Federal Court  Cour fédérale

Date: 20170605

Docket: T-485-17

Citation: 2017 FC 548

Ottawa, Ontario, June 5, 2017

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

INNOVATOR COMPANY

Applicant

and

THE ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH

Respondents

ORDER AND REASONS

[1] The Applicant identified itself in instituting this judicial review application as "Innovator Company". That is not its real name, but a pseudonym used to keeps its identity confidential.

[2] The Applicant is an innovative pharmaceutical company who filed a New Drug Submission ("NDS") with Health Canada with the view of obtaining approval to market in Canada a certain drug, the identity of which it also wishes to keep confidential. The Minister of

Health determined that the Applicant's submission makes a direct or indirect comparison to a product for which another innovator (the "Other Innovator") whose identity is also undisclosed, has one or more patents listed on the Patent Register maintained pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended, (the "*Regulations*"). As such, the Minister determined that the Applicant is a Second Person as defined in the *Regulations*, that s 5 of the *Regulations* is triggered and that the Applicant is required to address the patents listed against the Other Innovator's product.

[3] The Applicant seeks judicial review of the Minister's decision. In particular, it alleges that its submission references certain clinical studies in respect of which both the Applicant and the Other Innovator have propriety rights to use the resulting data, as well as publicly available journal articles relating to the product at issue. The Applicant submits that the Minister erred in mechanically applying the *Regulations* and failing to consider that the Applicant is not merely a generic seeking to use an innovator's confidential data or to early-work a listed patent, but an innovator in its own right, who has a proprietary interest in the data generated by the studies and the right to use it.

[4] The Notice of Application seeks an order declaring that the Applicant's NDS does not trigger the application of s 5 of the *Regulations*, an order quashing the Minister's decision finding that the NDS triggers the application of s 5 of the *Regulations* and an order directing the Minister to process the NDS without requiring the filing of Form Vs.

[5] The Applicant now brings this motion seeking a confidentiality order in respect of its own identity, the identity of its drug product, the entire content of its NDS and any information it provided to the Minister in support of its NDS. Although not specifically stated in the proposed order, the confidentiality order would extend to the identity of the Other Innovator.

[6] The Other Innovator is not named as a respondent to the judicial review, even under a pseudonym, and was not served with or notified of either the Notice of Application or the motion for a confidentiality order. The Applicant's submissions and evidence on this motion are to the effect that the Applicant would stand to suffer irreparable harm if the Other Innovator were to become aware that it has filed an NDS in relation to the drug product at issue.

[7] In response to the motion, the Attorney General takes the position that the Other Innovator is a necessary respondent to this application and that the confidentiality order sought cannot be granted so as to deprive the Other Innovator of the right to be notified of the Application and to decide whether or not to participate in it. The Attorney General further submits that it is premature to fix the other terms of the confidentiality order until the Other Innovator has been notified, has had an opportunity to decide whether to participate, and if so, to speak to the parameters of the confidentiality order that would strike the appropriate balance between the protection of the Applicant's rights, the Other Innovator's rights to meaningfully participate in the application and the public interest in open and accessible court proceedings.

[8] For the reasons that follow, I agree with the Attorney General's position.

[9] The circumstances of this matter are indistinguishable from the circumstances in *Apotex Inc. v Canada (Minister of Health)*, 2006 FC 846 (*Apotex 2006*). In that case, Apotex had instituted an application for judicial review seeking an order to compel the Minister to process its Abbreviated New Drug Submission for a drug product without regard to the *Regulations*. There, as is the case here, the issue to be determined in the underlying application was whether the Regulations apply to the submission. There, as here, the applicant had not notified the innovator who had an interest in the drug product to which the Minister had determined the ANDS had directly or indirectly made reference. In determining that this innovator was as necessary party, the Court considered relevant case law and held as follows:

> 12 The respondent points to two decisions of this Court, in respect of the NOC Regulations, in which the applicant generic had not disclosed the innovator's identity and was required to do so. In Apotex Inc. v. Attorney-General of Canada et al., (1994), 79 F.T.R. 235, 56 C.P.R. (3d) 261 (T.D.) Justice Simpson concluded that a patent holder has an interest which on its application may lead to the granting of party status in proceedings between the generic and the Minister and that it was necessary to so identify the patent holder so it could decide whether to take steps to participate.
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> 13 In Apotex Inc. v. Canada (Minister of Health(2000), 186 F.T.R. 84, 4 C.P.R. (4th) 421 (T.D.) the generic sought to use a foreign product not sold in Canada as the Canadian Reference Product and disclosed the innovator's identity only in the face of motions to intervene brought by several other companies and an industry association. Apotex then sought to have the participation of the innovator with the proprietary interest limited. Justice McGillis held that the innovator was entitled to unrestricted party status.
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> 14 I see no substantial difference between what Apotex seeks to achieve in the present matter and what it attempted to do in the case before Justice McGillis in 2000. <u>It seeks to litigate its dispute with the Minister over the application of the NOC Regulations without the inconvenient intervention of an innovator company which may have proprietary rights over the Canadian Reference Product upon which it seeks to rely in its ANDS</u>.

> 15 The overarching principle at issue in this matter is that of the public interest in open and accessible court proceedings. The authority to grant a protective order is a discretionary exception to that principle. The commercial interests of the applicant are of secondary importance but can be accommodated where, as set out in Sierra Club, the salutary effects of a protective order outweigh its deleterious effects. When faced with a motion to grant such an order, a prothonotary has the responsibility to ensure, in my view, that the party seeking the exercise of the Court's discretion has served notice on all persons who may be directly affected by the underlying application.
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> 16 The motion for a protective order in this context cannot be isolated from the question of whether all of the necessary parties have been properly served notice of the underlying application as one effect of granting the order will be to prevent anyone who may have an interest from learning of the proceedings. I agree with the respondent that it was apparent that the proprietary interests of a third party innovator may be directly affected by the application and the motion. Given the nature of the regulatory scheme, evidence to establish this was not required.
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> [Emphasis added]

[10] The Applicant relies on the subsequent decision of a Prothonotary in *Novopharm Limited v The Minister of Health and Attorney General of Canada*, 2010 FC 566. My colleague in that case seems to have found grounds to distinguish *Apotex 2006* and the preceding line of jurisprudence on the basis of the question at issue in the underlying application. The question in the *Novopharm* case was whether the Applicant was required to address a patent put on the Register after it had filed its ANDS, which the Prothonotary considered to be a different issue from those raised in *Apotex 2006* and the other two cases relied upon by the Court in *Apotex 2006*.

[11] I am not persuaded that this distinction is warranted. At its root, whatever the Applicant's basis might be to argue that s 5 of the *Regulations* does not apply, the relevant issue before the

Court is the validity of the Minister's decision that the Applicant's submission triggers the application of the *Regulations*; the order sought in all cases is one that would set aside the Minister's decision. The Courts have consistently held that a proceeding seeking to set aside a decision by the Minister to the effect that a patent listed on the Register must be addressed directly affects the innovator who listed the patent against the referenced product.

[12] The analysis conducted in the recent case of *Hospira Healthcare Corp. v Canada (Minister of Health)*, 2014 FC 179, upheld at 2014 FC 235 and 2014 FCA 19, although it considered a different regulatory regime, confirms that the rationale behind that conclusion is that the Minister's decision that the *Regulations* are engaged confers a direct benefit to the innovator whose patent is referenced, and that a proceeding to set aside that decision directly affects that innovator. This is so whether or not the innovator participated in the Minister's decision or is even aware of it:

> 19 Sanofi's Eloxatin and oxaliplatin have been listed on the Register of Innovative Drugs. Sanofi is therefore entitled to benefit from the market exclusivity promised by section C.08.004.1 and to the protection of its data against direct or indirect comparison by others. The Minister has determined, in the decision under review, that Hospira has made such a comparison and impinged upon the protection extended to Sanofi. He has determined that market exclusivity has been triggered against Hospira's product and in favour of Sanofi. Hospira's application seeks to reverse that decision and withdraw the protection and benefits to which the Minister has determined Sanofi was entitled. It is beyond question that the order sought will directly prejudice Sanofi, as it will remove the protection and its right to the exclusion of Hospira's product from the market, both of which were intended for Sanofi's direct benefit.
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> 20 The fact that the Food and Drugs Regulations do not contemplate the participation of Sanofi in the Minister's initial determination or a specific legal recourse in the event the data protection regime is triggered or breached does not negate Sanofi's

> standing. As formulated in Forest Ethics Advocacy, above, the test for standing does not require that legal rights or obligations flow to a person from the order sought; it is sufficient that it be prejudicially affected in a direct way.

[13] The Applicant submits that its right to maintain the confidentiality of its NDS is paramount, and should be preserved as long as possible. It argues that it is not necessary or in the interest of justice to involve the Other Innovator at the stage of this judicial review, as the Innovator's legal rights, if any, will still be protected: if the application is unsuccessful and the Applicant is obliged to address and does address the Other Innovator's patents, all its rights under the *Regulations* will be available. If the application is successful and the Minister eventually issues a NOC to the Applicant, the Other Innovator will then have standing to seek judicial review of the Minister's issuance of the NOC, as confirmed by the Federal Court of Appeal in *Ferring Canada Inc. v Canada (Minister of Health)*, 2007 FCA 276.

[14] This was one of the arguments my colleague retained in *Novopharm*. I note however that the decision in *Novopharm* seems to proceed from the understanding that the only interest sufficient to require that a party be named as a respondent to a judicial review application is where a legal right is affected. The Court considered that an innovator's legal rights, in the context of the *Regulations*, are only those triggered once a Second Person chooses to address a listed patent by serving a Notice of Allegation, or those recognized to arise when the Minister decides to issue an NOC. The Prothonotary in *Novopharm* did not consider that the Minister's decision that the *Regulations* were engaged conferred any enforceable legal rights on the innovator. He viewed the loss of the market exclusivity inherent to the scheme of the *Regulations*

to be a commercial interest only, and insufficient to mandate the inclusion of the innovator as a respondent in the case before him.

[15] The decision of the Court of Appeal in *Forest Ethics Advocacy Association v Canada (National Energy Board)*, 2013 FCA 236 has since clarified that a party has a direct interest and standing to bring or be named a respondent in a judicial review proceeding, not only when its legal rights are affected or legal obligations are imposed on it, but also when "it is prejudicially affected in some direct way" (at para 20). As later referred to and applied in *Hospira*, above, it has now become clear that even though an innovator has no direct legal right to participate in the Minister's decision as to whether the *Regulations* are engaged or to compel the Minister to enforce the *Regulations*, once a decision has been made by the Minister that the *Regulations* are engaged in favour of a particular innovator, a direct commercial benefit is conferred on that innovator, sufficient to give it standing as a respondent in a judicial review of that decision.

[16] I am satisfied that the Other Innovator is a person directly affected by the order sought in the underlying application, and that it ought to have been named as a respondent. I am further satisfied that the motion for a confidentiality order cannot be considered without giving an opportunity to the Other Innovator to be heard.

[17] The Applicant tendered a confidential affidavit at the hearing, in support of the merits of its motion for a confidentiality order. The Applicant asked that, if I determined that the motion should be adjourned and that the Other Innovator should be notified, the confidential affidavit be returned to the Applicant to preserve its confidentiality as against the Other Innovator.

[18] As I have decided to adjourn the motion without considering its merits or the confidential affidavit, there is no need to retain the confidential affidavit in the Court's record and the Applicant's request will be granted.

ORDER

THIS COURT ORDERS that:

1. The Applicant's motion is adjourned to a date to be fixed after the Applicant will have served the Notice of Application, the motion materials and this Order on Other Innovator, as it is described by the Applicant in the Notice of Application;

2. The Applicant has 20 days within which to effect service, and to file proof of such service;

3. The Other Innovator shall have 10 days from the date of service of the materials to serve and file a Notice of Appearance.

4. The parties, including the Other Innovator if it has served and filed a Notice of Appearance, shall, within five (5) days of the service of a Notice of Appearance or the expiration of the time to do so, provide the Court with their mutual dates of availability to participate in a case management telephone conference for the purpose of rescheduling the hearing of the motion.

5. The confidential affidavit tendered by the Applicant at the hearing shall be removed from the record and returned to the Applicant. It shall, until it is returned to the Applicant, be treated confidentially.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-485-17
STYLE OF CAUSE:	INNOVATOR COMPANY v THE ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	MAY 31, 2017
ORDER AND REASONS:	TABIB P.
DATED:	JUNE 5, 2017

APPEARANCES:

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