Federal Court Cour fédérale

Date: 20190111

Docket: T-727-18

Ottawa, Ontario, January 11, 2019

PRESENT: Case Management Judge Mireille Tabib

BETWEEN:

NOVO NORDISK CANADA INC.

Applicant

and

THE MINISTER OF HEALTH
AND TEVA CANADA LIMITED

Respondents

and

BIOTECanada

Intervener

ORDER

UPON the motion of BIOTECanada, made in writing pursuant to Rule 369 of the *Federal Courts Rules,* for an order granting it leave to intervene in this application, including on the motions to strike brought by the Respondents, to make submissions on the issue of standing and the impact of the Minister's decision on the Canadian biotechnology industry, and related relief;

CONSIDERING the respective motion records of BIOTECanada and of the Respondents, and the written representations in reply of BIOTECanada;

BIOTECanada wishes to intervene in this application on the very narrow issue of the Applicant Novo Nordisk Canada Inc.'s standing to bring this judicial review application, and more particularly, on the Applicant's public interest standing, given the impact of the Minister's decision on the Canadian biotechnology industry. To the extent the Applicant's standing is subject to be determined in the context of the Respondents' pending motions to strike, BIOTECanada's request for leave to intervene extends to these motions. BIOTECanada is not intent on establishing its own standing to seek judicial review of the Minister's decision, either as a person directly affected or on grounds of public interest.

It is paramount to keep this distinction firmly in mind as one analyzes the issues on this motion. Indeed, the Respondents' representations in response tend to conflate the test for standing and the test for intervention, and as a result, improperly veer into considering whether BIOTECanada has shown that there is a genuine public interest in this judicial review being pursued. With respect, that determination is the subject of the motions to strike and is properly to be determined in that context (or in the context of the merits of the application, if the Court determines the issue should be deferred to the merits). What is solely at issue on the present motion is whether BIOTECanada should be granted leave to intervene in the motions to strike, and as needed, on the merits, to make submissions as to the Applicant's public interest standing.

There is little disagreement between the parties as to the law and criteria applicable to a motion for leave to intervene. The key considerations are twofold: (1) Will the proposed intervener bring further, different and valuable insight and perspectives that will assist the Court

in determining the matter and (2) is the position of the proposed intervener adequately defended by the parties. The remainder of the criteria set out in the case of *Rothmans, Benson & Hedges Inc. v Canada (Attorney General)* [1990] 1 FC 90 are to be applied flexibly and are meant to assist in the task of determining whether in a given case, the interest of justice requires that leave to intervene be granted or refused.

It is clear to the Court that the perspective BIOTECanada would bring to the Court on the issue of the public interest aspects of the Minister's decision is different from those brought by the Applicant and the Respondents. *Inter alia,* BIOTECanada's proposed submissions highlight the consultation process between Health Canada and stakeholders in the biotechnology industry, including BIOTECanada, that led to the development of the regulatory framework at issue. The proposed submissions argue that this process created a legitimate expectation within the Canadian biotechnology industry as to a clear and consistent regulatory pathway in respect of biologic medicines. The proposed submissions further argue that the Minister's decision, which they submit appears to depart from the established procedure without explanation or reason, creates uncertainty that stifles investment in this industry. This chilling effect is said to go beyond the participants in the development of biologic medicines in Canada, affecting the biotechnology industry as a whole, including in other regulated biotechnology fields that depend on clear and consistent regulatory pathways, such as health products, veterinary products or agricultural products.

The perspective from which these arguments stem is that of a national non-governmental organization that advocates on behalf a wide variety of participants in the industry, and whose interest lies in the broader policy aspects of process and consistency. While the Applicant and the Respondent Teva are, naturally, financially motivated in pursuing the particular outcome of the

judicial review that affects their respective business interests, BIOTECanada does not seek to take a position on a particular outcome of the judicial review on its merits, and its position appears genuinely limited to advocating for the public interest in allowing the issues raised by the proceedings to be brought before the Court for judicial determination. In that, the perspective of BIOTECanada is more directly opposed to the public policy perspective of the Attorney General on the issue of standing.

Without pronouncing on the merits of the proposed submissions, I am satisfied that the perspective of BIOTECanada on the issue of public interest standing is germane, valuable and will be of assistance to the Court in determining one of the key issues before it: that of whether, should there be an absence of direct interest standing on the part of the Applicant to challenge the Minister's decision, the Court should nevertheless recognize that there is a public interest in allowing the Applicant to pursue the judicial review.

It is also clear to the Court that the position of BIOTECanada is not adequately defended or presented by any of the parties. The evidence and arguments proposed by BIOTECanada are not advanced by any of the parties. Indeed, the Court is satisfied that the Applicant is not in as good a position to bring that evidence and arguments to the Court as BIOTECanada would be. While the proposed submissions, if accepted by the Court, would ultimately assist in reaching the result sought by the Applicant on the issue of standing, that is not the same as being duplicative of the position and arguments of the Applicant. The Court further does not accept the submissions of the Respondents to the effect that BIOTECanada is no more than a proxy or an advocate for the Applicant. The evidence on record establishes that while the Applicant brought the existence and status of these proceedings to BIOTECanada's attention and suggested that it seek leave to intervene, BIOTECanada's decision to do so and its selection of the nature of the

evidence and arguments it would seek to present were the product of its own independent choices, motivated by consideration of the wider and more diverse interests of the participants in the industry it seeks to represent.

I now turn to considering briefly the other *Rothmans* factors.

While BIOTECanada is not directly affected by the outcome, the Court is satisfied that it has a sufficient, genuine interest in the issue on which it seeks to intervene. As Justice Stratas in *Canada (Attorney General) v Pictou Landing First Nation*, 2014 FCA 21, the Court is satisfied that this level of interest is sufficient in the circumstances and that being directly affected is not necessary. It is to be noted that BIOTECanada is not, as the Respondents seem to imply, attempting to substitute itself as an Applicant in this judicial review.

Again, as Justice Stratas in *Pictou Landing*, the Court is of the view that the issue of whether the judicial review itself raises a justiciable issue and a veritable public interest is a matter that properly belongs to the determination of the judicial review itself. This criterion is perhaps more appropriately framed as whether the issue or argument the proposed intervenor wishes to bring to the Court's attention raises a justiciable issue of public importance. As mentioned above, BIOTECanada's proposed submissions do go to a fundamental aspect of the issue of public interest standing in this case, the determination of which is clearly justiciable and of public importance.

The existence another reasonable or efficient means to submit the question to the Court is not a factor that is at issue her. BIOTECanada is not attempting to bring its own issues to the Court under the guise of an intervention, but to contribute helpful submissions to an issue that is already before the Court.

The Court can, of course, hear and decide the case on its merits without BIOTECanada. However, as mentioned above, it would be doing so without a contribution from BIOTECanada which the Court has already concluded would be helpful and is not adequately presented by the parties. This factor therefore is no reason to refuse the intervention.

Finally, with respect to the interest of justice, the Court recognises that the intervention does have a disruptive effect on the progress of this matter. The very late presentation of the motion to intervene has already caused the adjournment of the scheduled hearing of the motion, and if granted, leave to intervene will require that the Respondents prepare and file submissions responsive to BIOTECanada's submissions. This consideration, in the Court's view, stands as the only factor militating against granting leave, but is not sufficient, in the circumstances of this particular case, to outweigh the other, more important factors that do support granting leave.

While the intervention is sought rather late and has disrupted the proceedings, the evidence on record does not suggest that BIOTECanada was aware of the proceedings and could have acted much earlier than it did. Again, the Court does not subscribe to the view that BIOTECanada is to be considered as a mere proxy for the Applicant, such that the Applicant's delay in alerting BIOTECanada to the proceedings and the issues they raise should count against the proposed intervenor. Once it became aware of the proceedings, BIOTECanada acted with reasonable despatch in considering and deciding whether to seek leave to intervene, and having obtained a mandate from its board, acted expeditiously in alerting the parties and the Court of its intentions, in briefing the motion and in submitting its proposed intervention. Finally, the Court notes that the proceedings have proceeded at a fairly leisurely pace, and that the Respondents will suffer no prejudice from the relatively short delay caused by the intervention. The Court is

satisfied that the interests of justice are better served by allowing the intervention than by denying it, notwithstanding the comparatively minor disruption and delay it might cause.

THIS COURT ORDERS that:

1. BIOTECanada is granted leave to intervene in this application to make submissions on the issue of standing, and the impact of the Minister's decision on the Canadian biotechnology industry.

2. BIOTECanada is permitted to file a motion record, as set out as schedule "A" to its motion record, with respect to the Respondents' motion to strike out the application scheduled to be heard on January 23, 2019.

3. BIOTECanada is permitted to attend the motions to strike solely for the purposes of answering any questions that the Court may have with regards to its submissions and policy considerations.

4. No costs shall be awarded against or in favour of BIOTECanada.

5. The Respondents may serve and file responding materials to BIOTECanada's motion record by January 18, 2019.

"Mireille Tabib"

Case Management Judge