raising the following three distinct causes of action:

a. an action pursuant to section 6(1) of the *Regulations* for a declaration that the making, constructing, using or selling of Glatect 40 mg in accordance with the SNDS would infringe the '437 Patent;

b. an action pursuant to section 6(1) of the *Regulations* for a declaration that the making, constructing, using or selling of Glatect 20 mg in accordance with the SNDS would infringe the ‘437 Patent; and

c. an action for a declaration that the making, constructing, using or selling of Glatect 20 mg since August 2017, in accordance with the NOC already issued to Pharmascience, infringes and will continue to infringe the ‘437 Patent. Although that is a cause of action available pursuant to section 55 of the *Patent Act*, Teva appears to also assert that cause of action pursuant to section 6(1) of the *Regulations*.

[13] Pharmascience does not contest that Teva has a reasonable cause of action pursuant to section 6(1) of the *Regulations* in respect of Glatect 40 mg. With respect to the second and third causes of action, Pharmascience argues that Teva does not have a valid cause of action at all pursuant to section 6(1) of the *Regulations* in respect of Glatect 20 mg. Pharmascience concedes that Teva would have a reasonable cause of action under section 55 of the *Patent Act* in respect of Glatect 20 mg, but it asserts that such an action cannot be joined to Teva’s section 6(1) action in respect of Glatect 40 mg, by reason of section 6.02 of the *Regulations*.

[14] The issues on this motion therefore go beyond the question of whether a regular patent infringement action can be joined to a section 6(1) action in the circumstances of this case. The principal issue to be resolved is, rather, whether it is reasonably arguable that Teva has a cause of action pursuant to section 6(1) of the *Regulations* in respect of Glatect 20 mg, and if so, whether that cause of action includes a cause of action for past and current infringement. In addition, Pharmascience submits that the allegations of the Statement of Claim to the effect that Glatect 20

mg is the subject of Pharmascience's SNDS are frivolous, vexatious and an abuse of process. Finally, to the extent no reasonable cause of action exists under section 6(1) of the *Regulations* in respect of past or current infringement by Glatect 20 mg, the Court will need to consider whether the allegations of the Statement of Claim to that effect should be struck as contrary to section 6.02 of the *Regulations*.

## III. ANALYSIS

### A. *Does Teva have a reasonably arguable cause of action in respect of Glatect 20 mg pursuant to section 6(1)?*

[15] To the extent Pharmascience's motion to strike is based on Rule 221(1)(a) and asserts that the impugned provisions disclose no reasonable cause of action, it must, in accordance with Rule 221(2), be considered without reference to the evidence adduced by Pharmascience. The Court must take the material facts pleaded in the Statement of Claim as true, unless the allegations are based on assumption and speculation (*R v Imperial Tobacco*, 2011 SCC 42).

[16] Key to the Court's analysis is the allegation of paragraph 22 of the Statement of Claim to the effect that "Pharmascience filed a submission for a Notice of Compliance, namely a SNDS filed on November 1, 2018, in respect of a drug, namely Glatect"; Teva defined "Glatect" in paragraph 1.a as including Glatect 20 mg and Glatect 40 mg. While Pharmascience, throughout its motion record and argument, asserts that this allegation is misleading, incorrect and without basis, the Court is not satisfied that this allegation is based on speculation or assumption. According to the *Regulations*, Pharmascience was required to serve on Teva a copy of the relevant portions of its SNDS. Teva would accordingly be in a position to base its allegations on

the content of the SNDS rather than on speculation or assumption. Further, in order to support its assertion that Glatect 20 mg is not the subject of its SNDS, Pharmascience relies on facts that are not pleaded in the Statement of Claim but are set out in affidavits filed in support of its motion. As mentioned, the use of affidavit evidence in determining whether the allegations of a Statement of Claim disclose a reasonable cause of action is proscribed, especially if it aims to contradict the truth of facts set out in the Statement of Claim.

[17] For the purpose of this analysis, the Court will therefore take as true the allegation that Pharmascience's SNDS also relates to Glatect 20 mg.

[18] Teva's position is simple. It relies on the plain wording of section 6(1) and relates each of the requirements set out in section 6(1) to the allegations made in its Statement of Claim.

[19] Section 6(1) reads as follows:

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| 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 date 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 | 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 |

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| set out in that notice. | tout certificat de protection supplémentaire visé par une allégation faite dans cet avis. |

(Emphasis added)

[20] Teva thus identifies the essential elements of the cause of action set out in section 6(1) and relates them to the facts alleged in its Statement of Claim as follows:

a. Teva is a first person;

b. The NOA sent by Pharmascience to Teva is a NOA referred to in paragraph 5 (3)(a);

c. Pharmascience's SNDS is a supplement as referred to in subsection 5(2);

d. Pharmascience's SNDS relates to both Glatect 20 mg and Glatect 40 mg;

e. The Statement of Claim seeks a declaration that the making, constructing, using or selling of Glatect 20 mg, in accordance with the SNDS, will infringe the '437 Patent;

f. The '437 Patent is the subject of an allegation set out in the NOA.

[21] Thus, according to Teva, it does not matter that the '437 Patent is not listed against the 20 mg/1 mL dosage strength, or that the NOA does not mention Glatect 20 mg. What matters is that, as alleged in the Statement of Claim, if a NOC is issued pursuant to the SNDS, then Glatect 20 mg will be made, constructed, used or sold in accordance with the SNDS and will infringe a patent in respect of which allegations are made in the NOA. The cause of action contemplated in section 6(1) is, pursuant to Teva's argument, no longer predicated on the content of the NOA and on whether the allegations are justified, as it was under the old regime, but on the content of the

submission and on whether a drug made in accordance with that submission would infringe a listed patent.

[22] Pharmascience, for its part, argues that Teva's literal reading of section 6(1) offends the purpose and intent of the *Regulations*, which remain, as they were before the 2017 amendments, focused on creating an appropriate balance between the early working rights of generics and the patent rights of innovators. Thus, relying on the reasoning of the Supreme Court in *AstraZeneca Canada Inc. v Canada (Minister of Health)* 2006 SCC 560, [2006] 2 SCR 50, Pharmascience argues that a first person's right of action under section 6(1) cannot exist independently of, or be wider than, a second person's obligations under section 5 of the *Regulations*. Essentially, Pharmascience submits that a purposive interpretation of section 6(1) requires that the words "a drug" be read as referring to the drug in respect of which the NOA was required to be served, so that, in keeping with the previous regime, there be a clear relationship between the rights of action conferred by section 6(1) and the obligation of second person to serve a NOA. Given that the '437 Patent is not listed against the 20 mg/1 mL dosage strength, that Pharmascience already holds a NOC for Glatect 20 mg, and that Pharmascience is not required to address and did not address the '437 Patent in its NOA in respect of Glatect 20 mg, Pharmascience's obligations under section 5 were not triggered in respect of Glatect 20 mg and Teva cannot benefit from a right of action pursuant to section 6(1) in respect of that particular drug formulation.

[23] Counsel for Pharmascience presented the rationale for this argument in a full, cogent and compelling fashion at the hearing, and the Court is grateful for her submissions. However, the threshold for striking a claim as disclosing no reasonable cause of action is very high. The Court must be satisfied that, assuming the facts alleged to be true, the action has no reasonable prospect

of success. As persuasive as Pharmascience's argument may be, Teva's position is also eminently arguable. The proper interpretation and the determination of the scope of section 6(1) raises complex issues of statutory interpretation in the context of a new regulatory scheme. Just as the Court, in a long line of jurisprudence involving the proper interpretation of section 8 of the *Regulations*, refused to strike out pleadings on preliminary motions while the law regarding the right of action conferred by that section remained in an "embryonic state", the Court should hesitate to strike out an action brought under the new regime at the pleadings stage where arguable issues of statutory interpretation are raised (see *Apotex Inc v Eli Lilly and Co.* 2001 FCT 636; *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (2001), 16 C.P.R. (4th) 473 (F.C.T.D.), aff'd (2002, 20 C.P.R. (4th) 190 (F.C.A.); *Apotex Inc. v. Merck & Co.* (2004) 248 F.T.R. 82, [2004] F.C.J. No. 1495 (QL); *Apotex Inc. v Astrazeneca Canada Inc.* 2007 FC 696.)

[24] The Court is not satisfied that it is plain and obvious that Teva does not have a reasonable cause of action to seek a declaration, pursuant to section 6(1) of the *Regulations* that the making, constructing, using or selling of Glatect 20 mg in accordance with the SNDS would infringe the '437 Patent.

B. *Does Teva have a reasonably arguable cause of action under section 6(1) in respect of past or current infringement by Glatect 20 mg?*

[25] As alleged in the Statement of Claim, Pharmascience is and has been selling Glatect 20 mg since August 2017. Section 6(1) of the *Regulations* specifically contemplates that an action be for a declaration that the making, constructing, using or selling of a drug in accordance with the submission would infringe the patent. The Statement of Claim does not allege that the past or

current making, constructing, using or selling of Glatect 20 mg was in accordance with the SNDS. Indeed, it is plain and obvious that Pharmascience's past or current activities in respect of Glatect 20 are not made "in accordance to the SNDS" since that SNDS was not filed until November 1, 2018 and since, pursuant to section 7 of the *Regulations*, the Minister is prohibited from issuing a NOC in respect of that SNDS until at least the time that the present action is dismissed or 24 months have elapsed since its inception.

[26] Teva's argument is not so much that section 6(1) can be interpreted as extending the rights of action created pursuant to it to all versions of the same drug, regardless of the submission or supplement pursuant to which they are made, but that the section must be interpreted to allow such claims because section 6.01 of the *Regulations* would otherwise unfairly bar Teva from asserting them. Section 6.01 reads as follows:

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| 6.01 No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(a) in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or<br>(2) unless the first person or the owner of the patent did not, within the 45 day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection. | 6.01 Aucune autre action qu'une action intentée en vertu du paragraphe 6(1) ne peut être intentée contre la seconde personne pour la contrefaçon d'un brevet ou d'un certificat de protection supplémentaire visé par un avis d'allégation signifié en application de l'alinéa 5(3)a) relativement à la fabrication, à la construction, à l'exploitation ou à la vente d'une drogue conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou<br>2) sauf si la première personne ou le propriétaire du brevet n'avait pas, dans la période de quarante-cinq jours prévue au paragraphe 6(1), de motifs raisonnables pour intenter une |

> action en vertu de ce paragraphe.
>
> (Emphasis added)

[27] Teva asserts that because the '437 Patent is "a patent that is the subject of a notice of allegation" then it must necessarily include its claim for past infringement of that patent by Glatect 20 mg in its section 6(1) action, because it would otherwise be barred from bringing an action for that infringement. Teva relies on the Regulatory Impact Analysis Statement issued alongside the 2017 amendments to the *Regulations*, which explains that the amendments are intended to preserve innovators' rights of action and to even permit allegations of infringement with respect to patents that are not subject of a NOA, as further support for its position that the *Regulations* should not be interpreted in a way that would remove existing rights of action (Regulatory Impact Analysis Statement re: *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, 2017: Canada Gazette, Vol. 151, No. 28 – July 15, 2017 ("RIAS").

[28] Teva's interpretation of section 6.01 is unreasonable. Both on its plain meaning and by its intent, as clarified by the RIAS, section 6.01 only applies to actions for infringement that could have been brought as declaratory actions under section 6(1) by the exercise of due diligence. The RIAS states, in relation to section 6.01:

> If a first person or patent owner chooses not to commence a proceeding under the Regulations in respect of a patent listed on the patent register and addressed in an NOA, the Regulations prohibit subsequent actions from being brought against the second person for infringement of that patent, unless the first person or owner of the patent did not have a reasonable basis for bringing an action under the Regulations within the prescribed period. Possible situations where the first person or owner of the patent could be

> found not to have had a reasonable basis for commencing litigation include situations where the information provided by the second person was false, materially misleading, or materially incomplete (including as a result of a subsequent change in the generic product).
>
> The provision promotes legal certainty by preventing strategic delay in litigating a patent listed on the patent register. At the same time, the provision incentivizes considerable disclosure on the part of a second person seeking to benefit from the provision. (…)
>
> (Emphasis added)

[29] There is no reason for the *Regulations* to seek to interfere with the exercise of rights of action arising out of the *Patent Ac*t in respect of products that are already being sold, and for which the identification of potentially infringing features does not require particular disclosure by the second person.

[30] Teva's argument that an action for past infringement of the '437 Patent by Glatect 20 mg would be barred by section 6.01 simply because the '437 Patent is "a patent that is the subject of a notice of allegation" further ignores the words "in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to". This phrase directly mirrors the provisions of section 6(1) and ties the prohibition to actions for infringement in respect of a drug made in accordance with that specific submission. The closing words of section 6.01 also clarify that in order for the prohibition to apply, the first person should not have had a reasonable basis for bringing an action "under that subsection", that is, under section 6(1).

[31] As the past and current making, constructing, using or selling of Glatect 20 mg is not alleged to be and cannot be in accordance with the SNDS of November 1, 2018, Teva does not

and cannot have a basis in law for bringing an action for the infringement of the ‘437 Patent by that product under section 6(1) of the *Regulations*, and an action for that infringement cannot be barred by section 6.01 of the *Regulations*. There is accordingly no curtailment of Teva’s rights of action under the *Patent Act* that might justify straining the plain meaning and intent of section 6(1). It is worth noting that Pharmascience has expressly taken the position at the hearing of this motion that as section 6(1) and 6.01 must be interpreted consistently, section 6.01 could not bar a subsequent action based on any portion of the Statement of Claim which this Court might strike as disclosing no reasonable cause of action under section 6(1).

[32] The Court is satisfied that it is plain and obvious that Teva has no reasonable cause of action pursuant to section 6(1) of the *Regulations* in respect of the past or current infringement of the ‘437 Patent by Glatect 20 mg.

C. *Are Teva’s allegations to the effect that the SNDS relates to Glatect 20 mg frivolous, vexatious or an abuse of process?*

[33] As mentioned above, Teva’s action in respect of Glatect 20 mg hinges on the interpretation of section 6(1) as tying the right of action to the submission or supplementary submission pursuant to which a drug is to be made, used or sold, and on the allegation that the SNDS that is at issue in this action relates to Glatect 20 mg. In the first part of this analysis, the Court proceeded on the assumption that this allegation, as made in the Statement of Claim, was true, and refrained from considering the evidence tendered by Pharmascience on that issue.

[34] Pharmascience submits that evidence is, however, admissible in considering a motion based on Rule 221(1)(c) asserting that a pleading is frivolous or vexatious or on Rule 221(1)(f) asserting that it is an abuse of process. Pharmascience argues that Teva's allegation that the SNDS relates to Glatect 20 mg is without foundation and made for the sole purpose of supporting the improper joinder of a cause of action in respect of Glatect 20 mg in a section 6(1) action so as to frustrate the purpose and intent of the regulatory regime.

[35] Pharmascience states that, while the product monograph it has filed as part of its SNDS does refer to Glatect 20 mg and Glatect 40 mg, the purpose of the SNDS was only to seek approval for the 40 mg/1 mL strength, since it already has a NOC for Glatect 20 mg. It submits that no substantial changes are made to the 20 mg/1 mL strength and that Teva has simply seized on the fact that the product monograph refers to both strengths as a pretext to allege that the SNDS relates to Glatect 20 mg.

[36] To support its position, Pharmascience relies on the affidavit of its Director of Global Regulatory Affairs. That affidavit is short and what is establishes is quite limited: it establishes that the SNDS seeks approval for Glatect 40 mg, that Pharmascience already has a NOC for Glatect 20 mg, that there are no listed patents against Teva's 20 mg glatiramer acetate product, and that the NOAs Pharmascience has sent to Teva in November 2018 are in respect of Glatect 40 mg and do not address Glatect 20 mg. Notably, the affidavit does not make any assertion in respect of whether the SNDS, beyond seeking approval for Glatect 40 mg, relates to Glatect 20 mg in any manner, shape or form.

[37] Teva has not cross-examined the affiant, and indeed does not really contest any of the facts that are set out in her affidavit. In response, however, Teva has introduced the affidavit of a law clerk for the purpose of introducing, amongst other documents: the Acknowledgement and Certification of Information Received that was attached to the NOA, which confirms that the submission is in the form of a SNDS, and which names the drug as "Glatect" without specifying a dosage strength; the draft product monograph that was included with Pharmascience's NOA, was the only portion of the SNDS communicated to Teva by Pharmascience, and which applies to both the 20 mg and 40 mg strengths; the approved product monograph for the current version of Glatect 20 mg; and the current version of the product monograph for Teva's own Copaxone 20 mg and 40 mg product.

[38] On the basis of those few documents, both counsel have made extensive arguments as to whether or not Glatect 20 mg is addressed in the SNDS, whether any changes were made to the product monograph in relation to Glatect 20 mg that required the filing of an SNDS, and whether Pharmascience was required to make its submission for Glatect 40 mg as a SNDS if no significant changes were made in respect of Glatect 20 mg. These arguments have involved reviewing Guidance Documents published by Health Canada as to how and when approval for changes must be sought by way of SNDS, and comparing portions of Pharmascience's current Glatect 20 mg product monograph with the portions of the proposed product monograph that mention Glatect 20 mg and with the portions of Teva's product monograph for Copaxone, to discern whether the differences that can be observed reveal any substantive changes to any aspect of the 20 mg/1 mL strength of Glatect that would require the filing of an SNDS for that dosage strength, so as to justify Teva's allegation that the SNDS "relates to" Glatect 20 mg.

[39] The Court has significant doubts as to the propriety of using Rule 221(1)(c) or (f) as a means of adducing evidence that goes specifically to disproving the truth of an allegation of fact made in a pleading, so as to then be in a position to argue that the allegation is frivolous, vexatious or abusive. It strikes the Court that this would be an indirect way of bringing evidence on a motion to strike a pleading as disclosing no reasonable cause of action, or would have the effect of turning a preliminary motion to strike into a motion for summary judgement. Be that as it may, even assuming that the evidence led by Pharmascience can be considered for the purpose of this motion, the Court is not satisfied that Pharmascience has met its burden.

[40] For such a motion to be granted, the Court must be satisfied that the claim is so clearly futile that it has not the slightest chance of succeeding (*Apotex Inc. v Syntex Pharmaceuticals International Ltd et al.* 2005 FC 1310, at paragraphs 32 and 33).

[41] On the face of the documents filed, it is clear that some modifications are proposed to be made in the product monograph as it relates to Glatect 20 mg. While these changes are subtle and appear minimal, they could arguably have the effect of "increasing the exposure levels of the drug", as that concept is defined in the Guidance Document issued by Health Canada, and have required the filing of a supplement in respect of Glatect 20 mg itself, irrespective of the proposed addition of a 40 mg dosage strength. However, the Court is not satisfied that the material before it is sufficient to come to any conclusion on the matter, whether in favour of Teva or in favour of Pharmascience. This is an issue that should be allowed to proceed to trial so that it can be determined on a complete record. The evidence falls well short of showing that Teva's case is so

clearly futile and baseless that it does not have any chance of success and should be struck as frivolous, vexatious or an abuse of process.

D. *Should the allegations relating to past or current infringement in respect of Glatect 20 mg be struck as contrary to section 6.02 of the Regulations?*

[42] As determined above, Teva does not have a reasonable cause of action pursuant to section 6(1) of the *Regulations* in respect of the past or current infringement of the '437 Patent by reason of the making, constructing, using or selling of Glatect 20 mg pursuant to the existing NOC. Teva's cause of action in that regard arises only pursuant to section 55 of the *Patent Act*.

[43] Section 6.02 of the *Regulations* provides that:

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|---|---|
| 6.02 No action may be joined to a given action brought under subsection 6(1) during any period during which the Minister shall not issue a notice of compliance because of paragraph 7(1)(d) other than<br>(a) another action brought under that subsection in relation to the submission or supplement in that given action; and<br>(b) an action brought in relation to a certificate of supplementary protection that is added to the register after the filing of the submission or supplement in that given action, if the patent that is set out in that certificate of supplementary protection is at issue in that given action. | 6.02 Aucune action ne peut être réunie à une action donnée intentée en vertu du paragraphe 6(1) durant la période pendant laquelle le ministre ne peut délivrer d'avis de conformité en raison de l'alinéa 7(1)d), sauf :<br>a) une autre action intentée en vertu de ce paragraphe relativement à la présentation ou au supplément visé dans cette action donnée;<br>b) toute action relative à un certificat de protection supplémentaire ajouté au registre après le dépôt de la présentation ou du supplément visé dans cette action donnée, si le brevet mentionné dans ce certificat de protection supplémentaire est en cause dans cette action donnée. |

(Emphasis added)

[44] The RIAS explains this provision and the rationale for its inclusion as follows:

> During the 24-month period in which the Minister is prohibited from issuing an NOC, the Regulations prohibit joinder of any action, other than an action in relation to an allegation of the second person included in a submission or supplement in the main action or an action in respect of a CSP that sets out a patent at issue in the main action. This, in appropriate circumstances, allows for joinder of (i) separate actions brought by a first person and a patent owner in response to the same Notice of Allegation (NOA), and
>
> (ii) separate actions brought in response to multiple NOAs that address different patents but are served in respect of the same submission. Other actions, such as an action alleging infringement of a patent that cannot be litigated under the Regulations, may not be joined. The limit on joinder is necessary to restrict the number of issues in dispute to facilitate resolution within 24 months. It is also necessary to avoid further complicating the assessment of damages arising from delayed market entry. If the 24-month period has expired or otherwise does not apply by operation of the Regulations, the Court is free to order joinder where appropriate.
>
> (Emphasis added)

[45] It is plain and obvious that section 6.02, according to both its plain wording and to the purpose and intent of the *Regulations*, prohibits the joinder of a regular infringement action under the *Patent Act* with an action pursuant to section 6(1). Teva does not suggest that the provision is amenable to any different interpretation that would validate the inclusion of its infringement action in the section 6(1) proceeding. What Teva argues is that in the particular circumstances of this case, where the same patent, the same invalidity allegations, the same medication and substantially the same infringement allegations are at issue, allowing the regular infringement action to proceed as part of the section 6(1) action would not frustrate and would even better align with the purpose of the *Regulations.*

[46] Teva argues that the only significant difference in the prosecution of the actions in the present circumstances relates to the financial remedies, which can be bifurcated. Otherwise, Teva points out that section 6(4) of the *Regulations* allows the Court the flexibility to issue the appropriate relief for the infringement action, that the joinder in the present case would not hinder the prosecution of the action in the 24 month period, that it promotes the legal certainty and the prevention of strategic delay that underlies section 6.01 and eliminates the inefficiencies, costs, delays and dual litigation that motivated the amendments to the regulatory regime.

[47] Teva's points are all valid and could be taken into account if the Court had discretion to order this joinder, as it has under the *Federal Courts Rules*. However, the *Regulations* being specific and remedial, the express procedural provisions they contain must be taken as overriding the more general provisions of the *Federal Courts Rules* in the event of a conflict. Section 6.02 is clear and mandatory. Unlike many other provisions of the *Regulations*, it does not provide for the exercise of the Court's discretion to modify or depart from its provisions. Accordingly, the Court is bound to apply it, irrespective of any efficiency that might otherwise be gained. It should be noted that if Teva were to institute its infringement action as a separate proceeding, the efficiencies to which it alludes could, in the appropriate circumstances, be achieved through cooperation between the parties and by scheduling the trial of common issues to proceed simultaneously, without running afoul of section 6.02 (see *Bayer Inc et al v Teva Canada Limited et al* 2019 FC 191).

[48] The inclusion of Teva's infringement action in respect of Glatect 20 mg as part of its section 6(1) action is clearly prohibited by section 6.02 of the *Regulations* and is, for that reason,

an abuse of process justifying that the relevant portions of the Statement of Claim be struck. It should also be understood that Teva remains free to assert that cause of action as part of a separate proceeding.

[49] Teva asked that, should the Court strike any portion of its claim in respect of Glatect 20 mg, it also issue an order granting it leave to file an infringement claim under the *Patent Act* in respect of Glatect 20 mg, notwithstanding section 6.01 of the *Regulations*. Given the earlier determination that Teva's claim for current and past infringement by Glatect 20 mg cannot be brought under section 6(1) and cannot, accordingly, be barred by section 6.01, there is no need to make the order sought by Teva.

E. *Costs*

[50] Success being divided, costs of the motion shall be in the cause.

**ORDER**

**THIS COURT ORDERS that:**

1. The following portions of the Statement of Claim are struck, without prejudice to the Plaintiffs' right to assert the cause of action they frame in a separate proceeding:

    a. That portion of subparagraph 1(b) that follows the word "valid";

    b. Sub-paragraphs 1(c ) to (f);

    c. Paragraph 21;

    d. In paragraph 27, the words "The making, constructing, using and/or selling of Glatect does, and";

    e. In paragraph 28, the words "is and/or";

    f. In paragraphs 29 to 41, 49 to 52 and 57 the words "is and";

    g. In paragraphs 42 to 48, 54 and 58, the words "does and"

    h. Paragraph 53;

    i. In paragraph 56, the words "do and", each of the four times they are used;

    j. In paragraph 59, the words "ongoing and"; and

    k. In paragraph 60, the words "foregoing activities and", "have and" and "has made and".

2. The Defendant’s motion is otherwise dismissed, costs in the cause.

"Mireille Tabib"
Prothonotary

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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|---|---|
| **DOCKET:** | T-2182-18 |
| **STYLE OF CAUSE:** | TEVA CANADA INNOVATION ET AL V PHARMASCIENCE INC. |
| **PLACE OF HEARING:** | OTTAWA, ONTARIO |
| **DATE OF HEARING:** | FEBRUARY 20, 2019 AND APRIL 1, 2019 |
| **ORDER AND REASONS:** | TABIB P. |
| **DATED:** | MAY 7, 2019 |

**APPEARANCES:**

| | |
|---|---|
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| KAVITA RAMAMOORTHY<br>KERRY ANDRUSIAK | FOR THE DEFENDANT |

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