Federal Court  Cour fédérale

Date: 20100526

Docket: T-1862-09

Citation: 2010 FC 566

Toronto, Ontario, May 26, 2010

PRESENT: Kevin R. Aalto, Esquire, Case Management Judge

BETWEEN:

NOVOPHARM LIMITED

Applicant

and

THE MINISTER OF HEALTH AND
THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR ORDER AND ORDER

[1] While notionally this is a motion for a confidentiality order pursuant to Rule 151 of the *Federal Courts Rules*, in reality there is a much more significant issue at stake. That issue concerns the application of the *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations"). More particularly, should a patentee be joined as a party to an application judicially reviewing a decision of the Minister of Health (the "Minister") requiring a generic (in this case the Applicant,

"Novopharm"), to address a patent of the patentee's listed on the Canadian Patent Register (the "Register")?

[2] Novopharm filed an Abbreviated New Drug Submission ("ANDS") and the Minister has made a decision that Novopharm, before it can obtain a Notice of Compliance ("NOC"), must address a specific patent listed on the Register. Novopharm takes issue with the decision of the Minister on various grounds and seeks to judicially review the decision in this Court. Only the Minister's decision is being attacked in this Notice of Application for Judicial Review. Should this matter proceed under the guise of a confidentiality order in which the patent in issue is referred to only by letter and the drug in issue only referred to by letter? As set out by the Minister in its written representations:

> Through the issuance of a Protective Order and the subsequent filing of a Confidential Affidavit, a party directly affected and having the right to participate in this proceeding will not be in a position to know that it has that right. In essence, the proceeding will be kept secret from those most interested in it.

Facts

[3] This Notice of Application for Judicial Review arises from a filing by Novopharm of an ANDS with the Minister for a drug, which for the purposes of this motion and the application to date, has been designated as Drug A. Novopharm has represented to the Minister that the ANDS is such that it does not attract the application of the Regulations. The Minister has disagreed taking the position that the Regulations apply and therefore has refused to issue an NOC. In this application, Novopharm seeks to quash the Minister's decision and seeks a declaration that the

Regulations do not apply to the ANDS. The Decision is dated October 16, 2009 ("the Decision"), is made pursuant to s. 5(1) of the Regulations, and, requires that Novopharm address Canadian Patent No. X in order to receive a NOC for its ANDS in connection with Drug A. There is a companion proceeding also involving a decision of the Minister in relation to Patent Y and Drug B.

[4] The Notice of Application in these two proceedings identifies the patents by way of letters and the drugs in issue by letters without identifying either the patents or the drugs. The essence of the applications is that Novopharm need not address Patent X or Y since they were added to the Register after Novopharm had purchased the Canadian Reference Products against which they were listed and after Novopharm had completed its clinical studies. Novopharm's position is that Drugs A and B were developed prior to Patent X and Y being issued and listed on the Register.

[5] Novopharm seeks the following Orders on the Application:

1. a writ of *certiorari* quashing the Decision and a declaration that the Applicant is not required to address Canadian Patent No. X in order to receive a Notice of Compliance for its Abbreviated New Drug Submission concerning Drug A;

2. in the alternative, a declaration that s. 5(1) of the *NOC Regulations* is *ultra vires* and, in consequence of that:

    (a) a writ of *certiorari* quashing the Decision that was purportedly made under that *ultra vires* provision; and

    (b) a declaration that the Applicant is not required to address Canadian Patent No. X in order to receive a Notice of Compliance for its Abbreviated New Drug Submission concerning Drug A;

3. an interlocutory order consolidating this application for judicial review with the Applicant's application for judicial review concerning the Minister's decision of October 16, 2009 concerning Drug B;

4. its costs of this application; and

5. such further and other relief as counsel may advise and this Honourable Court may grant.

[6] The relief sought in the companion proceeding T-1863-09 seeks similar relief.

[7] The legal issue described by Novopharm in its Notice of Application is whether or not a generic manufacturer must address every patent listed on the Patent Register or must address only those patents that cover inventions that are being "early worked". The Regulations set out the conditions that must be met before an NOC is issued to an "early worker" of an invention.

Position of Novopharm

[8] Novopharm argues that it is appropriate to issue a confidentiality order pursuant to Rule 151of the *Federal Courts Rules* in order to ensure that all of its dealings with the Minister related to the review of its ANDS will be maintained in the strictest confidence. Novopharm has succinctly set out its position as follows:

> 5. Novopharm respectively submits that the innovator of Drug A and Drug B is not a proper party to these applications. The Minister's decisions that Novopharm must address Patent X were made in the context of Novopharm's confidential ANDS. Such decisions were the Minister's alone and were not subject to input from any other party, including the innovator of Drug A and Drug B. Only Novopharm and the Minister are privy to the decisions and, accordingly, the innovator has no standing in the judicial review thereof.
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> 6. The innovator of Drug A and Drug B is also not a proper intervener to these applications. The innovator only has a

> commercial interest (as opposed to a legal interest) in the outcome of these applications, which is insufficient to convey intervener status. Further, the Respondents are perfectly capable of addressing all of the legal and factual issues on the applications. Finally, no innovator has sought intervener status since the commencement of these applications.
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> 7. The confidentiality order sought by Novopharm is necessary to prevent a serious harm to its commercial interest. Disclosure of any of the contents of Novopharm's ANDS would necessarily entail disclosure of Novopharm's business strategy with respect to Drug A and Drug B to the public and, more significantly, to Novopharm's competitors. In such an event, Novopharm would suffer serious prejudice to its business interests by reason of interference and/or intermeddling by the innovator of Drug A and Drug B.

[9] The Minister's position is that an innovator has certain rights in proceedings such as this and as those rights may be curtailed it clearly is one directly affecting such innovator which must be named as a respondent. Rule 303(1) of the *Federal Courts Rules* requires that every person directly affected by an order sought in an application shall be named as a respondent. The Minister argues that where a generic manufacturer launches a proceeding involving the rights of an innovator under the Regulations, the innovator has the right to participate as a party to the proceeding.

Issues

[10] The issues to be determined are as follows:

a. Are the rights of the innovator affected such that the innovator should be a party to these proceedings?

b. If not, is a confidentiality order appropriate in which neither the patent nor the drug nor the name of the innovator are named?

Analysis

[11] This Court has dealt with issues of confidentiality in proceedings on many occasions. Confidentiality has been rejected on the basis that the overarching principal at issue in any proceeding is that of the public interest in open and accessible court proceedings (see *Novopharm Limited v. Company X*, 2008 FC 840 and *Apotex Inc. v. Canada (Minister of Health)*, 2006 FC 846).

[12] Confidentiality and protective orders are part of the ordinary process of intellectual property actions where proprietary commercial and scientific interests would be seriously harmed by production or disclosure of information. Indeed, these types of orders are typically issued in virtually every proceeding under the Regulations and invariably in most patent infringement or invalidity actions.

[13] Essential to the position of Novopharm is the recognition both by the Minister and this Court that drug submissions are confidential as between the Minister and the drug sponsor. This Court has stated that confidentiality is a cornerstone of the regulatory scheme in the Regulations [see *AB Hassle v. Canada (Minister of National Health & Welfare)* (2000), 5 C.P.R. (4th) 149 (F.C.A.) (at paras. 3-7). In this case, there is no doubt that as between Novopharm and the Minister, the ANDS is a confidential document. It is submitted in confidence and all generic manufacturers, not only Novopharm, and the Minister act on the basis that an ANDS will be held in the strictest confidence as between the generic manufacturer and the Minister. As this Court has observed:

> [2] The existence, contents, and status of the applicant's submission for a NOC is confidential. To preserve such confidentiality, the drug in question is referred to as "pms-X/Y" rather than by its proposed brand name. The components it contains are referred to as "component X" and "component Y" rather than by their molecular names, and the condition for which approval is sought is referred to as "condition A" rather than the condition itself. The applicant's submission for a NOC was made with reference to a Canadian reference product which, for the same reasons of confidentiality, will be referred to as "REFPRO," MANUFACTURED BY ANOTHER COMPANY, "Pharmacompany."
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> *Pharmascience Inc. v. Attorney General of Canada*, 2007 FC 1323 at para. 2 (per Kelen, J.)

[14] From a public perspective, it has been noted that the public has little, if any interest, in the contents of such submissions (see *AB Hassle v. Canada (Minister of National Health & Welfare*) (2003), 5 C.P.R. (4th) 149 at para. 7 (F.C.A.) wherein the Court of Appeal observed:

> Let us not be naive. There is little, if any, public interest in knowing the specific content of drug processes and no one can seriously argue that the issuance of protective orders of the type at issue in NOC proceedings imperils the principle of open justice. The parties themselves may challenge the true confidentiality of specific documents by the very terms of the orders and the Court will always be prepared to hear challenge by a third party, whether or not the terms of the order so provide.

[15] Novopharm seeks a protective order that protects the details of its ANDS for both Drug A and Drug B and the Minister's review of the ANDS from the public. In reality, not confidential from the public but from the patentee and Novopharm's competitors. To that end, Novopharm seeks in its protective order to identify the Patent only as Patent X and Patent Y and the drugs as Drug A and Drug B. Novopharm has not disclosed the identity of either Drug A or Drug B to the

general public and apart from the Minister and Novopharm there is no party that knows the identity of Patent X, Patent Y and Drugs A and B.

[16] Novopharm argues that disclosure of any of the details relating to the ANDS will entail disclosure of Novopharm's legal and business strategy which will result in serious prejudice to its commercial interests. Commercial interests are specifically noted as one of the risks to be protected. Novopharm points to possible steps taken by an innovator to intervene in this application or delay Novopharm's market entry if it had knowledge of the ANDS. This leads to a consideration of whether or not the innovator is a proper party and should be added to these proceedings.

[17] Of note, it is for the Minister alone to decide whether a second person (Novopharm) falls within the scope of section 5(1) of the Regulations as the result of the filing of an ANDS. It is the Minister's decision whether or not Novopharm need address patents listed on the Register. The innovator is not involved in any part of this process. Recently, Hughes J. reviewed the nature of proceedings under the Regulations and made the following observation:

> [92] *Ferring* makes a further argument that the decisions of the Minister were made without warning to *Ferring* and giving it an opportunity to be heard. This, argues *Ferring*, is unfair and contrary to the principles of natural justice.
> [94] The parties refer to the Supreme Court of Canada decision in *Baker v. Canada (Minister of Citizenship and Immigration)* (1999), 174 D.L.R. (4th) 193 at paragraphs 21 to 28 for the purposes of considering what the duty of fairness might require in any particular circumstances. L'Heureux-Dube J. said in the majority decision at paragraph 21 of that decision that the concept is eminently variable and depends on the particular circumstances in each case. In paragraph 23 she stated that the closer a procedure is to a judicial process, the more likely it would be that there would be procedural protection, such as that afforded a litigant. Second, the terms of the

particular legislation must be considered. A third consideration is the importance to the individual affected. Fourth is the legitimate expectation of persons challenging the decision. Fifth is the choice of procedure afforded to the decision maker.

[93] The Minister submits that the decision is administrative in nature and there is nothing in the *NOC Regulations or Food and Drug Regulations* that obliges him to advise an innovator who has listed patents as to whether a generic is seeking an NOC or to afford the innovator a right to be heard before a decision is made.

[95] In considering these criteria: first, the decision of the Minister to grant an NOC, including whether a generic is caught up in section 5(1) is administrative in nature; second, the *Regulations* do not specify any form of notice or hearing being afforded to others; third, an innovator is affected by the decision in that it may lose an opportunity to institute proceedings under the *NOC Regulations* thus losing an opportunity to gain a two month stay, however, this is an exceptional remedy and cannot be considered to be available as of right; fourth, there is nothing in the *Regulations* such as would give an expectation to an innovator to be consulted and heard before an NOC is given to a generic other than to receive a notice of allegation if and when the generic is obliged as a "second person" under section 5(1) to send such a notice, otherwise all proceedings are confidential as between the generic and the Minister; fifth, there is no choice given to the Minister as to whether to engage the innovator or not.

[96] There is no history of the Minister notifying an innovator or affording it an opportunity to be heard during the process of granting an NOC to a generic. There is a reference, in the Trial Division Reasons in the AstraZeneca case (2004), 36 C.P.R. (4^{th}) 519 at paragraphs 55 and 56 to communications between the Minister and the innovator. A review of the record in that case indicates that the Minister wrote to the innovator on January 13, 2004, without disclosing that there was a pending NOC submission from a generic. The Minister simply requested information as to whether the innovator's LOSEC 20 capsules had been marketed in Canada since the date of its NOC on June 4, 1999. The innovator was not asked to make submissions of any kind as to the impact that the failure to market might have. There was no hearing of any kind conducted by the Minister; there was a simple request for information.

[18] In concluding this discussion Hughes J. went on to observe that there was no requirement to inform an innovator of the generic's pending submission. He concluded that such a submission is to remain confidential. Further, Hughes J. noted there was nothing in the Regulations that required the Minister to afford an innovator the right to be heard before making a decision as to whether or not the provisions of section 5(1) of the Regulations applied to the generic. Thus, Hughes J. concluded that the innovator had no standing to seek judicial review of the Minister's decision to grant an NOC. However, the Federal Court of Appeal overruled that part of the judgment and found that the innovator did have standing to challenge the Minister's decision to issue an NOC to the generic because it was made by the Minister in the course of his administration of the Regulations.

[19] However, such is not the case here. There has been no decision to issue an NOC. There is only a decision as to what patents Novopharm is required to address. At best, the innovator would have an interest in these proceedings as a party if Novopharm is required to address the patents or if a NOC is issued. All of the steps taken to date are between the generic and the Minister and are confidential. If the Minister's decision is overturned on this judicial review application and thereafter the Minister issues an NOC to Novopharm, then the patent holder will have standing to seek judicial review of that decision. If the Minister's decision is upheld then Novopharm will be required to address the patents. In either case, the rights of the innovator are preserved.

[20] At this stage of the proceedings, as the decision is only a decision that affects the rights of Novopharm, the patent holder does not appear to be a necessary party. The innovator has no interest if Novopharm is correct and it does not have to address the subsequently registered patents and if Novopharm is not correct then the innovator's legal rights are protected as Novopharm is required to address the innovator's patents. It may be that as the case unfolds, developments may occur which will change the landscape such that the innovator may be a necessary party. But it does not appear to be so as matters currently stand.

[21] The Supreme Court of Canada, in *Sierra Club of Canada v. Canada* [2002] 2 S.C.R. 522, has set out the test to be met to obtain a confidentiality order:

> (a) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
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> (b) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.

[22] Novopharm's commercial interests are clearly at stake. It has dealt with the Minister under a cocoon of confidentiality. It is only the Minister's decision that is in issue. There is currently no direct interest of the patent holder at stake which gives the patent holder a right to be added as a party.

[23] While the overarching principle of our judicial system is open and accessible courts, this is one of those rare exceptions where the genuine commercial interest of Novopharm ought to be protected at this stage. Novopharm engaged in a process which is treated by all participants as confidential and now finds itself in the position of having to divulge its commercial interests to challenge a decision which it deems to be wrong. Novopharm has the right to challenge the decision.

[24] Counsel on behalf of the Minister endeavoured to bifurcate the issue as between a decision of the Minister and the entitlement of the patentee to participate, as opposed to a court decision-making process in which the patentee had a right to participate. The argument was articulated as follows:

> a. Novopharm mistakenly asserts that "…counsel for the Respondents is effectively inserting the innovator into the Minister's decision-making…" In the instant case, of course, it is the Court's decision-making that is at issue; the Minister's decision-making is concluded. At this point, the overarching principle is that of the public interest in open and accessible court proceedings.
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> b. Furthermore, Novopharm asserts that the innovator will have the right to seek judicial review of the Minister's issuance of the NOC. That, however, does not mean that the innovator need not participate in this proceeding; indeed, the assertion reinforces the Respondents' position, as follows. If Novopharm were to succeed in the underlying judicial review here, and that Minister were to issue an NOC, the innovator would clearly have standing to challenge that issuance. Paradoxically, however, any such challenge by the innovator would be unlikely to succeed, because the issue will have already been decided – without the innovator's participation – in this proceeding.

[25] On this basis, so the argument goes, the innovator is directly affected. Thus, following the principle of open and accessible court proceedings as the innovator is a party affected by any decision of the Court in this proceeding it ought to be a party. I disagree.

[26] It is the Minister's decision which is in issue. That decision is one that affects only the rights of Novopharm. The innovator was not involved in the deliberations or building the record upon which the decision of the Minister was made. The innovator has an interest after the fact. The Minister is, in part, abdicating the responsibility of substantiating the decision in this judicial review proceeding by inviting the innovator to come and help support the decision on grounds that would be directed primarily to protecting the interests of the innovator and not the integrity of the Minister's own internal decision-making process and record. In order to do so, the Minister would be revealing to the innovator the record upon which the Minister's decision was made and thereby revealing information of Novopharm which is inherently confidential in the context of the ANDS procedure.

[27] There were several cases cited during the course of argument to support the open-court principle as articulated by counsel for the Minister. While this Court fully endorses the overarching open-court principle, this is one of the few exceptions where sufficient evidence has been put before the Court to justify maintaining the confidentiality of the patents in issue and the drugs in issue. The cases cited in support of the Minister's position are distinguishable on their facts from this case.

[28] In *Apotex Inc. v. Canada (Attorney General)*, [1994] F.C.J. No. 879 [*"Apotex 1994"*] the Applicant did not disclose the Applicant's identity. Several innovators moved to intervene and Apotex was ordered to identify the innovator so that it could determine whether it wished to be added as a party. However, in that case the issue concerned whether a NOC should be issued to Apotex. Thus, the innovator with a proprietary interest was determined to be a necessary party or at least have the right to determine if it wished to participate in the proceeding. This case does not concern the issuance of an NOC. It deals with whether the Regulations should be engaged so that Novopharm is required to address a patent on the Patent Register. To that extent the rights of the innovator are not in play at this juncture of Novopharm's ANDS. This is not a judicial review proceeding requiring the Minister to issue a NOC.

[29] In *Apotex Inc. v. (Minister of Health)*, 2006 FC 846 ("*Apotex 2006"*) the issue also involved a confidentiality order. Again, the innovator was not identified. The Court determined that no confidentiality order would be granted until the innovator was served as a party. In that case, on appeal from the Prothonotary's decision, Mosley J. observed:

> . . . 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.
>
> [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.

[30] In that case, the Regulations had been engaged. However, there is a clear distinction between that case and this. The position of Novopharm is that the Minister is wrong in requiring Novopharm to address a patent on the Register which was put thereafter the ANDS. This is not the same issue as was before the Court in *Apotex 2006*. While the Regulations are engaged in this decision, it is a matter relating to the Register. At this juncture only the innovator's commercial interests are engaged but not their legal interests.

[31] The Minister argues that the decision was solely made by application of the Regulations. Ergo, the Minister argues that the legal rights of the innovator are automatically engaged and has a legal right to enforce the Regulations. While the innovator has a legal right to ensure that the Regulations are followed, this case deals with a specific aspect of the process that does not yet engage the rights of the innovator.

[32] Other cases relied upon by the Minister, are also distinguishable in that at issue was whether the Regulations applied [for example see *Apotex Inc. v. Canada (Minister of Health*, [2000] F.C.J. No. 248; and, *Apotex Inc. v. Canada (Minister of Health)* [1994] F.C.J. No. 879].

[33] Finally, the Minister relies upon *Novopharm Limited v. Company "X"*, 2008 FC 840, in which it was held that the proceeding could not continue without including the proper name of the Respondent. The open-court principle was clearly in issue and the decision was that the proceedings must continue in the proper name of the Defendant. The facts are clearly distinguishable from this case.

[34] While the Regulations are being applied this is one of those rare cases where Novopharm should be able to protect its ANDS from the public scrutiny of both its competitors and the innovator of drugs which it argues were not listed on the Register when it filed its ANDS. In the result, the confidentiality order shall issue in the form proposed by counsel for Novopharm with references to the patents and drugs in issue identified by letters.

ORDER

THIS COURT ORDERS that a confidentiality order shall issue in the form attached as Schedule "A" to the Notice of Motion herein.

"Kevin R. Aalto"
Case Management Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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