Federal Court  Cour fédérale

Date: 20180919

Docket: T-402-18

Citation: 2018 FC 932

Ottawa, Ontario, September 19, 2018

PRESENT: Case Management Judge Mandy Aylen

BETWEEN:

HOFFMANN-LA ROCHE LIMITED and GENENTECH, INC.

Plaintiffs

and

PFIZER CANADA INC.

Defendant

PUBLIC ORDER
(Identical to Confidential Order issued September 4, 2018)

[1] The Defendant, Pfizer Canada Inc. [Pfizer], seeks to bring a motion for summary judgment or summary trial in relation to this action, which was commenced pursuant to section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PMNOC Regulations*].

[2] Pursuant to Rule 213 of the *Federal Courts Rules* [*Rules*], a party may bring a motion for summary judgment or summary trial on all or some of the issues raised in a pleading at any time

after the defendant has filed a defence but before the time and place for trial have been fixed. In this proceeding, and like all other section 6(1) actions commenced under the recently-amended *PMNOC Regulations*, the time and place for trial was fixed at an early stage of the action - less than five weeks after the Statement of Claim was filed. The practice of fixing the time and place for trial within the weeks following commencement of a section 6(1) action has been adopted by the Court in light of the statutory requirement that the action be determined within 24 months of its commencement.

[3] I acknowledge that motions for summary judgment or summary trial can, in appropriate circumstances, be useful vehicles for resolving the entirety or key portions of actions on a preliminary basis, including section 6(1) actions. In that regard, I note that the *PMNOC Regulations* do not contain any limit or bar on a party bringing a motion for summary judgment or summary trial. However, as a result of the early scheduling of trial dates, most parties in section 6(1) actions – like Pfizer in this action – will need to obtain leave of the Court to dispense with compliance with Rule 213 before they will be entitled to bring such a motion.

[4] Pursuant to Rule 55, in special circumstances, the Court may vary a rule or dispense with compliance with the *Rules*. The Court's plenary power to regulate procedure and the discretion under Rule 55 to dispense with the *Rules* are governed by the objectives set out in Rule 3 – namely, achieving the just, most expeditious and least expensive determination of every proceeding on its merits. Using these powers and in pursuit of these objectives, it is open to the Court to permit a motion for summary judgment or summary trial to proceed notwithstanding that a trial date has already been fixed. It is implicit in considering the special circumstances

referred to in Rule 55 that, on the one hand, justice be done and, on the other hand, there be no prejudice [*Yearsley v Canada*, 2001 FCT 732 at para 7].

[5] Therefore, in considering whether to exercise the Court's discretion to dispense with compliance with Rule 213, the Court must consider whether permitting the motion to be brought will promote the just, most expeditious and least expensive determination of the proceeding on its merits. Whether or not to dispense with compliance with Rule 213 is a discretionary decision and must be considered based on the facts of the particular case before the Court, keeping in mind the overarching principle of proportionality and the efficient use of the parties' resources and the judicious use of limited Court resources. In undertaking this analysis, some of the considerations that the Court may take into account include:

A. Whether special circumstances exist;

B. Whether there will be a significant savings of costs, savings of time and efficiencies from permitting the motion to proceed, including a consideration of whether the motion seeks a determination of all or a portion of the issues raised in the action, whether the motion can reasonably be heard and determined sufficiently in advance of the existing trial date, and which procedural steps and expenses could be avoided if the motion is successful;

C. Whether any of the parties would be prejudiced by permitting the motion to proceed;

D. The level of cooperation of the moving party exhibited to date in the proceeding as required by section 6.09 of the *PMNOC Regulations*; and

E. Whether the moving party seeks to bring the motion in a timely manner.

[6] In considering what savings of costs, savings of time and efficiencies may arise from permitting the motion to proceed, it is important for the Court to recognize that section 6(1) actions already proceed on an expedited timetable and that, absent extraordinary circumstances, the action cannot be held in abeyance pending the determination of the motion for summary judgment or summary trial. Rather, the motion and the action will have to progress in parallel, which has the effect of reducing the efficiencies and savings inherent in such motions.

[7] By way of background, this action pertains to Herceptin (trastuzumab) which is marketed in Canada by the Plaintiff, Hoffmann-La Roche Limited [Roche] for the treatment of early breast cancer, metastatic breast cancer and gastric cancers.

[8] Pfizer filed two new drug submissions [NDSs] under the same Dossier ID E201411 for a proposed product called Trazimera, a biosimilar to Herceptin. NDS No. 212140, which is referred to by Pfizer as the "full label", includes all of the indicated in the Herceptin product monograph. NDS No. 212273, which is referred to by Pfizer as the "skinny label", is allegedly a carve-out, as Pfizer asserts that it does not include all of the indications or information in the Herceptin product monograph. Following amendments to the pleadings in this action and T-401-18, it would appear that this proceeding relates to only the skinny label for Pfizer's proposed product, whereas T-401-18 relates to the full label for Pfizer's proposed product.

[9] There is a clear dispute between the parties as to the propriety of Pfizer having filed two NDSs for the same proposed product. Pfizer asserts that it carved out indications and information in the skinny label as Pfizer anticipated such indications and information would be alleged to

constitute infringement of Genentech's patents. In order to facilitate earlier market entry, Pfizer asserts that it filed the second narrower NDS related to the skinny label in parallel to the full label NDS.

[10] Genentech asserts that this is not an accurate characterization of Pfizer's two NDSs and that both NDSs seek the same approvals – namely, that Pfizer's proposed product be approved for all indications for which Herceptin is approved – notwithstanding that Pfizer has filed draft product monographs which presently appear slightly different.

[11] On June 21, 2018, Pfizer advised the Court that it intended to bring a motion for summary judgment or summary trial and provided the Court with a draft notice of motion. Pfizer subsequently proposed the following timetable for perfection of the motion:

- Service of Pfizer's evidence (approximately 4-5 affidavits) by July 30, 2018;
- Service of Genentech's responding evidence (estimated by Pfizer to require 4-5 affidavits) by September 28, 2018 (2 months later);
- Completion of cross-examinations by October 29, 2018 (one month later);
- Service and filing of Pfizer's motion record by November 21, 2018 (three weeks later);
- Service and filing of Genentech's motion record by December 12, 2018 (three weeks later); and
- Hearing of the motion during the week of December 17, 2019 (five days after the last record filed).

[12] Genentech opposed Pfizer's ability to bring the motion for a variety of reasons and also took issue with Pfizer's proposed timetable, stating that Pfizer's timetable was not achievable and proposing the following timetable in the event that the motion was permitted to proceed:

- Service of Pfizer's evidence by September 1, 2018;
- Service of Genentech's responding evidence by January 1, 2019 (four months later);
- Completion of cross-examinations by March 2, 2019 (two month later);
- Service and filing of Pfizer's motion record by March 23, 2019 (three weeks later);
- Service and filing of Genentech's motion record by April 23, 2019 (one month later); and
- Hearing of the motion during the month of May 2019.

[13] On July 11, 2018, I directed that a case management conference be convened to address whether the motion could be brought in light of Rule 213 and if so, to address the timetable for the motion. I invited Pfizer to serve its evidence on the motion by its proposed deadline of July 31, 2018, pending the resolution of the Rule 213 issue. It is my understanding that Pfizer did not do so.

[14] A case management conference was held on August 2, 2018, during which I heard submissions from the parties as to whether Pfizer should be permitted to bring its intended motion. I directed Pfizer to serve and file its finalized notice of motion and written submissions regarding whether Pfizer should be permitted to bring its motion by August 9, 2018, the Plaintiffs to serve and file responding submissions by August 17, 2018 and Pfizer to serve and file any reply submissions by August 22, 2018. I have now had an opportunity to review the written submissions of the parties and Pfizer's finalized notice of motion.

[15] Pfizer asserts that the basis for its proposed motion for summary judgment or summary trial is that the making, constructing, using and selling of its proposed product in accordance

with the skinny label will not infringe or induce infringement of any of Genentech's patents, as the skinny label is a carve out that does not include all of the indications or information in the Herceptin product monograph. Pfizer asserts that the issues raised by its motion are discrete and focused on the non-infringement of Pfizer's skinny label. Pfizer asserts that issues of validity of Genentech's patents will not need to be determined on the motion, nor will issues of infringement with respect to Pfizer's proposed product at issue in T-401-18, which includes all of the indications from the Herceptin product monograph. As such, Pfizer asserts that all issues in T-402-18 will be addressed on the motion and if Pfizer is successful, the action need not proceed to trial. Genentech takes issue with this characterization of the motion and its potential impact on the underlying action, but for the purpose of the determination of the motion, I have accepted Pfizer's characterization.

[16] In considering what savings of costs, savings of time and efficiencies may arise from permitting the motion to proceed, I have considered the proposed timetable for perfection of the motion. As Pfizer did not serve its evidence on the motion by July 31, 2018, Pfizer's proposed timetable must be adjusted. Assuming that Pfizer would be in a position to serve its evidence by September 30, 2018, the hearing of the motion pursuant to Pfizer's proposed timetable would be in mid-February 2019. It is important to keep in mind that a consideration of the proposed timetable must also take into account an allocation of time for the Court to make a determination on the motion. For the purpose of this analysis, I have estimated that allocation of time at one month, which in my view is conservative. On that estimate, the motion would be determined in mid-March 2019.

[17] However, I have concerns regarding Pfizer's proposed schedule. I have no evidence before me as to the nature of the evidence that would need to be filed on the motion, but I assume, given the nature of the issues on the motion, that expert evidence will need to be filed by the parties. Providing Genentech with two months to prepare and serve responding evidence may not be sufficient. Likewise, completing all cross-examinations within four weeks of the service of Genentech's evidence may pose a challenge given the potential number of affiants, which on Pfizer's own estimate could be in the range of eight to ten as between the two parties. Moreover, Pfizer proposes that the motion be heard only five days after the delivery of Genentech's responding motion record. Such a short window would not allow the Court sufficient preparation time for the hearing of the motion. As such, I find that the timetable for the motion requires a further adjustment pushing the date for determination of the motion out by another month to mid-June 2019.

[18] My concerns regarding the timetable are compounded by the lack of co-operation that has occurred on this file, T-401-18 and the related impeachment actions to date. The Court has addressed this issue with the parties repeatedly and even went so far as to impose cost sanctions against Pfizer in relation to a case management conference (see the Court's Order dated June 22, 2018). The parties' improper conduct was also addressed by Justice Manson in his Order dated August 1, 2018 on a documentary production motion, wherein he noted that the parties had engaged in "significant, unnecessary, obstructive jockeying and delays" in dealing with the motion. As such, it is foreseeable that the motion will not proceed smoothly in accordance with Pfizer's proposed timetable and will require the Court's intervention to address disputes possibly related to the materials filed and/or the conduct of the cross-examinations. Should that occur, the determination of the motion could be further delayed beyond the projected date of mid-June

2019. Moreover, the lack of cooperation exhibited by Pfizer to date, in and of itself, favours not granting Pfizer leave to bring the motion.

[19] The trial of this action, T-401-18 and the related impeachment actions is scheduled to commence on November 18, 2019 for 10 days. Assuming that the determination of the motion was released to the parties by mid-June 2019, the motion would only be determined five months before the commencement of the trial. As such, there is the prospect of a five-month savings of time (should Pfizer be successful on the motion) and as a result, it is possible that Pfizer's product could enter the market five months earlier.

[20] However, should Pfizer be permitted to proceed with its motion, it will have to proceed in parallel with the timetable for the action. In that regard, neither party has suggested that the action be held in abeyance while the motion is determined. By April 1, 2019, the Plaintiffs will have served their expert reports on patent infringement and Pfizer will have served its expert reports on invalidity (if any). The subsequent deadline for responding expert reports is July 15, 2019. Assuming that the motion decision is released in mid-June 2019 and assuming that Pfizer is successful on the motion, there is the potential savings of not having to finalize the responding expert reports, as by mid-June 2019 the reports will already be underway. However, in recognizing these potential savings, there is an assumption that the same responding expert reports were not already prepared and filed on the motion. If they were, then there is in fact no such savings. None of the parties addressed this issue in their submissions.

[21] Assuming that Pfizer is successful on the motion, there would be no need for the trial of this action. However, the trial would still proceed in relation to T-401-18 and the related impeachment actions. Pfizer did not meaningfully address in its submission the extent of savings

associated with the elimination of the need to include T-402-18 in the allocated 10 days of trial. Given the substantial overlap between the issues raised in T-401-18 and T-402-18 and the related impeachment actions, it is difficult for me to envision any significant savings.

[22] On balance, I am not satisfied that Pfizer has demonstrated that there will be a significant savings of costs, savings of time and efficiencies if the motion is permitted to proceed.

[23] I am satisfied that the Plaintiffs will not be significantly prejudiced were the Court to permit the motion to proceed. While it would require the Plaintiffs to undertake additional work in parallel with their preparation for trial, such efforts do not constitute prejudice of the nature that would be required. The Plaintiffs have asserted that they would be prejudiced if the motion were permitted to proceed as they would be denied full discovery on the action. However, this assertion is inaccurate as the motion would have to proceed in parallel with the action and in any event, the discoveries are scheduled to be completed by August 30, 2018.

[24] I am satisfied that Pfizer has raised its motion in a timely manner and that this factor would favour permitting the motion to proceed. However, the Court's concern regarding the timetable for the motion and an absence of demonstrated significant savings of costs, savings of time and efficiencies is of far greater weight and does not favour permitting the motion to proceed.

[25] In light of the above, on the facts of this case, I am not satisfied that Pfizer has demonstrated that permitting the motion to proceed will result in significant savings and efficiencies so as to promote the just, most expeditious and least expensive determination of the action on its merits and result in a judicious use of the Court's limited resources. As such, I

decline to exercise my discretion pursuant to Rule 55 to dispense with compliance with Rule 213.

THIS COURT ORDERS that:

1. Pfizer Canada Inc.'s proposed motion for summary judgment or summary trial shall not be permitted to proceed.

2. There shall be no order as to costs.

"Mandy Aylen"
Case Management Judge