Federal Court Cour fédérale

**Date: 20191107**

**Docket: T-2182-18**

**Citation: 2019 FC 1394**

**Ottawa, Ontario, November 7, 2019**

**PRESENT: Case Management Judge 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] Pharmascience seeks an order directing the preliminary determination of a question of law pursuant to Rule 220 of the *Federal Courts Rules* SOR/98-106. The question as framed in Pharmascience's motion materials is as follows:

> "Does subsection 6 (1) of the *Patented Medicines (Notice of Compliance) Regulations* permit first persons to pursue an action thereunder in respect of a drug against which there is no listed patent and for which no section 5 obligations are triggered?"

[2] That question is essentially the same as was framed in an earlier motion brought by Pharmascience to strike portions of Teva's statement of claim as disclosing no reasonable cause of action, pursuant to Rule 221(1)(a). By order dated May 7, 2019 (reported at *Teva Canada Innovation et al v Pharmascience Inc.* 2019 FC 595), I dismissed Pharmascience's motion. I found, inter alia, that while Pharmascience's argument was compelling, Teva's countervailing argument was equally arguable, such that the matter did not rise to the plain and obvious standard required to strike a pleading as disclosing no reasonable cause of action. The Federal Court of Appeal denied leave to appeal, saying that "the interpretation of s 6(1) of the Regulations is better left to the trial judge".

[3] Pharmascience submits that the question it now proposes is a pure question of law and that given that the trial judge is already identified, it is appropriate and in the interest of justice that the question be determined preliminarily by the trial judge.

[4] For the reasons that follow, Pharmascience's motion will be dismissed.

## I. FACTUAL CONTEXT

[5] The facts surrounding this action, taken pursuant to s 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 ("the *Regulations*"), are more fully set out in the reasons issued on May 7, 2019 (2019 FC 595). For the purpose of this discussion, they may be summarized as follows.

[6] Teva holds NOCs in respect of a glatiramer acetate product sold under the brand name Copaxone, in strengths of 20 mg/mL and 40 mg/mL. The '457 Patent, which covers both strengths, is however only listed against the 40 mg/mL strength. There are no patents listed against the 20 mg/mL dosage. Pharmascience has already obtained a first NOC for a 20 mg/mL glatiramer acetate product, which it sells under the name Glatect.

[7] In November 2018, Pharmascience filed a submission in respect of a 40 mg/mL dosage strength of Glatect, as a Supplementary New Drug Submission (SNDS) to its original submission in respect of the 20 mg/mL strength. Because it compares Glatect 40 mg/mL to the 40 mg/mL dosage strength of Copaxone, Pharmascience was required to and did send a Notice of Allegation to Teva, which addresses only its Glatect 40 mg/mL product. Teva's responding action, filed pursuant to s 6(1), however seeks a declaration that the making, constructing, using or selling of both Glatect 20 mg/mL and Glatect 40 mg/mL in accordance with the SNDS will infringe the '437 Patent. Pharmascience has, from the outset, argued that Teva's action, insofar as it relates to Glatect 20 mg/mL, is inadmissible under s 6(1) of the *Regulations*.

## II. ANALYSIS

[8] The parties are ad idem as to the factors the Court should consider in exercising its discretion under Rule 220. They are set out at para 7 of the Federal Court of Appeal's decision of *Perera v Canada* [1988] 3 FC 381 and more fully discussed at paras 13-15 of that decision. The Court must be satisfied that:

a) the proposed question is a pure question of law;

b) the determination of the question may be conclusive of the action or of a substantial portion thereof; and

c) taking all circumstances into account, adopting that exceptional course will save time and money.

### A. *Is the question a pure question of law?*

[9] The question as proposed by Pharmascience in its motion record does frame a pure question of law, but that question is premised on two assumptions: the first, that there are no listed patents against the drug in respect of which the action is taken and second, that no section 5 obligations are triggered in respect of that drug. The first premise is indeed an undisputed fact; no patents are listed against glatiramer acetate in 20 mg/mL dosage strength. The second premise, however, is a hotly contested issue of mixed fact and law. Pharmascience is adamant that no section 5 obligations are triggered in respect of its Glatect 20 mg/mL product, because it alleges that its SNDS is not in respect of Glatect 20 mg/mL and that Glatect 20 mg/mL is not

compared to Copaxone in 40 mg/mL dosage strength, both of which are required for s 5 to be triggered. Teva alleges that the SNDS does relate to Glatect 20 mg/mL and that the SNDS, taken as a whole, does compare or make reference to Copaxone 40 mg/mL, in respect of which the '437 Patent is listed. As such, Teva is equally adamant that under a proper construction of s 5, obligations are triggered in relation to Glatect 20 mg/mL. The determination of whether s 5 obligations are triggered in the circumstances of this case therefore require determination of a contested factual issue as well as of a contested issue of statutory interpretation.

[10] Pharmascience submits that, despite this existing dispute, the proposed question remains a pure question of law. It submits that it is not necessary for the Court to resolve the mixed question of fact and law because it can determine the proposed question of law on the assumption that no s 5 obligations are triggered.

[11] I cannot agree with Pharmascience's submission. The jurisprudence of the Court requires that all necessary facts on the basis of which a question of law is to be determined be undisputed. While the case law has recognized that the undisputed factual matrix need not be the product of an agreement between the parties, I am aware of no case where the determination of a question of law has been based on facts that are disputed by the moving party's opponent. At a bare minimum, where a legal question is based on an assumption of truth, the facts assumed to be true must be found in the opponent's pleadings, or be undisputed by reason of issue estoppel (see *Berneche v. Canada* (F.C.A.), [1991] F.C.J. No. 515, at p 3, cited with approval at *Olmstead v. Canada (Attorney General)*, [1998] F.C.J. No. 1461, at para 23 and *Perera*, above, at para 13). In other

words, barring consent, the facts material to the determination of a question of law must be facts which the opposing party cannot dispute.

[12] Here, Pharmascience wishes the Court to determine a question of law that assumes the correctness of a mixed question of fact and law that is vigorously disputed by Teva. Pharmascience does not meet the first criterion for leave to be granted.

[13] If I am wrong in my interpretation of the case law and that the Court can authorize the determination of a question of law that relies on the assumption of the truth of a disputed issue of fact and law, I will continue my analysis by considering the second and third criteria.

B. *Would the determination be conclusive of the action or of a substantial portion thereof?*

[14] Assuming that the Court allowed the question as proposed to proceed, the only portion of the action that could conceivably be determined by the answer to the question of law would be the question of law itself. Indeed, the question as proposed presupposes that no s 5 obligations were triggered in this matter. Any answer to the question would only be effective insofar as the assumption on which it is based is eventually determined in Pharmascience's favour. This means that the entire issue of whether the SNDS relates to Glatect 20 mg/mL and how s 5 is to be interpreted would remain at issue and need to be determined following a full trial in order for the legal determination to have any effect at all.

[15] The determination of the proposed question will not be conclusive of any disputed issue of fact nor of any other contested legal issue. In the circumstances, the single issue of law for

which the determination would be conclusive cannot be considered a substantial portion of the action. I conclude that Pharmascience does not meet the second criterion of the test.

C. *Will there be savings of time and money?*

[16] As mentioned above, the determination of the question as proposed carries with it no broader disposition of other contested issues of fact or law. No time or money will be saved by permitting the exceptional remedy of excising a question from the broader context of the trial so that it can be determined in advance of the trial.

[17] Pharmascience submits that given the complexity of the factual and legal issues that might be determined at the trial and the limited 10-day duration of trial, which the Court usually imposes on actions taken pursuant to the *Regulations,* saving the time required to argue the issue of law from the total trial time is in itself a worthwhile endeavour. I cannot agree.

[18] It is true that the Court has indicated in recent guidelines that it expects the trials of actions taken under the *Regulations* to be completed in two weeks, but that limit is not mandatory. The Court has full discretion to allocate as many days of trial as the determination of the issues in the proceeding reasonably require. On the other hand, the 24-month time within which such an action must be determined on its merits, including all necessary pretrial steps, is mandated by the *Regulations,* and that time can only be extended in specific circumstances.

[19] It seems to me that the time period that must be carefully husbanded and used wisely is the entirety of that 24-month period rather than the specific trial time.

[20] Pharmascience's motion has already consumed significant time and costs for its first stage, including the joint case/trial management conference that was convened to schedule the prospective steps of that motion, the constitution of the motion records for the first stage, and half a day of hearing. If the determination is allowed to proceed, more time will be required for the parties to brief the second stage and a full day of hearing has been requested and set aside. It would be naïve to think that, whatever the outcome, the unsuccessful party would not choose to appeal. An appeal, whether as of right or by leave, would result in a further expenditure of time, effort and money, at a time where the parties ought to be focusing their efforts on getting ready for a trial.

[21] Saving even one day of argument at trial is not worth the distraction, time and costs of resolving that lone question of law as a preliminary matter.

[22] Finally, I would note that beyond the possible savings of time and money, the Court must consider all the circumstances of the case which militate either for or against the granting of the motion, including the desirability that questions of law not be determined in a vacuum (*Perera*, above, at para 15).

[23] The question as proposed seeks the statutory interpretation of s 6(1), a key provision of an entirely new legislative scheme, but it would isolate that determination from the other equally important and difficult question of the proper interpretation of s 5 of the *Regulations.*

[24] It is a canon of statutory interpretation that provisions of a statute must be interpreted in context and harmoniously with the entire scheme of the statute. To divorce the interpretation of s 6(1) from the interpretation of s 5 and its factual context goes against that fundamental principle. This would be a sufficient reason, in and of itself, to deny Pharmascience's motion.

## III. Alternative question

[25] At the very end of the hearing, as part of her submissions in reply, counsel for Pharmascience suggested an alternative formulation to the proposed question of law, as follows:

> "Are s 5 obligations triggered and is there a right of action pursuant to subsection 6(1) of the *Regulations* in respect of Glatect 20 mg/mL where the following facts are assumed, for the sole purpose of the determination:
>
> a) the SNDS relates to Glatect 20 mg/mL;
>
> b) the SNDS compares Glatect 20 mg/mL to Copaxone 40 mg/mL;
>
> c) no patent is listed against Copaxone in 20 mg/mL;
>
> d) two patents are listed against Copaxone 40 mg/20 mL?"

[26] The new proposed formulation would include in the questions for determination the issue of the proper interpretation of s 5 of the *Regulations*, and adopt a set of assumed facts that Pharmascience presumes Teva would not dispute. This new formulation would address the primary concerns expressed above in respect of whether the factual basis for determination is undisputed. It would also, if determined in Pharmascience's favour, have the potential of rendering irrelevant the determination of the assumed facts, and thus, be conclusive of a significant portion of the action. Finally, it would eliminate the Court's concerns as to the

propriety of engaging in the statutory interpretation of s 6(1) in isolation from the interpretation of s 5 of the *Regulations*.

[27] That new formulation constitutes a radical departure from the motion as it was brought, briefed and argued. In all fairness, Pharmascience should have requested leave to amend its notice of motion in order to propose that modified question. Instead, Pharmascience suggested the modification as one which the Court has discretion to impose in granting its motion. The Court is not inclined to exercise its discretion to salvage a motion that was destined to fail, for the following reasons.

[28] The facts proposed to be used as the premise for the determination are unlikely to be contested by Teva, and can thus be considered undisputed. However, the Court must also be satisfied that those facts, as proposed, are in themselves sufficient to allow the Court to make the required determination.

[29] Pharmascience's last-minute formulation includes, for the first time, the proper interpretation and application of s 5 of the *Regulations*. With respect, neither the parties nor the Court have had the time or opportunity to give due consideration of what that determination entails and what facts might be necessary or relevant for the proper determination of these questions. The factual record for the determination of such important and complex questions as the statutory interpretation of the new and unique regime created by the recent amendments to the *Regulations* is not something that can be improvised or cobbled together on a whim. I do not

consider that I have been given sufficiently thorough submissions to be satisfied that the proposed facts are indeed sufficient for the Court to make the determination sought.

[30] I further note that this Court has been hesitant to determine complex issues of statutory interpretation of the regime created under the *Regulations* by way of preliminary motions, including motions for summary judgement and motions for the determination of a question of law (*Apotex Inc v Merck & Co*, 2005 FC 1452 and *Apotex Inc v Merck & Co. Inc*, 2004 FC 314). Pharmascience has not indicated how this case differs from these earlier cases and why the Court should exercise its discretion to permit this exceptional process in this instance.

[31] In any event, even if the determination as reformulated was allowed to proceed, I am not persuaded that it could be determined within a sufficiently short timeframe as would achieve the savings of time and money it promises.

[32] The trial of this action is scheduled for August 2020, with the first expert reports to be served and filed by April 20, 2020. The parties cannot afford to hold off conducting the discoveries and the preparations for trial in respect of the facts that may be relevant to Teva's action in respect of Glatect 20 mg/mL pending the determination of the questions of law. The hearing for the determination of the question of law, if permitted, is scheduled to take place on December 4, 2019. Given the novelty and complexity of the issues, it could be several months before a decision is rendered, during which the parties will have no choice but to continue to proceed with discoveries, refusals motions, and even experts reports.

[33] The issue then arises as to whether trial preparation on the issues related to Glatect 20 mg/mL can or should continue in the event the decision of the trial judge were favourable to Pharmascience. What if the parties lay down their tools, only to find the decision is reversed on appeal? Would there still be time for the parties to make up for lost time in order to be ready for the August trial? I very much doubt it.

[34] The preliminary determination of a question of law may well be a useful tool, in certain cases, to narrow issues ahead of a trial and thus save time and expenses. However where, as here, there is insufficient time to hear and finally resolve the question before trial, this tool becomes a source of distraction, of duplication of efforts and is ultimately wasteful of the parties' and the Court's time and resources.

## IV. Costs

[35] Teva having been successful on this motion, it should recover its costs. It submits that the costs ought to be assessed at the highest end Column IV of the Tariff, including a provision for second counsel, for an amount that is roughly equivalent to $5000. Although the issues that Pharmascience wished to bring to determination as a question of law are complex and novel, there was nothing particularly complex or novel in the determination of the first stage of this motion. The Court is satisfied that the amount of $2500, as suggested by Pharmascience, is adequate in the circumstances.

## ORDER

**THIS COURT ORDERS that:**

1. The motion of Pharmascience is dismissed, with costs payable to Teva, in the amount of $2500.

"Mireille Tabib"
Case Management Judge

**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:** | NOVEMBER 4, 2019 |
| **ORDER AND REASONS:** | TABIB P. |
| **DATED:** | NOVEMBER 7, 2019 |

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