Federal Court  Cour fédérale

Date: 20170926

Docket: T-485-17

Citation: 2017 FC 864

Ottawa, Ontario, September 26, 2017

PRESENT: The Honourable Mr. Justice Mosley

BETWEEN:

INNOVATOR COMPANY

Applicant

and

THE ATTORNEY GENERAL OF CANADA
AND THE MINISTER OF HEALTH

Respondents

ORDER AND REASONS

[1] This is an appeal pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106 to set aside the Order of Prothonotary Tabib dated June 5, 2017.

[2] The applicant, "Innovator Company", a drug manufacturer employing a pseudonym, sought an order for confidentiality in respect to its own identity and information relating to a New Drug Submission (NDS) filed with the Minister of Health (Minister). The Prothonotary adjourned the motion until another drug manufacturer could be provided notice of the

proceedings pursuant to Rule 303 of the *Federal Courts Rules*. The applicant seeks to have the June 5, 2017 Order quashed and its motion for a confidentiality order proceed solely as between itself and the respondent Ministers.

[3] For the reasons that follow, this appeal is dismissed.

I. Background

[4] In 2016, the applicant filed a NDS with Health Canada's Office of Patented Medicines and Liaison (the OPML).

[5] On March 3, 2017, OPML, acting on behalf of the Minister, held that the applicant's NDS triggered the application of s 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*Regulations* or *PM(NOC) Regulations*).

[6] On March 31, 2017, the applicant filed a Notice of Application for judicial review of the Minister's decision, in which it describes itself as "Innovator Company". In its motion materials, the applicant refers to another drug manufacturer as the "Other Innovator".

[7] The applicant and the "Other Innovator" had conducted joint clinical studies for a drug. This ultimately led to the commercialization of a drug in dosage strength A by the Other Innovator. The Other Innovator also has a product in dosage strength B for which one or more associated patents are listed on the Canadian Patent Register (the Register). Notwithstanding

their earlier collaboration, they are now described by the applicant as competitors in the pharmaceutical market.

[8] The NDS filed by the applicant sought approval of its proposed drug in dosage strength B. With its submission, the applicant made representations that it need not be treated as a Second Person, as defined by the *Regulations,* due to: 1) its references to clinical studies containing data relating to dosage strength A to which it had rights, notwithstanding that the data was also relied upon by the Other Innovator; and 2) because of publicly available journal articles that compare products having dosage strength B to dosage strength A.

[9] The Notice of Application for judicial review of the Minister's decision seeks an order declaring that the applicant's NDS does not trigger the application of s 5, an order quashing the Minister's decision and an order directing the Minister to process the NDS without requiring the filing of the forms required under s 5 of the *Regulations*.

[10] The applicant's motion before Prothonotary Tabib sought a broad confidentiality order in respect of its own identity, the identity of its drug product, the entire content of its NDS and any information provided to the Minister in support of its NDS. While it was not specifically stated in the proposed order, Prothonotary Tabib interpreted the motion as extending to the identity of the Other Innovator.

[11] In response to the motion, the Attorney General took the position that the Other Innovator was a necessary respondent to the application and that the confidentiality order sought could not

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 contended that it was premature to fix the terms of the confidentiality order until the Other Innovator has been notified and has had an opportunity to decide whether to participate. If it chose to do so, the Attorney General argued, the Other Innovator could speak to the parameters of an order that would strike an 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.

[12] Prothonotary Tabib agreed with the Attorney General's position and ordered that the applicant serve the Notice of Application, the motion materials and the June 5, 2017 Order on the Other Innovator. Her Order also set out a schedule for service and filing of materials and for the hearing of the motion. In this Court, in addition to its appeal, the applicant filed a separate motion for a stay of the June 5, 2017 Order pending disposition of this appeal. That motion was granted on consent.

[13] At the hearing on June 28, 2017, the applicant provided a confidential affidavit that was not part of its motion record and requested that the Court read it. Following a brief explanation of its content and upon counsel for the respondents not objecting, I read the affidavit. The content concerned the competitive relationship between the applicant and the Other Innovator. As this was not in dispute between the parties, I did not consider it necessary to retain the affidavit as part of the Court record and returned it to counsel for the applicant. I have not relied on the content of the affidavit in arriving at a decision on this appeal.

II. Issues

[14] The applicant submits the following issues for determination:

A. Whether the Prothonotary erred in law by requiring service of the Notice of Application to the Other Innovator;

B. Whether the Prothonotary made a palpable and overriding error by finding that the facts are indistinguishable from those in a previous case; and

C. Whether the Prothonotary made a palpable and overriding error by finding that the Other Innovator is a person directly affected by the order sought in the underlying application.

[15] In my view, the issues can be reduced to the following:

A. Did the Prothonotary make a palpable and overriding error by finding that the Other Innovator is a person directly affected by the order sought in the underlying judicial review application?

III. Relevant Legislation

[16] The following provisions of the *Federal Courts Rules* are relevant in this appeal:

Appeal	**Appel**
51 (1) An order of a prothonotary may be appealed by a motion to a judge of the Federal Court.	**51 (1)** L'ordonnance du protonotaire peut être portée en appel par voie de requête présentée à un juge de la Cour fédérale.

[…]	[…]
Respondents	**Défendeurs**
303 (1) Subject to subsection (2), an Applicant shall name as a Respondent every person	**303 (1)** Sous réserve du paragraphe (2), le demandeur désigne à titre de défendeur :
(a) directly affected by the order sought in the application, other than a tribunal in respect of which the application is brought; or	a) toute personne directement touchée par l'ordonnance recherchée, autre que l'office fédéral visé par la demande;
(b) required to be named as a party under an Act of Parliament pursuant to which the application is brought.	b) toute autre personne qui doit être désignée à titre de partie aux termes de la loi fédérale ou de ses textes d'application qui prévoient ou autorisent la présentation de la demande.
[…]	[…]

[17] The following provisions of the PM(NOC) Regulations are also relevant:

Register and Patent List	**Registre et liste de brevets**
[…]	[…]
5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which	**5 (1)** Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré

a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the Register in respect of the other drug,	à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation :
[…]	[…]

IV. Standard of review

[18] The parties submit, and I agree, that discretionary orders of prothonotaries should only be interfered with when such decisions are incorrect in law, where the exercise of discretion is based on a wrong application of principle, or the prothonotary has made a palpable and overriding error in regard to the facts: *Federal Courts Rules*, r 51; *Hospira Healthcare Corp v Kennedy Institute of Rheumatology*, 2016 FCA 215 at paras 64–69, [2017] 1 FCR 331 [*Hospira v Kennedy*]; *Housen v Nikolaisen*, 2002 SCC 33, [2002] 2 SCR 235 [*Housen*].

V. Analysis

A. *Did the Prothonotary make a palpable and overriding error by finding that the Other Innovator is a person directly affected by the order sought in the underlying judicial review application?*

[19] The applicant submits, in essence, that the Other Innovator is not a person directly affected by the order sought in the underlying judicial review application and would not be so affected unless the application failed. Merely bringing an application for judicial review of the Minister's decision does not grant rights to the Other Innovator, the applicant contends. As such,

the Other Innovator is not directly affected by the order sought, and is not a proper party to be named in the underlying proceeding: *Novopharm Ltd v Canada (Minister of Health)*, 2010 FC 566, [2010] FCJ No 678 [*Novopharm 2010*].

[20] The practical effect of Prothonotary Tabib's order, the applicant argues, would be to alert the Other Innovator, a known competitor, to the possible timing of the applicant's market entry. Such commercial business information, the applicant submits, is routinely protected under the *Food and Drugs Act*, RSC, 1985, c F-27 ("*FDA*") to prevent unfair commercial use by competitors.

[21] Moreover, the applicant submits that the Prothonotary erred in finding that the circumstances of this case are indistinguishable from the circumstances in *Apotex Inc v Canada (Minister of Health)*, 2006 FC 846 at para 16, [2006] FCJ No 1070 [*Apotex 2006*]. In the alternative, the applicant invites me to find that *Apotex 2006*, a decision I authored, should not be followed.

[22] The respondent's position, in brief, is that since a confidentiality order may prevent anyone who may have an interest in a proceeding from learning of its existence, a motion for such an order cannot be isolated from the question of whether all necessary parties have been properly served notice of the underlying application: *Federal Courts Rules*, r 303; *Apotex 2006*, above, at para 16. The Other Innovator is such a party, the respondent submits.

[23] I agree with the respondent that the key question underlying Rule 303 of the *Federal Courts Rules* is whether the relief sought in the application for judicial review will affect a party's legal rights, impose legal obligations upon it or prejudicially affect it in some direct way. If so, the party should be added as a respondent: *Forest Ethics Advocacy Association v Canada (National Energy Board)*, 2013 FCA 236 at paras 20–22 [*Forest Ethics*], [2013] FCJ No 1068.

[24] I also agree with the respondent that reliance on the *FDA* by the applicant is not helpful in the present context. Unlike the *PM(NOC) Regulations*, made under the *Patent Act*, R.S.C. 1985, c. P-4, with the goal of protecting an innovator's patent rights, the object of the *FDA* and the *Food and Drugs Regulations*, C.R.C., c. 870 is to protect the public's health and safety. Issues relating to the safety and efficacy of drugs are generally of no direct concern to third party manufacturers and the economic impact on them is not sufficient to hold that they are "directly affected" by the issuance of a Notice of Compliance (NOC) to a competitor: *Hospira Healthcare Corp v Canada (Minister of Health)*, 2014 FC 179 at para 13[*Hospira 2014*], citing *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).

[25] In contrast, under the *PM(NOC) Regulations*, an innovator whose patents are listed against a drug on the Register does have standing where the issue in a judicial review is whether or not the rights and protections afforded to it under the *PM(NOC) Regulations* are engaged by another manufacturer's application for an Notice of Compliance (NOC): see *Hospira 2014*, above, at para 14, citing *Apotex Inc v Canada (Attorney General)*, [1994] FCJ No 879 [*Apotex*

1994]; *Apotex 2006*, above; *Nu-Pharm Inc v Canada (Attorney General)*, 2001 FCT 973, 2001 CarswellNat 1895 [*Nu-Pharm*]; *Apotex Inc v Canada (Minister of Health)*, [2000] FCJ No 248, 186 F.T.R. 84; *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276, [2007] FCJ No 1138.

[26] The distinction between proceedings under the *PM(NOC) Regulations* and the *Food and Drug Regulations*, was discussed by Justice Lemieux in *Reddy Cheminor Inc v Canada (Attorney General)*, 2001 FCT 1065 at paras 41–46 affirmed 2002 FCA 179. He noted, at paragraph 42, that innovator drug companies have no right to enforce the *Food and Drug Regulations* but they do have "[…] the right to object to the issuance of a NOC on the grounds of non-compliance with the [PM(NOC) Regulations] because their purpose is to provide additional patent protection."

[27] In *Novopharm 2010*, above, a generic manufacturer brought a motion for a confidentiality order in the context of its application for judicial review of the Minister's decision that it must address patents on the Register before obtaining a NOC. In that matter, the applicant's position was that the drugs for which it sought an NOC had been developed before the patents in question had been issued and listed on the Register. The Prothonotary held that it was for the Minister alone to decide whether a second person falls within the scope of subsection 5(1) of the *Regulations* as a result of the filing and that the rights of the innovator had not yet crystallized as there had been no decision to grant the NOC.

[28] The Prothonotary further observed, at paragraph 20 of *Novopharm 2010*, that the innovator would have no interest if the generic was correct and it did not have to address the subsequently registered patents. If the generic was found to be incorrect, it would then have to address the innovator's patents. The innovator may become a necessary party at some stage of the case but until then had only commercial interests and was not, therefore, a person "directly affected". With respect, that distinction is not supported by the jurisprudence.

[29] On this motion, the applicant has argued that the Other Innovator is not directly affected because, if its application is dismissed and the Minister's decision stands, he will then have to give notice to the Other Innovator of its position on the patents in accordance with the *PM (NOC) Regulations*. The applicant contends that the Other Innovator will not therefore be prejudiced.

[30] The test under Rule 303 of the *Federal Courts Rules* is whether a person is "directly affected" by the order sought in the application. The test does not require that legal rights or obligations flow to a person from the order sought; it is sufficient that the other party be prejudicially affected in a direct way: *Hospira 2014*, above, at para 20, citing *Forest Ethics*, above. The test is not whether the Other Innovator will be prejudiced by one possible disposition of the application.

[31] The meaning of the words "directly affected" in Rule 303 (1) (a) of the *Federal Courts Rules* was discussed by Justice David Stratas in *Forest Ethics*, above, at paras 18–21:

> 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" at ss. 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 ss. 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] 2 F.C. 500 (C.A.); *Irving Shipbuilding Inc. v. Canada (A.G.)*, 2009 FCA 116.
>
> 21. Translating this to Rule 303(1)(a), the question is whether the relief sought in the application for judicial review will affect a party's legal rights, impose legal obligations upon it, or prejudicially affect it in some direct way. If so, the party should be added as a respondent. If that party was not added as a respondent when the notice of application was issued, then, upon motion under Rule 104 (1) (b), it should be added as a respondent.
>
> [Emphasis added]

[32] I read the references to "direct interest" in the cited paragraphs to be synonymous with the words actually used in the statute and rules; "directly affected".

[33] A decision by the Minister that s 5 of the *PM (NOC) Regulations* is engaged confers rights on the patentees whose patents must be addressed. These rights have been consistently

described by the Federal Court as “legal rights” or “legal interests”: *Merck & Co v Canada (Attorney General)*, [1993] FCJ No 245, at para 17; *Apotex 1994*, above, at para 12; *Nu-Pharm*, above, at para 23–28. Even if they are construed as something other than “legal rights” or “legal interests”, the innovator holding patents listed on the Register would be prejudicially affected in a direct way by the application in this proceeding.

[34] There is no compelling reason, in my view, why a patentee should be required to await the issue of a NOC to a competitor before being able to address the issue whether the Minister was correct in her interpretation and application of the *Regulations*. As the respondent submits, this could lead to a multiplicity of legal proceedings and the possibility of inconsistent decisions and is not in the interests of judicial economy.

[35] Prothonotary Tabib described the Other Innovator’s interests at issue in these proceedings at paragraph 15 of her reasons:

> The decision of the Court of Appeal in *Forest Ethics* […] 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.

[36] Confidentiality orders are discretionary exceptions to the principle of open and accessible courts. Under the framework established by the Supreme Court of Canada in *Sierra Club of Canada v Canada (Minister of Finance),* 2002 SCC 41at para 53, confidentiality orders may be justified where (1) is necessary to prevent a serious risk to an important interest that cannot be addressed by reasonably alternative measures and (2) the salutary effects of a confidentiality order outweigh its deleterious effects.

[37] In *Apotex 2006*, the issue on appeal from the Prothonotary's decision was also whether a confidentiality order would be granted without naming the innovator as a respondent. In that matter, I observed:

> [14] … [The applicant] 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.
>
> [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 that 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, the prothonotary has a 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.
>
> [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 would 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 the 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.

[38] I see no reason to depart from those views. It is anathema to the open court principle, in my opinion, for a commercial enterprise, using a pseudonym, to ask this Court to conduct a judicial review of a decision by a public official essentially in secret. That would be the practical effect of the requested order and stretches the notion of an exception to the principle of openness and transparency in judicial affairs beyond reason. I don't doubt that the commercial interests of the applicant are important but it has not been demonstrated that any serious risk to those interests cannot be addressed by reasonably alternative measures. Such measures could be proposed and considered by the Case Management Prothonotary as set out in the June 5, 2017 Order.

[39] I am satisfied that the prothonotary did not err in finding that the Other Innovator's interests were directly affected and that service of notice of the underlying application and motion was required before the motion could be considered. Accordingly, this appeal will be dismissed and the stay that was previously granted will be vacated. As no costs were requested, none will be awarded.

THIS COURT ORDERS that:

1. The appeal is dismissed;

2. This Court's Order issued on June 28, 2017 staying the effect of the Prothonotary's Order of June 5, 2017 is vacated;

3. The time-table set out in the Prothonotary Tabib's Order of June 5, 2017 shall begin to run from the date of issuance of this Order and Reasons; and

4. The parties shall bear their own costs.

"Richard G. Mosley"
Judge

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:	JUNE 28, 2017
ORDER AND REASONS:	MOSLEY J.
DATED:	SEPTEMBER 26, 2017

APPEARANCES:

Jamie Mills Jillian Brenner	FOR THE APPLICANT
Sanderson Graham Adrian Bieniasiewicz	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Borden Ladner Gervais LLP Ottawa, Ontario	FOR THE APPLICANT
Deputy Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENTS