Federal Court  Cour fédérale

Date: 20241106

Docket: T-2108-23

Citation: 2024 FC 1766

Toronto, Ontario, November 6, 2024

PRESENT: Case Management Judge John C. Cotter

BETWEEN:

BOEHRINGER INGELHEIM (CANADA) LTD.

Applicant

and

**THE MINISTER OF HEALTH,
ATTORNEY GENERAL OF CANADA AND
JAMP PHARMA CORPORATION**

Respondents

JUDGMENT AND REASONS

[1] This is a motion by two of the respondents, the Minister of Health [Minister] and the Attorney General of Canada [AGC], for an order striking the notice of application, and costs of the motion. For the reasons set out below, the motion is granted.

[2] The moving parties seek to strike out the notice of application on the ground that the applicant, Boehringer Ingelheim (Canada) Ltd. [BI Canada], lacks standing.

I. The Notice of Application

[3] The notice of application was issued October 6, 2023 [Notice of Application]. It is an application for judicial review in respect of a September 6, 2023, decision of the Minister [Decision] to grant the respondent JAMP Pharma Corporation [JAMP] a notice of compliance [NOC] for JAMP Nintedanib 150 mg nintedanib (as nintedanib esylate) capsules.

[4] In the Notice of Application, BI Canada seeks:

> a. An order quashing the Decision and the NOC issued as a result of the Decision;
>
> b. An order precluding the Minister of Health from issuing a notice of compliance for JAMP Nintedanib 150 mg, without the 100 mg strength of nintedanib (as nintedanib esylate);
>
> c. The costs of this application; and
>
> d. Such further and other relief as this Honourable Court may deem just.

[5] As explained below, for the purposes of this motion, all of the facts set out in the Notice of Application are taken to be true. The facts set out in the Notice of Application include the following:

> 5. BI Canada markets and sells nintedanib esilate capsules in Canada in strengths of 100 mg and 150 mg of nintedanib under the brand name OFEV®, pursuant to Notices of Compliance issued by the Minister of Health.
>
> […]
>
> 7. Treatment with OFEV® requires close oversight and monitoring by health care professionals. BI Canada has a risk management plan and a patient support program for OFEV®.
>
> 8. OFEV® is the only nintedanib product marketed in Canada.

> 9. On June 17, 2022, BI Canada received a letter from JAMP, which was asserted to be a "Notice of Allegation" pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("JAMP Letter").
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> 10. The JAMP Letter referred to nintedanib capsules in strengths of 100 mg and 150 mg (the "JAMP Products").
>
> 11. The JAMP Letter asserted that JAMP had filed with the Minister of Health an abbreviated new drug submission, No. 262177 ("ANDS"), seeking a Notice of Compliance for the JAMP Products.
>
> 12. On July 28, 2023, Boehringer Ingelheim International GmbH ("BII") and BI Canada brought an action pursuant to section 6(1) of the *PMNOC Regulations* seeking a declaration that the selling, *etc*. of the JAMP Products in accordance with the ANDS would infringe or induce infringement of two Canadian patents owned by BII. BII and BI Canada waived the statutory stay pursuant to section 7(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations* at the time the action was commenced.

[6] The Decision is described in paragraphs 13 to 15 of the Notice of Application as follows:

> **D. The Decision**
>
> 13. On September 6, 2023, the Minister of Health issued the NOC for JAMP Nintedanib 150 mg. The NOC did not refer to a 100 mg strength capsule.
>
> 14. JAMP Nintedanib 150 mg is a generic version of BI Canada's OFEV® 150 mg strength product.
>
> 15. The NOC identifies OFEV® as the Canadian reference product.

[7] The Notice of Application also refers to and quotes from what it identifies as the "JAMP Nintedanib product monograph" [JAMP Product Monograph] (paras 17 and 18), as well as the product monograph for OFEV, the product marketed and sold by BI Canada (paras 5 and 6).

[8] Also of significance for present purposes are the grounds of review asserted in the Notice of Application, which are:

> **F. Grounds of Review**
>
> 19. The applicant submits that the Minister of Health erred, including in law, and in the alternative was unreasonable in making the Decision, *inter alia*, as follows:
>
> a. In issuing the NOC for JAMP Nintedanib 150 mg, without the 100 mg strength, when the 100 mg strength is required for dose reduction purposes as referenced in the approved product monograph for JAMP Nintedanib 150 mg;
>
> b. Failing to consider the prejudice to the applicant and its OFEV® product caused by issuing the NOC for only the 150 mg strength for JAMP's nintedanib capsules; and
>
> c. Failing to consider the impact on patient safety caused by issuing the NOC for only the 150 mg strength for JAMP's nintedanib capsules without approval of the lower strength recommended for safety reasons.
>
> 20. The applicant relies upon:
>
> a. Sections 18, 18.1 and 18.2 of the *Federal Courts Act*, R.S.C. 1982, c.F-7, as amended;
>
> b. The *Food and Drugs Act*;
>
> c. Division 8 of the *Food and Drug Regulations*, C.R.C., c. 870, as amended;
>
> d. The *Federal Courts Rules*, Rule 300 et seq.; and
>
> e. Such further and other grounds as counsel may advise and this Honourable Court may permit.

II. Affidavit evidence filed on the motion

[9] Some of the parties filed evidence on this motion, including BI Canada. As a general rule, affidavits are not admissible in support of motions to strike applications for judicial review (*Canada (National Revenue) v JP Morgan Asset Management (Canada) Inc*, 2013 FCA 250 [*JP*

Morgan] at paras 51-52). There is no need for affidavit evidence on the facts alleged in the Notice of Application as they are taken as true for the purposes of a motion to strike (*JP Morgan* at para 52; see also *Iris Technologies Inc v Canada*, 2024 SCC 24 [*Iris Technologies*] at para 26).

[10] Exceptions to the rule should be permitted only where the justifications for the general rule of inadmissibility are not undercut, and the exception is in the interests of justice (*JP Morgan* at para 53). It is useful to review what Justice Stratas stated about the justifications for the general rule (*JP Morgan* at para 52):

> [52] This general rule is justified by several considerations:
>
> - Affidavits have the potential to trigger cross-examinations and refused questions and, thus, can delay applications for judicial review. This is contrary to Parliament's requirement that applications for judicial review proceed "without delay" and be heard "in a summary way."
>
> - A respondent bringing a motion to strike a notice of application does not need to file an affidavit. In its motion, it must identify an obvious and fatal flaw in the notice of application, *i.e.* one apparent on the face of it. A flaw that can be shown only with the assistance of an affidavit is not obvious. A respondent's inability to file evidence does not normally prejudice it. It can file evidence later on the merits of the review, subject to certain limitations, and often the merits can be heard within a few months. If an application has no merit, it will be dismissed soon enough. And if there is some need for faster determination of the merits, a respondent can always move for an order expediting the application.
>
> - As for an applicant responding to a motion to strike an application, the starting point is that in such a motion the facts alleged in the notice of application are taken to be true: *Chrysler Canada Inc. v. Canada*, 2008 FC 727, [2008] 5 C.T.C. 174, at paragraph 20, affd on appeal, 2008 FC 1049, [2009] 1 C.T.C. 145. This obviates the need for an affidavit supplying facts. Further, an applicant must state "complete" grounds in its notice of application. Both the Court and opposing parties are entitled to assume that the notice of application includes everything substantial that is required to grant the relief sought. An

> affidavit cannot be admitted to supplement or buttress the notice of application.

[11] One of the exceptions to the rule against affidavit evidence on a motion to strike is an affidavit merely appending a document referred to and incorporated by reference into a notice of application (*JP Morgan* at para 54).

[12] In *JP Morgan* Justice Stratas went on to state the following regarding affidavit evidence:

> [62] For the benefit of future cases, however, I will offer some brief guidance.
>
> [63] In the circumstances of this case, I disagree with the Prothonotary's view that the affidavit tendered by JP Morgan was admissible because the Court's jurisdiction was in issue. In drafting the grounds in support of their notices of application, applicants should plead the reasons why the Court has jurisdiction. After all, the Court's jurisdiction is statutory, the Court must have jurisdiction to entertain the application and grant the relief sought, and paragraph 301(e) requires relevant statutory provisions to be pleaded.
>
> [64] In my view, the affidavit tendered by JP Morgan is admissible only to the extent it describes, in an uncontroversial way, the policies mentioned in the notice of application which, on a fair reading, are incorporated into the notice of application by reference. The remainder of the affidavit, however, is either irrelevant or adds information not included in the grounds offered in support of the application. Regardless of whether this additional information in the affidavit was known to the Minister, it should not have been before the Court on the motion to strike.

[13] In my view, as with issue of jurisdiction which was addressed in *JP Morgan*, the Notice of Application should set out the basis for standing for the same reasons. As stated in *JP Morgan*:

> [38] In a notice of application for judicial review, an applicant must set out a "precise" statement of the relief sought and a "complete" and "concise" statement of the grounds intended to be argued: *Federal Courts Rules*, SOR/98-106, paragraphs 301(d) and (e).

> [39] A "complete" statement of grounds means all the legal bases and material facts that, if taken as true, will support granting the relief sought.
>
> [40] A "concise" statement of grounds must include the material facts necessary to show that the Court can and should grant the relief sought. It does not include the evidence by which those facts are to be proved.

[14] The moving parties, the AGC and Minister, did not file any evidence on the motion. JAMP was not a moving party, but a responding party supporting the position of the AGC and Minister that the application should be struck. JAMP filed two affidavits which are discussed below.

[15] In response to the motion, BI Canada filed two affidavits:

a) Affidavit of Dr. Martin Kolb sworn March 7, 2024 [Expert Affidavit]; and

b) Affidavit of a law clerk with applicant's counsel affirmed March 7, 2024 [Applicant's Law Clerk Affidavit].

[16] BI Canada argued that its affidavit evidence was admissible and should be considered as it is evidence that is supportive of the facts alleged in the Notice of Application. However, this is the type of evidence that *JP Morgan* makes clear is not admissible (see, for example, paras 38 to 40, 52 of *JP Morgan*). An exception to the inadmissibility of BI Canada's affidavit evidence is Exhibits "A" to "D" of the Applicant's Law Clerk Affidavit, discussed below.

[17] Regarding BI Canada's Expert Affidavit, in addition to being evidence that is not admissible on a motion of this type, even if it was admissible, it does not assist BI Canada for the reasons explained below.

[18] Regarding the Applicant's Law Clerk Affidavit:

a) Exhibits "A", "B", "C" and "D" are documents referred to in the Notice of Application. They are: (i) Health Canada's "Notice of Compliance Information" document on the NOC that is the subject matter of the Decision (paras 13 to 15 of the Notice of Application); (ii) the JAMP Product Monograph (paras 16 to 18 of the Notice of Application); (iii) the statement of claim issued July 28, 2023; and (iv) the related letter from counsel submitted with it (para 12 of the Notice of Application). These documents are incorporated into the Notice of Application by reference, and affidavit evidence simply appending these documents is acceptable.

b) The balance of the exhibits are problematic. They are: (i) a statement of claim issued February 22, 2024 that is not referred to in the Notice of Application (having been issued after the Notice of Application was issued); (ii) a letter from counsel for the AGC and Minister to applicant's counsel taking the position that BI Canada lacks standing, the application should be discontinued, and opposing delivery of the certified tribunal record; and (iii) documents stated to be obtained from "the HeadStart website at ofev.ca". The information in the documents from the "the HeadStart website" is all inadmissible hearsay in addition to being inappropriate evidence on a motion to strike.

[19] As noted above JAMP filed two affidavits:

a) Affidavit of a law clerk in the office of JAMP's counsel affirmed February 6, 2024 [JAMP Law Clerk Affidavit]; and

b) Affidavit of service regarding service on BI Canada on January 9, 2024, of what is stated in the affidavit of service to be a notice of allegation by Apotex Inc. regarding 100 mg capsules of Nintedanib Esilate, with OFEV as the reference product [Affidavit of Service].

[20] Regarding the JAMP Law Clerk Affidavit, Exhibits "A" to "D" are copies of correspondence among counsel seeking to determine if BI Canada is relying on public interest standing. The admissibility of these Exhibits does not need to be considered as BI Canada subsequently confirmed it is not asserting public interest standing (para 5 of BI Canada's responding written representations dated March 7, 2024 [BI Canada's Written Representations]). Regarding the balance of that affidavit, and the Affidavit of Service, there is no basis for admitting that evidence on this motion.

III. Issue

[21] The issue on this motion is whether the Notice of Application should be struck out on the basis that BI Canada lacks standing.

IV. Test – Motion to strike a notice of application for judicial review

[22] Although there is no specific rule in the *Federal Courts Rules*, SOR/98-106 [*Rules*] providing for a motion to strike a notice of application, the Federal Court has jurisdiction to do so. As stated in *JP Morgan*, the jurisdiction "is founded not in the rules but in the Courts' plenary jurisdiction to restrain the misuse or abuse of courts' processes" (at para 49).

[23] The test on a motion to strike a notice of application for judicial review was described as follows by Justice Statas in *JP Morgan*:

> [47] The Court will strike a notice of application for judicial review only where it is "so clearly improper as to be bereft of any possibility of success" [footnote omitted]: *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, 1994 CanLII 3529 (FCA), [1995] 1 F.C. 588 (C.A.), at page 600. There must be a "show stopper" or a "knockout punch"—an obvious, fatal flaw striking at the root of this Court's power to entertain the application: *Rahman v. Public Service Labour Relations Board*, 2013 FCA 117, at paragraph 7; *Donaldson v. Western Grain Storage By-Products*, 2012 FCA 286, at paragraph 6; *Hunt v. Carey Canada Inc.*, 1990 CanLII 90 (SCC), [1990] 2 S.C.R. 959.

[24] As recently stated by the Supreme Court of Canada in *Iris Technologies* (see also para 62):

> [26] There is no dispute on the proper test to be applied on a motion to strike in this context. A court seized of a motion to strike assumes the allegations of fact set forth in the application to be true and an application for judicial review will be struck where it is bereft of any possibility of success (*JP Morgan Asset Management (Canada) Inc. v. Canada (National Revenue)*, 2013 FCA 250, [2014] 2 F.C.R. 557, at para. 47). It is understood to be a high threshold and will only be granted in the "clearest of cases" (*Ghazi v. Canada (National Revenue)*, 2019 FC 860, 70 Admin L.R. (6th) 216, at para. 10).

[25] The application of the test on a motion to strike a notice of application on the basis of a lack of standing was stated by Justice Diner in *Canadian Council for Refugees v Canada (Immigration, Refugees and Citizenship)*, 2017 FC 1131 as follows:

> [22] The moving party bears the onus on a motion to strike for lack of standing (*League for Human Rights of B'nai Brith Canada v Canada*, 2008 FC 146 at para 13, rev'd on other grounds in 2008 FC 732 [*B'Nai Brith* (FC)]). The test to be used on such a motion is whether it is "plain and obvious" that the application for judicial review is "bereft of success" because the impugned party has no standing (*Apotex* at para 11, cited recently in *Arctos Holdings Inc v*

> *Canada (Attorney General)*, 2017 FC 553 at para 46 [*Arctos*]). If the answer to this question is "yes", then the motion succeeds and the application is dismissed or the party without standing is struck out. Such a finding may only be made in exceptional cases (*Arctos* at para 45).
>
> [23] If, on the other hand, it is not plain and obvious that the party has no standing, then the motion to strike fails. In that case, the matter of standing is not actually decided, but rather is left to the judge hearing the application (*Arctos* at para 75; *Apotex* at para 24).

[26] Also important on this motion is the following teaching from *JP Morgan* that: "in considering a motion to strike, the Court must read the notice of application with a view to understanding the real essence of the application" and the "Court must gain 'a realistic appreciation' of the application's 'essential character' by reading it holistically and practically without fastening onto matters of form" (see paras 49, 50 and 102).

V. Analysis – standing issue

[27] Applying the teaching from *JP Morgan* discussed in the paragraph immediately above to the Notice of Application, including the grounds of review set out in paragraph 19, the real essence of BI Canada's application is a challenge to the Decision on the basis of patient safety and the commercial or competitive consequences to BI Canada. While this alone would be sufficient to strike out the Notice of Application for lack of standing on the basis of the case law discussed below, I will also consider the two bases for standing asserted by BI Canada in responding to this motion.

[28] BI Canada asserts two bases for standing:

a) "the impact of the Decision on the operation of BI Canada's patient assistance program, HeadStart" (para 6 of BI Canada's Written Representations); and

b) "the effect of the Decision on BI's rights under the *Patented Medicines (Notice of Compliance) Regulations* […]. In particular, the Decision has effectively bifurcated a single abbreviated new drug submission into two submissions, one for each strength." (para 7 of BI Canada's Written Representations]

[29] A useful starting point for any discussion of standing is section 18.1(1) of the *Federal Courts Act*, RSC, 1985, c F-7 [*Act*] which provides:

> An application for judicial review may be made by the Attorney General of Canada or by anyone directly affected by the matter in respect of which relief is sought.
>
> [Emphasis added.]

[30] The meaning of "directly affected" was considered by the Federal Court of Appeal in *Forest Ethics Advocacy Association v Canada (National Energy Board)*, 2013 FCA 236 [*Forest Ethics*]. In that case, Justice Stratas discussed the meaning of "directly affected" in Rule 303(1)(a) when considering the meaning of those same words in subsection 18.1(1) of the *Act*, and stated:

> [18] The words "directly affected" in Rule 303(1)(*a*) mirror those in subsection 18.1(1) of the *Federal Courts Act*. Under that subsection, only the Attorney General or "anyone directly affected by the matter in respect of which relief is sought" may bring an application for judicial review. Rule 303(1)(*a*) restricts the category of parties who must be added as respondents to those who, if the tribunal's decision were different, could have brought an application for judicial review themselves.
>
> [19] Accordingly, guidance on the meaning of "direct interest" in Rule 303(1)(*a*) can be found in the case law concerning the meaning of "direct interest" in subsection 18.1(1) of the *Federal Courts Act*. This was the approach of the Federal Court in *Reddy-Cheminor, Inc. v. Canada*, 2001 FCT 1065, 212 F.T.R. 129, aff'd 2002 FCA 179, 291 F.T.R. 193 and seems to have been the approach implicitly adopted by the Federal Court in *Cami International Poultry Inc. v. Canada (Attorney General)*, 2013 FC 583 at paragraphs 33-34.

> [20] A party has a "direct interest" under subsection 18.1(1) of the *Federal Courts Act* when its legal rights are affected, legal obligations are imposed upon it, or it is prejudicially affected in some direct way: *League for Human Rights of B'Nai Brith Canada v. Odynsky*, 2010 FCA 307 at paragraphs 57-58; *Rothmans of Pall Mall Canada Ltd. v. Canada (M.N.R.)*, 1976 CanLII 2258 (FCA), [1976] 2 F.C. 500 (C.A.); *Irving Shipbuilding Inc. v. Canada (A.G.)*, 2009 FCA 116.

[31] Of significance for present purposes, Justice Stratas went on in *Forest Ethics* to state the type of prejudice that is required:

> [23] I accept that the relief sought in the judicial review, if granted, would cause real, tangible prejudice to Enbridge and Valero within the meaning of the *Odynsky* test, not just general inconvenience or general impact on their businesses as a result of detrimental or unhelpful jurisprudence. But Enbridge and Valero must go further under the *Odynsky* test and show that they will be prejudiced in a direct way.
>
> [24] In Enbridge's case, the prejudice is direct. The Board's proceeding is about whether Enbridge's project should be approved. If the relief sought in the judicial review is granted, the proceedings before the Board will have to be rerun to some extent, delaying Enbridge's project. Further, if the relief sought is granted, potentially many persons and organizations from different perspectives will have rights of participation where, before, they did not. The Board might accept some of the new participants' arguments, leading to the rejection of Enbridge's application for approval of its project. The risk of that happening directly affects Enbridge, the proponent of the project.
>
> [25] Valero, however, stands in a different position. It is in a commercial relationship with Enbridge, the proponent of the project. The success of that relationship depends upon the approval of the project. But it is not itself the proponent of the project.
>
> [26] Those in a commercial relationship with the proponent of a project who stand to gain from the approval of the project of course will suffer financially if the project is not approved. But that financial interest is merely consequential or indirect.
>
> [27] Valero stands in the same position as any suppliers of materials for the project and any workers involved in the construction of the project. The project will provide them with

> income and work. But if it is not approved, it will not go forward, and the income and work will be lost. Their interests, no doubt significant, are consequential or indirect, contingent on the proponent of the project getting its approval.
>
> [28] One way to test this result is to consider a hypothetical situation and the concept of "direct interest" under subsection 18.1(1) of the *Federal Courts Act*. Suppose that the Board rules against Enbridge's application for approval. Suppose that Enbridge decides not to bring an application for judicial review. In those circumstances, could Valero maintain that since it stood to benefit economically from the approval it has a "direct interest" and, thus, has standing to bring an application for judicial review? Could all others who also stood to benefit economically in some way from the pipeline approval – construction companies and their employees, suppliers and transporters of construction materials, potential buyers of refined petroleum products – say the same thing? I think not.
>
> [29] I do not doubt that Valero's interest is most significant: see Exhibit "A" to the Affidavit of Louis Bergeron. However, Rule 303(1)(*a*) refers to a "direct interest," not a "significant interest." Valero does not have a "direct interest" and so it could not have been named as a respondent in the first place.

[32] The question of standing is determined in the context of the grounds of review on which an applicant relies (*Irving Shipbuilding Inc v Canada (Attorney General)*, 2009 FCA 116, at para 28; *Arctos Holdings Inc v Canada (Attorney General)*, 2017 FC 553, at para 47).

[33] As seen from the decision in *Novo Nordisk Canada Inc v Canada (Health)*, 2019 FC 822 [*Novo Nordisk*] quoted below, there is a long line of cases that have held that a first person (*i.e.*, an innovator drug manufacturer) is not directly affected by a decision of the Minister in respect of the issuance, or proposed issuance, of an NOC to another drug manufacturer under the *Food and Drug Regulations*, CRC, c 870, and that, therefore, such a manufacturer has no standing to institute or participate in an application to review those decisions under section 18.1 of the *Act*.

[34] As stated in *Novo Nordisk* by Associate Judge Tabib (then Prothonotary Tabib):

> [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)*, 1987 CanLII 5382 (FC), [1988] 1 FC 422, aff'd (1990) 1990 CanLII 7964 (FCA), 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.

[35] The conclusions reached in *Novo Nordisk* on the alleged consequences of the decision in issue in that case are also instructive, as all of those consequences were found to be exclusively economic, commercial and competitive:

> [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. […]
>
> [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.

A. *"The impact of the Decision on the operation of BI Canada's patient assistance program, HeadStart"*

[36] As noted above, the first ground on which BI Canada argues it has standing is the impact of the Decision on the operation of its patient assistance program, HeadStart. BI Canada argues that it is directly affected by the Decision because the JAMP Product Monograph refers to 100 mg nintedanib which JAMP does not offer and as a result, the reader is effectively referred to BI Canada's nintedanib since, at the time of the Decision, it was the only 100 mg on the market. BI Canada asserts that as a result, the "Decision may result in the unusual circumstance of BI Canada's HeadStart program supporting education of patients receiving JAMP 150 mg" (para 6 of BI Canada's Written Representations).

[37] This argument fails for each of the following reasons:

a) Although the Notice of Application refers to the existence of BI Canada's patient assistance program (para 7), it does not allege that the program is impacted in some way. However, even if it was alleged, it would be of no consequence for the reasons that follow.

b) BI Canada argues that the situation is somehow different from the other NOC cases and that there is a direct effect because of the reference in the JAMP Product Monograph to possible dose reduction from the 150 mg, which JAMP offers, to 100 mg, which JAMP does not offer. However, although the Notice of Application refers to the JAMP Product Monograph and states that it was "approved by the Minister" (para 16), it does not allege any specific link between the Decision and the JAMP Product Monograph. But, even if it did, it would not impact the outcome in this case for the reason set out in the subparagraphs that follow.

c) Any impact on BI Canada's patient assistance program is a commercial or economic impact which is insufficient for BI Canada to be directly affected by the Decision.

d) Even if the evidence of Dr. Kolb is considered, it does not assist BI Canada for the reasons set out above in the preceding subparagraphs and detailed below in paragraphs 38 and 39.

[38] In support of its position that BI Canada's patient assistance program will be impacted by JAMP's 150 mg nintedanib, BI Canada relies on the Affidavit of Dr. Martin Kolb. The scope of Dr. Kolb's evidence is addressed in paragraph 16 of his affidavit where he sets out his mandate:

> 16. Counsel asked me to provide evidence on the following subjects:
>
> i. How OFEV® is prescribed in Canada and at [sic] what doses.
>
> ii. The operation of the HeadStart program in relation to our clinical practice at the Interstitial Lung Disease (ILD) Clinic at the Firestone Institute for Respiratory Health.
>
> iii. Describe the patient assistance programs available when pirfenidone, another antifibrotic drug, was genericized in Canada.

[39] JAMP raises various issues with Dr. Kolb's evidence. However, it is only necessary to address one. Of significance, on cross-examination Dr. Kolb confirmed that he was not asked to and was not offering an opinion on whether and how BI Canada's HeadStart patient assistance program would be impacted if JAMP launches its 150 mg nintedanib. As a result, there is no evidence that BI Canada will be impacted by JAMP's 150 mg nintedanib. However, even if the impact on BI Canada's HeadStart patient assistance program was set out in the Notice of Application, or if there was admissible evidence on the point, it is still an economic and competitive impact. That is not sufficient for standing.

[40] BI Canada argues that none of the other decided cases deal with the particular factual situation asserted by BI Canada. However, even if this is a factual situation that has not been addressed before in the case law, it is still an economic and competitive impact, a point that has been addressed in the case law as not being sufficient for standing.

B. *"The effect of the Decision on BI's rights under the Patented Medicines (Notice of Compliance) Regulations […]. In particular, the Decision has effectively bifurcated a single abbreviated new drug submission into two submissions, one for each strength."*

[41] The second ground for standing is summarized in BI Canada's Written Representations as follows:

> 7. Second, BI Canada relies upon the effect of the Decision on BI's rights under the *Patented Medicines (Notice of Compliance) Regulations* (*PMNOC Regulations*). In particular, the Decision has effectively bifurcated a single abbreviated new drug submission into two submissions, one for each strength.
>
> 8. As a result of the Decision, JAMP filed a supplemental abbreviated new drug submission for approval of JAMP 100 mg and made a further allegation as required by the *PMNOC Regulations*. BI Canada was required to bring a second action in relation to JAMP 100 mg instead of the one action it initiated in relation to both strengths. An effect on legal rights under the *PMNOC Regulations* has been recognized by this Court as a basis for standing to challenge a decision of the Minister.

[42] This argument on standing also fails for each of the following reasons:

a) Although paragraph 12 of the Notice of Application describes the action commenced by BI Canada and Boehringer Ingelheim International GmbH on July 28, 2023, the facts that are asserted in paragraphs 7 and 8 of BI Canada's Written Representations reproduced above are not facts alleged in the Notice of Application. However, even if they were, it would not assist BI Canada for the reasons that follow.

b) The Decision does not require JAMP to seek regulatory approval for the 100 mg product, or to serve a notice of allegation relating to it. Even if the facts asserted in paragraph 8 of BI Canada's Written Representations are assumed to be true, namely that "JAMP filed a supplemental abbreviated new drug submission for approval of JAMP 100 mg" and served a notice of allegation under the *PMNOC Regulations*,

> these are steps taken by JAMP as a result of decisions JAMP made. The Decision did not require these steps to be taken by JAMP. Similarly, if BI Canada brought a second action [Second Action] following the above-noted steps taken by JAMP, that was as a result of a decision made by BI Canada; it was not something required by the Decision. None of these events, even if it is assumed that they prejudicially affect BI Canada, are direct affects of the Decision.

[43] As noted above, BI Canada argues that an affect on legal rights under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM(NOC) Regulations*] has been recognized by this Court as a basis for standing to challenge a decision of the Minister. However, if there is any impact on BI Canada under the *PM(NOC) Regulations* it is not as a direct result of a decision of the Minister under those regulations, but many steps removed (see subparagraph 42 b) above for a discussion of those steps).

[44] JAMP argues that if there is any impact on BI Canada under the *PM(NOC) Regulations* as a result of the Second Action, it is actually a benefit. This is because under the first action, BI Canada had renounced the 24 month stay. Under the Second Action, commenced on February 22, 2024, BI Canada had another opportunity to take advantage of the 24 month stay, which it did. However, in light of the findings above, I need not decide this point.

VI. Conclusion and costs

[45] For the reasons set out above, the motion is granted, striking the Notice of Application. In light of the reasons set out above on the grounds for standing asserted by BI Canada, the Notice of Application is struck without leave to amend.

[46] Similar to the approach taken by Associate Judge Duchesne (as he then was) in *Suss v Canada*, 2024 FC 137 at para 59, this proceeding is dismissed pursuant to Rule 168 of the *Rules*. This is because it is not possible for BI Canada to continue this application as a result of the Notice of Application being struck without leave to amend.

[47] Having regard to Rule 400 of the *Rules*, including the factors articulated in subrule (3), costs of this motion are awarded to the moving party respondents. The factor that is of particular significance in arriving at this conclusion is the result of the motion. Having regard to Tariff B of the *Rules*, costs are fixed in the amount of $3,000.

JUDGMENT in T-2108-23

THIS COURT'S JUDGMENT is that:

1. The Notice of Application is struck out without leave to amend, and the application dismissed.

2. Cost are awarded to the moving parties, the Minister of Health and the Attorney General of Canada, fixed in the total amount of $3,000 to be paid by the applicant.

"John C. Cotter"
Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2108-23
STYLE OF CAUSE:	BOEHRINGER INGELHEIM (CANADA) LTD. v THE MINISTER OF HEALTH, ATTORNEY GENERAL OF CANADA AND JAMP PHARMA CORPORATION
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	APRIL 5, 2024
JUDGMENT AND REASONS:	CASE MANAGEMENT JUDGE JOHN C. COTTER
DATED:	NOVEMBER 6, 2024

APPEARANCES:

Katie Lee Nancy Pei	FOR THE APPLICANT
James Schneider Emma Ryman	FOR THE RESPONDENTS THE MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA
Jordan Scopa Jaclyn Tilak	FOR THE RESPONDENT, JAMP PHARMA CORPORATION

SOLICITORS OF RECORD:

Smart & Biggar LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPLICANT
Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENTS THE MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Goodmans LLP
Barristers and Solicitors
Toronto, Ontario

FOR THE RESPONDENT
JAMP PHARMA CORPORATION