Federal Court  Cour fédérale

Date: 20190617

Docket: T-727-18

Citation: 2019 FC 822

Ottawa, Ontario, June 17, 2019

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

NOVO NORDISK CANADA INC.

Applicant

and

THE MINISTER OF HEALTH
AND TEVA CANADA LIMITED

Respondents

ORDER AND REASONS

[1] The Applicant, Novo Nordisk Canada Inc. is a manufacturer of innovative pharmaceutical products, and in particular, a class of complex molecules manufactured using recombinant DNA procedures commonly referred to as biologic drugs. One of its biologic products is Victoza, a drug containing liraglutide as its active ingredient and that is used in the treatment of adults with type 2 diabetes. Novo Nordisk brings this judicial review application to challenge the decision of the Minister of Health to accept for review an Abbreviated New Drug

Submission (ANDS) filed by Teva Canada Limited, to seek approval to market its own liraglutide product based on a comparison with Victoza.

[2] Both Teva and the Minister of Health have brought motions to strike Novo Nordisk's application on a preliminary basis, on the grounds that Novo Nordisk lacks standing and that the application is in any event premature. For the reasons that follow, the motions will be granted and the application struck.

I. DIRECT STANDING

[3] There is a long and well established line of jurisprudence to the effect that an innovator such as Novo Nordisk has no standing to institute or participate in an application to review a decision of the Minister of Health in respect of the issuance or proposed issuance of a Notice of Compliance (NOC) to another drug manufacturer where the only issue raised pertains to matters of the safety and efficacy of the proposed drug product (*Merck Frosst Canada Inc v Canada (Minister of Health),* [1997] FCJ No 1847, *Glaxo Canada Inc v Canada (Minister of Health & Welfare)*, [1988] 1 FC 422, aff'd (1990) 31 CPR (3d) 29, *Pfizer Canada Inc v Canada (Minister of National Health and Welfare),* (1986), 12 CPR (3d) 438, *Lundbeck Canada Inc v. Canada (Minister of Health),* 2008 FC 1379, aff'd 2009 FCA 134). As mentioned at paragraph 13 of *Hospira Healthcare Corp. v Canada (Minister of Health)* 2014 FC 179, aff'd 2014 FCA 194, the rationale for these cases has consistently been that the Minister alone is charged with the protection of the public's health and safety, that issues of the safety and efficacy of drugs are of no concern to third-party manufacturers and that the economic and competitive impact on them is not sufficient to hold that they are "directly affected" by the issuance of a NOC to a competitor.

[4] These cases are determinative and binding upon the undersigned. Unless Novo Nordisk can show that the issues raised in this judicial review involve considerations other than public health and the safety and efficacy of drugs, and that these considerations directly affect it in a manner that goes beyond the commercial or competitive consequences of the issuance of a NOC to a competitor, its quest for direct interest standing is bound to fail.

[5] The grounds for review raised by Novo Nordisk in its Notice of Application, including as further fleshed out in the evidence it filed in response to the motions to strike, are exclusively centered on the issue of whether, given the alleged inherent complexity of biologic drugs, a generic version of a biologic drug (whether it is itself produced through recombinant DNA processes or chemically synthesized) can ever be shown, found to be or considered "pharmaceutically equivalent" to a biologic reference product. As alleged in the Notice of Application, such a demonstration or conclusion is simply impossible. As a result, and because a NOC granted pursuant to an ANDS constitutes a declaration that the generic product is the pharmaceutical equivalent of the Canadian Reference Product (CRP), a NOC for a generic version of a biologic could never properly or reasonably issue as a result of an ANDS. The Minister's decision to accept and review Teva's submissions for a NOC for Teva-liraglutide as an ANDS constitutes, according to Novo Nordisk, a determination that a generic product is capable of being declared the pharmaceutical equivalent of a biologic drug and is unreasonable.

[6] The determination of a drug's bioequivalence or pharmaceutical equivalence to a CRP is a central part of the Minister's determination of whether to issue a NOC in respect of the proposed drug, and is in its very essence a matter of safety and efficacy. The jurisprudence is

clear that Novo Nordisk can have no direct interest standing to seek judicial review of that decision, however unreasonable it alleges it might be, unless it can show that the Minister's decision affects it directly in a manner that goes beyond a mere commercial or competitive interest.

[7] The consequences Novo Nordisk alleges that it could suffer from the Minister's decision to accept Teva's submissions as an ANDS, including from a potential determination that Teva-liraglutide is pharmaceutically equivalent to Victoza, range from the simple erosion of its market share to a threat to the viability of its very business model, including: loss of revenue, of the ability to maintain certain programs and of the viability of important commercial agreements; the need to reduce its cost or to downsize across part or the entirety of its operations; uncertainty in commercial or business planning; difficulty in obtaining or maintaining funding for research and development; and exposure to product liability claims resulting from an alleged erroneous declaration of interchangeability.

[8] As severe as these consequences might be, they remain exclusively economic and commercial; none of Novo Nordisk's rights are engaged by the decision or its potential consequences. The closest Novo Nordisk comes to a possible effect on its rights is with respect to the alleged exposure to product liability claims. However, Novo Nordisk stops short of suggesting that there would be any foundation in law for such claims, given that the potential claims would arise from the use of a competitor's product, and would be based on the Minister's representation of bioequivalence rather than from any act or representation by Novo Nordisk. The Court is satisfied that this alleged exposure is also a purely economic and commercial risk.

[9] For the reasons above, the Court is satisfied that the issues raised in this judicial review application are essentially matters of safety and efficacy of drug products, that the effects of the decision at issue on Novo Nordisk are exclusively economic, commercial and competitive, and that it is plain and obvious that Novo Nordisk can have no direct interest in pursuing a judicial review of the decision at issue.

II. PUBLIC INTEREST STANDING

[10] Novo Nordisk seeks to distinguish the present circumstances from those in the above-mentioned line of cases by asserting that it should be recognized a public interest standing to challenge the Minister's decision. While Novo Nordisk's written materials raise public health issues and the interests of Canadian patients suffering from diabetes as grounds to support public interest standing, it did not pursue these arguments at the hearing. Indeed, the case law mentioned above establishes that it is the Minister's responsibility to consider health and safety issues and to assess a drug's safety and efficacy, and that third-party drug manufacturers may not rely on public health considerations as a basis for public interest standing.

[11] The public interest asserted is, rather, that there is a wider public interest in ensuring the certainty and consistency of the Minister's application of the regulatory approval process for biosimilar drugs. BIOTECanada, an association representing stakeholders in the Canadian biotechnology industry, was granted intervenor status to lead evidence and make submissions in support of Novo Nordisk's argument that it should be recognized public interest standing.

[12] The submissions of Novo Nordisk and BIOTECanada in respect of public interest standing do not focus on the ultimate issue of whether a biosimilar is or can ever be properly described as pharmaceutically equivalent to a biologic, but on the issue of the integrity of the regulatory filing process itself. Novo Nordisk and BIOTECanada submit that the regulatory review procedure regarding Biosimilars is set out in the Guidance Document *Information and Submission Requirements for Biosimilar Biologic Drugs* (the "Biosimilars Guidance Document"), which was developed through extensive consultations with stakeholders in the biotechnology industry. They submit that the Biosimilars Guidance Document specifies that a submission for the approval of a biosimilar must be by way of a New Drug Submission (NDS) and must satisfy the requirements of section C.08.002(2) of the *Food and Drug Regulations* CRC c. 870 (*FDR*). That standard is that of "similarity" with the CRP. Health Canada's acceptance of Teva's submission as an ANDS rather than as a NDS instead subjects the submission to the requirements of section C.08.002.1(2) of the *FDR*, which is based on "pharmaceutical equivalence" to the CRP, a different and less stringent standard. Novo Nordisk and BIOTECanada argue that the Minister's decision to accept Teva's submission through a different regulatory process and to subject it to a different standard constitutes a deviation from the established procedure that was made without explanation or consultation with those who participated in the development of the Biosimilars Guidance Documents and who have a legitimate expectation that it will be uniformly applied.

[13] Novo Nordisk and BIOTECanada submit that there is a significant public policy interest in ensuring that Health Canada operates within the established review procedures. Participants in the biotechnology field are required to make significant investments to develop new products

and must be able to count on a clear and consistent regulatory pathway for the approval of biosimilar products if the industry is to be viable in Canada. The Minister's ability to abruptly deviate from the established review procedure without explanation or consultation with stakeholders would have a chilling effect on the industry as a whole and stifle investment in the field.

[14] There is little dispute between the parties as to the test to be applied for the recognition of public interest standing. It was articulated in *Canada (Attorney General) v Downtown Eastside Sex Workers United Against Violence Society*, 2012 SCC 45 at paragraph 37, as follows:

> In exercising the discretion to grant public interest standing, the court must consider three factors: (1) whether there is a serious justiciable issue raised; (2) whether the plaintiff has a real stake or a genuine interest in it; and (3) whether, in all the circumstances, the proposed suit is a reasonable and effective way to bring the issues before the courts: *Borowski*, at p. 598; *Finley*, at p 626; *Canadian Counsel of Churches*, at p. 253; *Hy and Zel's*, at p 690; *Chaoulli*, at paras. 35 and 188. The plaintiff seeking public interest standing must persuade the court that these factors, applied purposively and flexibly, favour granting standing. All of the other relevant considerations being equal, a plaintiff with standing as of right will generally be preferred.

A. *Is there a serious justiciable issue?*

[15] The submissions of Novo Nordisk and BIOTECanada proceed from at least two fundamental assumptions, without which the existence of a serious justiciable issue is highly questionable. The first relates to whether Teva-liraglutide is subject to the Biosimilars Guidance Document on which Novo Nordisk relies, and the second, to whether a decision as to the correctness of the pathway has been made.

[16] First, as mentioned above, the public interest argument focuses on the Minister's alleged departure from the regulatory submission pathway established by the Biosimilars Guidance Document. That argument, however, assumes that Teva-liraglutide is in fact subject to the Biosimilars Guidance Document. That document, by its own terms, applies only to biosimilar biologic drugs. Submissions for the approval of drugs that are not biologic drugs, even if they rely on a comparison with a biologic drug, are not subject to the Biosimilars Guidance Document. The Biosimilars Guidance Document defines a biologic drug by reference to Schedule D of the *Food and Drugs Act*, RSC 1985, cF-27. Liraglutide would fall within the class of drugs listed in Schedule D based on the methodology by which it is made. Novo Nordisk's Notice of Application specifically acknowledges that Teva-liraglutide could be made either by recombinant DNA processes, in which case it would fall within the definition of a biologic drug, or by chemical synthesis, in which case it would not be a biologic drug and would not be subject to the Biosimilars Guidance Document. The argument that the Minister departed from the provisions of the Biosimilars Guidance Document would in the latter case be without any merit.

[17] The record before the Court does not establish how Teva-liraglutide is made. Unless it is established that it is in fact governed by the Biosimilars Guidance Document on which Novo Nordisk and BIOTECanada rely, the Minister's alleged departure from its provisions is purely speculative and does not present a serious issue.

[18] Second, the public interest argument relies on the assumption that the Minister's acceptance of Teva's ANDS for review constitutes a decision to the effect that Teva, as sponsor, has chosen the appropriate regulatory pathway for the approval of its liraglutide product. The

opening paragraph of the Notice of Application describes the decision under review as follows: "the decision of the [Minister] to receive and allow use of an [ANDS] by [Teva] to seek approval in respect of its [Teva-liraglutide] based on a comparison to Victoza". However, the conclusion that the Minister made a decision to "allow" the use of an ANDS in the circumstances is entirely speculative and lacks material support.

[19] Paragraphs 37 to 39 of the Notice of Application set out what Novo Nordisk knows of the decision made by the Minister, as follows:

> 37 Teva's ANDS was filed with the Minister through the TPD on June 30, 2017 (ANDS Submission No. 204738). Based on the Acknowledgement and Certification of Information Received provided by the Minister, and included in the NOA, the Minister certified Teva's ANDS on July 6, 2017 (the "Certification"). The Applicant became aware of the Certification when it received Teva's NOA on March 21, 2018.
>
> 38 Under Health Canada's *Management of Drug Submissions* Guidance Document, the Minister will commence reviewing an ANDS within 45 calendar days of the acknowledgement for submission completeness.
>
> 39 Therefore, by the time Teva served its NOA on the Applicant on March 21, 2018, the Minister had accepted for review and commenced reviewing Teva's ANDS for Teva-liraglutide.

[20] The decision at issue is therefore a decision that Novo Nordisk assumes the Minister of Health has made within 45 days of the Acknowledgement and Certification of Information Received. The Guidance Document *Management of Drug Submissions* ("Management Guidance Document") to which paragraph 38 refers was filed as Exhibit "D" of the affidavit of Jane Costaris. This document, at page 12, refers to the step that is to be taken within 45 days of the receipt of the original submission as an initial "screening", the purpose of which is as follows:

> 5.4 Screening of Information and Material
>
> Original information and material, and solicited and unsolicited information and material, will be screened by Health Canada for acceptability (with the exception of PSUR-Cs).
>
> Health Canada expects original information and material to contain the requisite information for the type of submission and to be submitted in acceptable format as outlined in the applicable guideline (s). The relevant drug submission screening form(s) is to be completed by the sponsor where applicable.
>
> All subsequent solicited and unsolicited information will also be screened to ensure that it is complete for the purpose intended. (…)
>
> (Emphasis added)

[21] Nothing in the Management Guidance Document or in the facts set out in the Notice of Application suggests that the "decision" to accept Teva's ANDS for review is anything more than an administrative screening to control that the information and material required for the type of submission selected have been included and are in an acceptable format. To extrapolate from the screening decision that the Minister has determined that Teva's submission for Teva-liraglutide is reviewable as an ANDS and capable of obtaining an NOC by way of ANDS is an unjustified stretch.

[22] In an attempt to bridge that gap, Novo Nordisk has filed the affidavit of Jane Costaris, an expert in the regulation of pharmaceutical and medicinal products and their approval in Canada. Ms. Costaris' affidavit presents the screening step as a "determination" by Health Canada of the drug submission pathway by focussing on the following aspects of the process: If a submission is accepted as complete in accordance with the pathway under which it was submitted, it will be reviewed as such, and a screening acceptance letter will be sent to the sponsor, which expressly

states that the drug submission has been accepted as either an ANDS or a NDS, according to the manner of submission. The acceptance will also trigger the invoicing of 75% of the submission review fees, (which vary according to the pathway) and the publication of the fact that a submission has been accepted for review under that pathway. Once that stage has been reached, the pathway cannot be "switched" – the sponsor cannot ask that its submission be reviewed under a different pathway. On the other hand, Ms. Costaris states that "if a submission was filed as an ANDS and should have been filed as a NDS, Health Canada will issue a Screening Rejection letter and advise the sponsor that the submission should be filed as a NDS". In such a case, the sponsor will have access to a formal reconsideration process under the Guidance document "Reconsideration of Final Decisions Issued for Human Drug Submissions", as that document does list Screening Rejections letters as decisions eligible for that process.

[23] Ms. Costaris does not assert that she has any experience or knowledge pertaining to the particular issue of whether a screening-in decision is treated or considered by Health Canada as a decision specifically pertaining to the validity of a sponsor's pathway decision. Rather, Ms. Costaris' affidavit evidence implicitly proceeds from the *a contrario* reasoning that if Health Canada can screen out a submission based on the inappropriate choice of pathway and if that decision is final and reviewable, then a submission's successful passage through the screening process must constitute a final determination of the validity of the pathway chosen.

[24] While the Court accepts the basic facts to which Ms. Costaris attests, it is not satisfied that the conclusions she reaches on the basis of those facts are reasonable or warranted.

[25] An analogy can be made to the process by which this Court may put an early end to litigation instituted before it, by refusing an originating document at the filing stage where it is formally deficient or by dismissing it on a preliminary motion to strike where it discloses no reasonable cause of action. In both cases, a final determination has clearly been made that the proceeding is inappropriate as brought, and the party against whom that determination was made may have recourse to challenge the decision. However, the mere fact that an originating document is accepted for filing, is not challenged by a preliminary motion or even survives a preliminary motion to strike does not constitute a determination, final or otherwise, of its propriety, validity or merit. It only means that any potential or alleged defect in form or substance is not so obvious that it merits determination as a preliminary matter.

[26] Ms. Costaris' affidavit also states that "the regulatory approval pathway is irrevocably fixed" at the time of a positive decision on screening. However, the fact that a sponsor who has chosen to file its submission under a specific pathway may not change course midstream does not justify the conclusion that the administrative acceptance of the submission amounts to a substantive approval of the pathway chosen. As Ms. Costaris points out, the type of information and materials required to be filed under each pathway is significantly different. The required materials are tailored to each specific pathway; they are not interchangeable and documents prepared for one pathway could not realistically be transferred for use under the other pathway. The Court also notes that Ms. Costaris does not assert that a sponsor whose submission is accepted at screening could not see its submission ultimately refused on the basis that it does not qualify for the chosen pathway. Nor does she suggest that, in such an event, the sponsor would be prevented from filing a new submission for the same drug under the alternative pathway.

[27] For there to be a serious justiciable issue to be submitted to the Court in respect of a decision by the Minister of Health to approve the use of the ANDS process for the approval of Teva-liraglutide, Novo Nordisk would first have had to establish that a decision to that effect has been made. The existence of such a decision has not been established and is at this point entirely speculative.

[28] The conclusions reached above, as to the speculative nature of the issues said to raise public interest concerns and Novo Nordisk's consequent failure to establish the existence of a serious justiciable issue, are sufficient to dispose of the question of public interest standing. Indeed, while the factors identified in *Downtown Eastside* must be considered and applied purposively and flexibly, the guiding principle in their application remains the need to strike a balance "between ensuring access to the courts and preserving judicial resources" and to "balance the underlying rationale for restricting standing with the important role of the courts in assessing the legality of government action": *Downtown Eastsid*e, above, at para 23.

[29] No matter how well-intentioned or keen a proposed litigant's interest in bringing an issue to the Court might be, it would be a misuse of scarce judicial resources to allow public interest litigation to proceed on a speculative matter. Neither can a proposed proceeding to resolve a speculative issue be reasonable, effective, or in keeping with the Court's role of assessing the legality of government action. It would, rather, have the effect of thrusting onto the Court the role of rendering advisory opinions at the behest of any person possessed of a sufficiently strong interest in clarifying or obtaining certainty on a potentially serious issue, but when that issue has

yet to crystallise and may never crystallize in a reviewable decision. That is not the proper role of the Courts.

[30] In any event, and even assuming that Novo Nordisk had established that Teva-liraglutide is a biologic drug subject to the Biosimilars Guidance Document and that a decision has been made by the Minister of Health to allow the filing and review of that submission as an ANDS, the Court is satisfied, for the reasons below, that the application for judicial review of that decision is premature. The prematurity of the judicial review is another element that would preclude a finding that a serious justiciable issue exists.

B. *Does Novo Nordisk have a real stake and a genuine interest in the issues raised?*

[31] Given the Court's conclusion that the speculative nature of the public interest issues raised is essentially determinative of this motion, it is not necessary for the Court to consider or determine whether Novo Nordisk has a genuine interest or a real stake in these issues. That said, to the extent a proposed litigant's interest is to be assessed in relation to that aspect of the issues that give rise to a recognizable public interest, the Court has serious concerns as to whether Novo Nordisk has the required interest.

[32] A distinction has been made, earlier in these reasons, between the grounds for review raised by Novo Nordisk in its Notice of Application and the issues identified by it and BIOTECanada as raising public interest concerns.

[33] The Court has no doubt that Novo Nordisk has a genuine interest and a real stake in ensuring that would-be sponsors of generic products using biologic drugs as CRPs be required to proceed by way of the lengthier NDS pathway and that these products not be recognized as pharmaceutically equivalent to biologic drugs. That interest is, as mentioned above, of a purely commercial and competitive nature.

[34] To the extent there is another, wider public interest in ensuring the integrity of the regulatory filing process, that interest arises from the assertion that the process set out in the Biologics Guidance Document created a legitimate expectation within the Canadian biotechnology industry as to a clear and consistent regulatory pathway in respect of biologic medicines. On its face, however, the Biologics Guidance Document is directed to and created for the benefit of sponsors. At paragraph 1.1, page 1 of the Guidance Document, the objective of the document is described as follows:

> The objective of this document is to provide guidance to sponsors to enable them to satisfy the information and regulatory requirements under the *Food and Drugs Act* and Part C of the *Food and Drug Regulations* for the authorization of biosimilars in Canada.

[35] Any legitimate expectations created by that document would appear to be in favour of those who submit requests for authorization, such as Teva, and not in favour of the owner of the CRP. If, in an appropriate case, a genuine public interest to control and ensure consistency and integrity in the application of such guidance documents were to be recognized (a matter which the Court does not determine), it would seem that the more immediate stake and most genuine

interest in that determination would be possessed by a sponsor of biosimilar products or an organization representing them rather than by a third party innovator such as Novo Nordisk.

C. *Is the proposed proceeding a reasonable and effective way to bring the issues before the courts?*

[36] Assuming that Teva-liraglutide is a biologic drug subject to the Biosimilars Guidance Document and that the Minister of Health has made a decision that Teva's submission may, notwithstanding that Guidance Document, proceed to be reviewed as an ANDS, it remains that at law, that decision is not final. The pathway decision, if it is subject to judicial review at all, should more reasonably and could more effectively be considered as part of a review of the Minister's final decision.

[37] The decision in *Lundbeck*, above, concerned a proposed judicial review of the Minister's decision to accept for review, at the screening stage, ANDSs filed by two generics that used Lundbeck's product as CRP. Lundbeck essentially argued that the decision or act of the Minister to accept and review the submissions identifying its product as an alleged CRP was unlawful and invalid because its product had been issued under a NOC/c (a Notice of Compliance with conditions) rather than an unrestricted NOC. Among the reasons given by the Court at first instance to dismiss the application was that the Minister's decision, after screening the ANDS, "is an interlocutory decision and not a final one because the final outcome involves the Minister's determination whether to issue an NOC under the FDR subject to the applicability of the NOC Regulations": *Lundbeck*, above 2008 FC decision at para 31. While the Federal Court's decision was upheld on appeal on the specific basis of another part of the decision, the Federal

Court has, on at least two other occasions, recognized that the Minister's acceptance for review of a submission under the *FDR* is not final, and any interim determinations of whether the criteria of safety and efficacy are met are subject to the Minister's own review and reconsideration at any time until the NOC is issued.

[38] In *Apotex Inc v Canada (Minister of Health)* 2011 FC 1308, aff'd 2012 FCA 322, Apotex was seeking an order requiring the Minister to issue a NOC for its Apo-omeprazole tablets, arguing it had a vested right since the review of its submission had proceeded and been completed to the point where it had received from the Minister a "patent hold" letter, a notice that the ANDS is approvable subject to the requirements of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 being met. Citing *Ferring Inc v Canada*, 2007 FC 300, [2007] FCJ no 420 (QL) for support, this Court held, at para 33:

> It seems quite obvious to me that until a NOC is issued, a proponent enjoys no vested interest in a favourable outcome at least with respect to issues that properly fall within the Minister's lawful discretion (ie. pertaining to public safety and efficacy). There is no legal significance attaching to an application for a NOC that has been placed on patent hold. The Minister is fully entitled to revisit scientific issues at any point in the process up to the actual issuance of a NOC. It is only at that point that the Minister's examination is completed in accordance with C.08.004 of the Food and Drug Regulations, RSC 1985, c F-27.

[39] As Novo Nordisk itself forcefully argues in support of its arguments on this motion, the Minister's conclusion as to the safety and efficacy of generic drug products submitted for approval through the ANDS pathway is premised, and therefore entirely dependent, on her determination that the generic product is pharmaceutically equivalent to the reference product. That is part and parcel of the ultimate issue to be determined by the Minister as part of her lawful

discretion, and can be revisited by her at any point in the process. If no legal significance attaches to the issuance of a patent hold letter in that process, then surely, none can attach to the issuance of a screening acceptance letter.

[40] To the extent there were a real public interest in determining whether the Minister has jurisdiction to process a submission for approval of a biosimilar under the ANDS pathway (a matter the Court does not determine), the reasonable and most effective approach to bringing the issue before the Court would be to allow the Minister to complete her examination of Teva's ANDS and to come to a final determination of whether Teva-Liraglutide is pharmaceutically equivalent to Victoza (and could thus properly, not only be accepted for review, but be approved under the ANDS pathway), before permitting a judicial review.

D. *Conclusion on Public Interest Standing*

[41] Novo Nordisk had the burden of persuading the Court, on this motion, that taking the three factors identified in *Downtown Eastside* into account, the Court should exercise its discretion in favour of granting it public interest standing notwithstanding its lack of direct standing, or at least, of persuading the Court that its argument on public interest standing had sufficient merit that it should be allowed to proceed to a hearing on the merits for final determination on a full evidentiary record. None of the three factors considered favour the granting of public interest standing in this matter. The Court is satisfied that it is not in the public interest for judicial resources to be expended to determine an issue which is speculative, premature, and in respect of which Novo Nordisk's interest, while keen, is essentially of a commercial and competitive nature.

III. PREMATURITY

[42] As discussed above, the Minister's screening decision, to the extent it constitutes a decision approving Teva's choice of pathway, in clearly not final. It remains subject to being reconsidered and revised by the Minister at any point until a NOC is finally issued. As such, a judicial review of that decision is *prima facie* premature. Novo Nordisk has argued on the basis of the decision of the Supreme Court in *Halifax (Regional Municipality) v Nova Scotia (Human Rights Commission)* 2012 SCC 10, that screening decisions, even where they are not final, may still be amenable to judicial review on the standard of reasonableness.

[43] The Court has considered the prematurity issue in the context of its analysis on public interest standing and its findings on that issue have contributed to the conclusion that there is no serious justiciable issue and that the present application is not a reasonable or effective means of bringing the matter forward. The Court's decision as to Novo Nordisk's lack of standing is fully determinative of the motion to strike. It is accordingly unnecessary for the Court to consider or determine whether the apparent prematurity of a review of the screening decision is also sufficient to justify striking the application on an interlocutory motion.

IV. ADMISSIBILITY OF EVIDENCE

[44] Teva and the Minister have raised various objections to the admissibility of the evidence adduced by Novo Nordisk in response to their motions to strike and to the propriety of the expert evidence submitted. While it is arguable that evidence should not be admissible in considering a motion to strike an application for judicial review on the basis that it discloses no reasonable

cause of action, the Court is satisfied that in principle, evidence is admissible for the purpose of the preliminary determination of whether a litigant should be recognized public interest standing.

[45] The Court has taken the allegations set out in the Notice of Application as to the alleged grounds for review and the consequences of the decision on Novo Nordisk as being true for the purpose of its analysis. The affidavits of Dr. Drucker and of Mr. Graham, which go into these issues in greater detail for the purpose of establishing them, add very little to the analysis, whether admissible or not. It is unnecessary, and the Court declines to rule as to their admissibility.

[46] The Court has considered the affidavit of Dr. Costaris in the context of its analysis on the issue of public interest standing, but has found it to be unhelpful on the issue of the applicability of the Biosimilars Guidance Document to Teva-liraglutide, and unpersuasive on the issue of whether a final decision has been made as to the validity of Teva's chosen pathway. It is, in the circumstances, unnecessary for the Court to go further and opine as to its alleged impropriety.

V. COSTS

[47] The Respondents have been successful on their motions and it is accordingly appropriate that they should recover their costs. The Minister claims its costs at the high end of Column III of the Tariff, while Teva seeks costs in a lump sum of $40,000, representing twice its calculation of the taxable costs at the upper end of Column V of the Tariff.

[48] Teva's grounds for seeking such an amount are simply that the matter involves sophisticated commercial litigants that have the means to pay for the legal choices they make, that the success of its motion shows Novo Nordisk's application to have been devoid of merit and the bald assertion that adherence to Tariff B would "dictate an unreasonable and unsatisfactory result for Teva". The Court is not satisfied that that the type of motion, the issues at play or any of the circumstances justify a departure from the Tariff. The Court is further satisfied that despite Novo Nordisk's attempt to set up a novel argument for being recognized public interest standing, the issues on the motion were not particularly complex and that an award of costs calculated in accordance with the upper end of Column III of Tariff B is adequate.

[49] The complexity and additional steps required by the introduction of a substantial volume of evidence by Novo Nordisk and the participation of BIOTECanada – which Novo Nordisk supported and on which it relied to assert public interest standing for itself – are adequately addressed by allowing a second claim for services related to the preparation and filing of motion materials, a claim for participation in a case management conference, a claim for counsel travel and a claim for second counsel, where contemplated by the Tariff. The permitted preparation and filing of submissions on costs following the hearing is recognized by the allowance of a claim for assessment of costs. This results in an award of $12,528.00, including disbursements, for the Minister (whose counsel travelled for the hearing) and of $10,158.00, including disbursement, for Teva. The Court notes that the draft bills of costs of both the Minister and of Teva have included several duplicative claims for services, as well as claims for services not contemplated by the Tariff. These claims have been disallowed in arriving at the Court's calculation of costs and disbursements.

ORDER

THIS COURT ORDERS that:

1. The Respondents' motions are granted and the Application is struck.

2. The Applicant shall pay costs to Teva Canada Limited in the amount of $10,158.00 and to the Minister of Health in the amount of $12,528.00.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

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